



**National Occupational Standard for**  
Quality Assurance Manager

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## 2 A COMPETENCY FRAMEWORK FOR INDIVIDUALS WORKING IN THE BIO-ECONOMY

### 2.1 What is a National Occupational Standard?

In Canada, National Occupational Standards are industry-developed and validated documents that identify, and group tasks/competencies associated with a particular occupation. They also describe the knowledge and skills that a worker must demonstrate to be considered competent.

The former Alliance of Sector Councils (TASC) outlined 11 guiding principles for creating National Occupational Standards (NOS). NOS for the Canadian bioeconomy meet all 11 principles and are developed to meet the current and future human capital management needs of the Canadian bioeconomy.

### 2.2 How are we defining a competency?

We define a competency as *a set of related behaviors that describe successful performance in a designated area. It is a behavioural expression of how people integrate knowledge, skills, attributes, and attitudes to produce a value-adding result in a defined situation.*

The competency statement includes a description that integrates skills, knowledge, and actions into a sequence of activities that deliver a value-added product or service.

**Performance Indicators** is the term we use for the behaviours grouped under each competency that describe the level of mastery the incumbent role must demonstrate when executing a task.

For this project, we have organized the competencies into four categories.

**Core Competencies** are those competencies that describe the "essence of the role" — that is, they are the one to three most critical competencies that may be applicable across multiple roles in a function or job family. All levels of personnel in this function would typically share them. These competencies may also act as qualifiers that differentiate the function from other functions.

**Technical Competencies** are those competencies related to specific roles or professions that enable an individual to work, function, and succeed in that role. They address the various responsibilities that job incumbents encounter in a role. For example, a surgeon's technical competencies would encompass multiple surgical tools, techniques, and conditions that could be part of the position. Similarly, technical competencies for a lawyer would contain various legal situations that they encounter in the context of a particular field of practice.

**Regulatory Competencies** are those competencies that describe compliance with prescribed practices and mandated obligations under applicable laws, regulations, and industry standards. They ensure that critical work processes are implemented and integrated into all work activities. They are of absolute importance where economic behaviours can impact human conditions.

**Personal/professional Competencies** are those competencies that enable an individual to be successful working with others and fulfilling their responsibilities in a work context. Personal and professional competencies are not necessarily role specific.

### 2.3 Levels of complexity of work

It is important to recognize how the complexity of work varies along an organizational continuum. At one end of this continuum is low-complexity, clearly defined, task-driven work. At the other end of the continuum is work that is higher in complexity, not as well-defined, and requires higher-level thinking and decision-making skills and a greater degree of autonomy. Results are recognised over a longer period and are more difficult to assess.

Figure 1: Demonstrates how the level of complexity changes with the role responsibilities

Complexity Level	Examples of Work at Different Complexity Levels	Typical Roles/Titles
Most Complex	Construct and pursue worldwide strategic plans in large corporations.	CEOs of the largest trans-global corporations
	Construct and pursue worldwide strategic plans.	C-suite executives at multi-national organizations
	Lead the accumulated impact of multiple business units.	C-suite executive at large, multi-location organizations
	Optimize the function of a single business unit or corporate support staff.	General manager; plant manager
	Manage multiple, interdependent projects, balance resources among departments.	Engineering manager
	Plan and carry out sequential projects while considering contingencies and alternatives.	Maintenance manager
	Accumulate information to diagnose and anticipate problems; proactive; notice trends.	Maintenance technician
Least Complex	Follow predefined procedures; seek help when encountering an obstacle. The ability to anticipate problems is not expected.	Maintenance labourer

We define the complexity levels within the profiles at four levels:

**Foundational** — performance focus is on the execution of procedures and tasks involving own job role.

**Operational** — performance focus includes some discretion in the planning and executing of work. The work typically includes assessing the quality of the work outcomes and taking corrective action to ensure quality.

**Specialist** — performance focus is on translating goals and standards to team members and ensuring that work done under the person's responsibility area complies with all corporate standards.

**Strategic** — performance focus is on leading work and the accumulated impact of work in an independent business unit or across a whole organization. The impact of work at this level is often not visible until the medium to longer term.

The following example illustrates the different complexity levels within a profile.

<p><b>Competency Name: Research Ethics</b></p> <p><b>Competency Definition:</b> Exercises integrity and professionalism to ensure all research is performed responsibly in keeping with the ethical principles of beneficence and nonmaleficence.</p> <p>Competence at this level is demonstrated when the <b>Research Manager:</b></p>			
Performance Indicators			
Foundational	Operational	Specialized	Strategic
Diligently follows research procedures and protocols mandated by legitimate authorities and professional organizations.	Regularly monitors own actions and decisions to ensure they align with professional and organizational values.	Holds self and staff accountable to the organization's values, ensuring compliance with the policies and procedures related to scientific ethics and rules of conduct.	Fosters an organizational culture of integrity and ethical business practices by unwavering personal example.

## 2.4 Overview methodology for the development of national occupational standards

National occupational standards were developed using a multi-step process.

Step	Description	Result/Output
1	Identify critical roles in the bioeconomy through primary and secondary research.	List of 50 key roles
2	Create draft profiles with critical competencies for the roles, performance, and knowledge indicators.	Draft profiles
3	Review the draft profiles with industry subject matter experts to refine the competencies, performance, and knowledge indicators.	Reviewed profile with design inputs from industry experts
4	Further validation and review by industry via online focus group.	Validated profiles by industry experts
5	Broader validation of the draft profiles via national online surveys.	Occupational Standards validated on a national level by experts from the different sectors
6	Addition of the Essential Skills and Canadian Language Benchmark (ES/CLB) ratings.	Nationally validated NOS profiles with ES/CLB profile for each NOS

### 3 QUALITY ASSURANCE MANAGER COMPETENCY FRAMEWORK

#### 3.1 Competency diagram for Quality Assurance Manager

Competencies		Complexity Level				Complexity Level Legend
		1	2	3	4	
<b>Core Competency</b>						<b>1. Foundational</b>
1	Build and Maintain a Quality Culture					<b>2. Operational</b>
2	Manage Change					<b>3. Specialist/Manager</b>
<b>Technical Competencies</b>						<b>4. Expert/Executive</b>
3	Quality Management Strategy					
4	Quality Management System Implementation					
5	Manage Quality Audits					
6	Critical Control Point Quality Assurance					
7	Quality Management Capability					
8	Product Release					
9	Quality Tracking and Reporting					
<b>Industry Regulatory Competencies</b>						
10	Records and Document Management					
11	Management Equipment and Instrument Qualifications					
<b>Work Process Competencies</b>						
12	Quality Process Improvement					
13	Risk Management					
<b>Personal and Professional Competencies</b>						
14	Fostering Collaboration					
15	Directing					
16	Professional/Emotional Intelligence					

## 3.2 Definition of occupation

The Quality Assurance (QA) Manager typically adds value by managing quality on at least three levels. Firstly, they ensure the company has a body of knowledge and quality management tools available from which they can initiate different interventions to provide quality products and services. Secondly, the QA Manager typically collaborates with various process owners within the organization to ensure that the quality principles are embedded in the end-to-end company work processes. Thirdly, the QA Manager is, directly, and indirectly, responsible for a team of quality management analysts and specialists.

QA Managers govern quality management practices within the organization by implementing a Quality Management System (QMS).

The QMS defines company practices, policies, responsibilities, resources, and records that are used to ensure continuous compliance with industry and regulatory standards relevant to the organization's objectives and practices, in addition to meeting customer needs. These processes are related to establishing internal requirements reflecting regulatory and customer quality requirements for product and service standards, competency and training requirements, standard work processes to be maintained, and quality that must be proved at the product and service levels. When deviances to work processes and/or product and service quality are detected, the quality methodology expects that action will be implemented to correct any deviances and elements of noncompliance. To maintain a consistent level of quality, numerous tools and techniques may be used such as Internal Audits, Statistical Process Controls, root cause analysis, cause and effect diagrams, control charts, Pareto charts, and flow charts.

The QA Manager is also responsible for product release by confirming and attesting to proper manufacturing procedures, quality control, and documentation to provide an audit trail. It is also expected that the QA Manager performs continuous improvement by identifying opportunities in the QMS, which will benefit improvements of the business processes.

Lastly, the QA Manager may be responsible as a manager for the departmental budget, finance and human resources duties, including the hiring of staff, employee performance evaluations, and the training and mentoring of junior staff. The QA Manager may work for Canadian biotechnology organizations of different sizes and in various biotechnology areas, such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioinformatics
- Bioproducts
- Biosciences
- Environment
- Food Processing

- Forestry
  - Genomics
  - Human and Animal Health
  - Industrial
  - Life Sciences
- Medical Devices
  - Nanotechnology
  - Natural Resources
  - Nutraceuticals
  - Pharmaceuticals

This role works in the following subsectors:

Applicable To	Bio-Health	Agri-Bio	Bio-Industrial	Bioenergy

The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/Management	Expert/Executive

### 3.3 Level of education, training, or designations requirements

Typical Education Required	Secondary	College	Bachelor	Master	PhD
Typical Starting Experience	0–5 yrs.	5–10 yrs.	10–15 yrs.	15–20 yrs.	20+ yrs.

- Bachelor's degree in related field (e.g., science, engineering, environment)
- Minimum five years of professional experience
- Quality management experience
- Proficiency with precision measuring tools
- Excellent analytical and problem-solving skills
- Strong knowledge of current regulations pertaining to the concerned area of work
- Capable of meticulous attention to detail while still maintaining an objective overview of the bigger picture
- Capable of working under pressure
- Interpersonal skills

### 3.4 Core competencies list for Quality Assurance Manager

#### 3.4.1 Build and Maintain a Quality Culture

Applies and participate in practices that systematically deliver a workplace where staff and team members complete their work with a commitment to quality and continuously collaborate to find and implement innovative ways to deliver products/services with higher quality.

Competency in this role is demonstrated when the individual:

- Facilitates the setting, communication, achievement, and measurement of corporate quality goals.
- Strengthens the corporate quality performance by ensuring the reward for achieving excellence in quality standards.
- Implements strategies to improve conformance to standards for the products or services as required by the user/consumer and in compliance with current regulations/industry standards.
- Creates and implements processes to ensure that employees participate in identifying areas of noncompliance and the cost of noncompliance so that teams can analyze quality-related problems, decide on preventative/corrective action, and implement decisions.
- Ensures quality achievements are publicized within the company and assists the development of corporate pride in achievements.

**Knowledge required for competency at this level:**

- In-depth understanding of the organizations' value chain and how cost of quality impacts the organization's revenue
- Working knowledge of which quality standards and regulations impact the organization's ability to do business in selected markets, i.e., ISO 9000; ISO 13485 (manufacturing of medical devices), Food and Drug Administration (FDA), Part C, Division 2 of the Food and Drug Regulations (Health Canada), and any other applicable regulations
- Working understanding of corporate culture development and group dynamics

**3.4.2 Manage Change**

Collaborates with senior leadership to build the organization's capacity to plan, design, and steward all required quality process changes and improvements, ensuring alignment with the organization's business objectives and operational needs.

Competency in this role is demonstrated when the individual:

- Communicate in an honest, respectful, and sensitive manner, demonstrating mature, respectful, fair, and equitable behaviour in all interactions and situations.
- Facilitates the development of change strategies required by the implementation of the organization's quality goals.
- Deploys and facilitates the adoption of the corporate change methodology regarding all quality assurance initiatives.
- Ensures a that process and tools for prioritizing/decision-making are available to teams when confronted with conflicting options and targets.
- Ensures subject matter experts will evaluate regulatory and quality impacts of changes, establish requirements, and post approval actions when needed.
- Ensures available and competent measures are in place to facilitate changes that benefit the company's quality improvement initiatives.
- Monitors, measures, and reports on key indicators, progress, targets.

**Knowledge required for competency at this level:**

- In-depth knowledge of change management frameworks, techniques, and tools

## 3.5 Technical competencies list for Quality Assurance Manager

### 3.5.1 Quality Management Strategy

Collaborates with senior business stakeholders to develop and drive the implementation of a clear vision/action plan (including allocation of resources) for how quality assurance and quality control goals will be achieved within the organization.

Competency in this role is demonstrated when the individual:

- Facilitates and collaborates with senior leadership within the organization to articulate and approve a quality strategy.
- Documents and drives the communication of the quality strategy throughout the organization.
- Ensures that the different quality management roles are identified and staffed.
- Ensures the different quality management responsibilities are allocated and clearly defined.
- Ensures corporate quality targets exist, get measured appropriately, and are shared with senior management on a regular basis.
- Ensures root causes are well assessed and defined regarding noncompliance events.
- Ensures that quality assurance and quality control personnel collaborate to solve identified root causes of nonconformance incidents.

#### **Knowledge required for competency at this level:**

- Working knowledge of the ICH (International Council of Harmonization) guidelines for Good Clinical Practice (GCP)
- Knowledge of the stipulations of Division 5 of the Food and Drugs Act and regulations
- In-depth understanding of applicable industry regulations related to products and services provided
- In-depth knowledge of QMSs and strategic deployment

### 3.5.2 Quality Management System Implementation

Delivers and maintain a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. These coordinate and direct an organization's activity to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Competency in this role is demonstrated when the individual:

- Provides, implements, and maintains the company's QMS.
- Ensures that the quality manual with the updated company quality policy and quality management process is available to all employees.
- Leads the definition, mapping, and documentation of the critical quality processes.
- Oversees the document management system to manage the relevant procedures, work instructions, and quality records and data.
- Provides and implements processes and controls to ensure all GxP data are complete, consistent, and accurate throughout the data lifecycle (ALCOA+).
- Assists the organization in identifying the different quality management stakeholder roles/responsibilities.
- Ensures employees are trained in the quality management procedures and requirements.
- Facilitates, monitors, and ensures the effective use of the quality management process and system within the organization.

**Knowledge required for competency at this level:**

- In-depth knowledge of the applicable regulations regarding good quality management practices within the industry, e.g.:
  - Food and Drug regulations — biomedical and pharmaceutical sectors with specific reference to quality control related to Active Pharmaceutical Ingredients (API), as applicable
  - Different acts regulating activities within the biotechnology in Canada, e.g., the Canadian Environmental Protection Act 1999
  - Regulations related to the Canadian Energy Resources Management Act
  - ISO standards/applicable system certifications
- In-depth knowledge of different quality management techniques and tools such as Hazard Analysis and Critical Control Points
- Current Data Integrity and Compliance with cGMP FDA Guidance for Industry

### 3.5.3 Manage Quality Audits

Applies knowledge of the QMS and standard industry practices to ensure a process of documented assessment is in place and is executed as required, by internal or external quality auditors, which will reveal the level of conformance or nonconformance of the QMS to the process and/or product standards required.

Competency in this role is demonstrated when the individual:

- Develops and implements an audit management process to ensure required data and documents are available for audits.
- Collaborates with process owners to finalize the required audit plan(s) and documentation.
- Participates in developing criteria, audit standards preparation, and conduct procedures for the different types of internal and external audits.
- Ensures that internal audit teams are competent and trained in the audit process, internal techniques, and documentation.
- Ensures that external supplier audits are completed by qualified quality auditing teams.
- Ensures all audit results are correctly documented and that the documents are managed according to the QMS standards.
- Ensures complete resolution and effectiveness of audit observations by the concerned responsible.

**Knowledge required for competency at this level:**

- Detailed knowledge of relevant ISO/AS/QS/IPC/IEC Standards and Mil-Specs requirements
- In-depth knowledge of the requirements of different regulatory agencies, as applicable

#### 3.5.4 Critical Control Point Quality Assurance

Applies their understanding of the company's operation and value chain process to identify control points, develop procedures, and implement assessment processes that will ensure the achievement of the desired quality goals and milestones.

Competency in this role is demonstrated when the individual:

- Ensures the correct control points are implemented to verify the quality of raw materials, components, in-process materials, and finished products.
- Ensures that the process to reject inferior raw materials and components provides the feedback loop needed to ensure issues are corrected at the responsible supply points.
- Ensures all new product development projects are designed to guarantee consistent quality.
- Collaborates with the manufacturing teams to ensure quality control reviews are implemented at the critical transitional points within the manufacturing process.
- Ensures the nonconforming material system proves/shows lower cost and higher product quality in the long term and eliminates the recurrence of nonconformance events.

- Implements processes and controls to ensure any changes to critical points are justified, duly evaluated for their impact, and documented appropriately.

**Knowledge required for competency at this level:**

- Detailed knowledge of the product and/or services
- Detailed knowledge of the product/service quality processes
- Detailed knowledge of the approval procedure before product release
- Working knowledge of failure mode and effects analysis

### 3.5.5 Quality Management Capability

Analyzes the company's quality management requirements and ensure that the correct certifications, competencies, tools, and techniques are maintained to enable the organization to deliver excellence in products and services.

Competency in this role is demonstrated when the individual:

- Collaborates with the different department leads to analyze the company's quality requirements and allocate the required competencies to the different roles.
- Identifies the roles that require formal quality management certifications and assign the different certification qualifications to the roles.
- Plans, monitors, and ensures progress on the achievement of the formal quality qualifications against targets set within the QMS.
- Identifies the different tools and techniques that teams require to successfully execute quality assurance planning.
- Ensures training procedures are in place to build competency in the application of the required quality tools and techniques.
- Collaborates with the different quality management stakeholders responsible for obtaining and managing corporate quality certifications to complete and maintain proof of competence.
- Identifies training needs from recurrences in nonconformances event and root causes associated with manpower.

**Knowledge required for competency at this level:**

- Detailed knowledge of the Standards Council of Canada requirements, as applicable
- Detailed knowledge of the different corporate level certifications applicable to the organization (e.g., ISO13485, ISO 9001, etc.)
- Working knowledge of The American National Standards Institute requirements, where applicable
- Working knowledge of any international standards required for placing products in relevant global markets (e.g., CE Mark for medical devices in the European market)

**3.5.6 Product Release**

Participates in finished product quality reviews to release the product for distribution and to ensure production and shipping records are properly completed, establishing an audit trail for queries, product complaints, or product recall when and if required.

Competency in this role is demonstrated when the individual:

- Assists with production and release planning and shipping, as well as logistics planning to prevent supply disruptions.
- Reviews and approves transportation and storage requirements of the product to ensure quality is maintained after release.
- Reviews records and documentation from suppliers and contract manufacturers and compiles final shipping documentation.
- Ensures and oversees that the release status information is shared with the required stakeholders.
- Assists other functions with Corrective and Preventative Action documents, as required.
- Ensures any deviation or investigation has been duly documented and approved before batch disposition.
- Ensures all documentation meets internal procedures and regulatory requirements, including data integrity, before release.

**Knowledge required for competency at this level:**

- Understanding of continuous delivery and integration pipelines
- Working knowledge of project management

**3.5.7 Quality Tracking and Reporting**

Analyzes the company's business strategy to set and track quality goals and measurements. They also report on the quality of the products/services and operations to ensure the alignment of the QMS processes and goals with that of the organization.

Competency in this role is demonstrated when the individual:

- Analyzes the business strategy, value chain components, and customer complaints to suggest critical process metrics.
- Designs, proposes, and obtains approval for a corporate quality measurement plan.
- Collects and analyzes the quality performance data to refine the metrics and increase the reliability and validity of the information.
- Integrates the different measures into a corporate quality scorecard to report to the different process owners.
- Ensures company quality metrics show continuous improvement based on the topics identified throughout the quality measurement plan.
- Implements corrective and preventive actions and evaluates their effectiveness on a continuous basis.

**Knowledge required for competency at this level:**

- Working knowledge of work and performance assessment

## 3.6 Industry regulatory competencies list for Quality Assurance Manager

### 3.6.1 Records and Document Management

Applies knowledge of the company operating processes, legal, and regulatory requirements, as well as quality management practices, to ensure that all quality-related process documentation is identified, classified, controlled, revised, archived, and destroyed in compliance with requirements.

Competency in this role is demonstrated when the individual:

- Leads and delivers a document management structure to reflect and integrate with the quality management architecture.
- Ensures a document management procedure exists describing the process and stakeholder responsibilities.
- Ensures that physical and electronic information storage infrastructure is available with appropriate access controls and privileges for appropriate users.
- Ensures that all documentation management users are trained.
- Ensures compliance to the management of the documents through regular audits (internal and external).

- Ensures destruction of documents is done in compliance with relevant legal and regulatory requirements.
- Provides and implements processes and controls to ensure all GxP data are complete, consistent, and accurate throughout the data lifecycle (ALCOA+).

**Knowledge required for competency at this level:**

- Detailed knowledge of the relevant sections of the Canadian Food and Drugs Act
- Working knowledge of the Personal Information Protection and Electronic Documents Act, as required
- Working knowledge of legal guidelines on retention of different documents
- Detailed knowledge of documentation requirements under relevant ISO standards such as ISO 2001 and ISO 13485
- Working knowledge of Good Manufacturing Practice (GMP) and Good Documentation Practice (GDP) requirements
- Working knowledge of Current Data Integrity and Compliance with cGMP FDA Guidance for Industry

### 3.6.2 Manage Equipment and Instrument Qualifications

Ensures the availability of documented evidence showing that all instruments and equipment perform appropriately as per intended purpose and specifications, and that they are properly calibrated, maintained, and verified as per manufacturer recommendations and SOPs to ensure confidence in the verification of generated products and data.

Competency in this role is demonstrated when the individual:

- Designs and implements procedures within the QMS to ensure that all equipment and instruments used are correctly installed, commissioned, verified, maintained, and decommissioned (Installation Qualifications).
- Ensures that instrument inspections, verification, and maintenance are performed regularly, and records are properly maintained (Operational Qualifications).
- Maintains records/documents of instrument/equipment verification showing effective and consistent performance within required specifications.
- Provides proof that all instruments are inspected and qualified at required intervals.
- Ensures the accuracy of different analytical procedures and the use of accuracy thresholds, certified reference materials, and control samples.
- Ensures a cleaning validation master plan is available when necessary and meeting regulatory requirements.
- Ensures a computer validation master plan is available when necessary and meeting regulatory requirements.

**Knowledge required for competency at this level:**

- Ability to analyze and apply the “Gold Sheet” intel and analysis of developments in FDA regulations and policies
- Ability to enact the Quality Inspection Agency procedures
- Understanding of the implications and requirements of ISO 9001
- Understanding of the implications and requirements of ISO 13485

### 3.7 Work Process competencies list for Quality Assurance Manager

#### 3.7.1 Quality Process Improvement

Collaborates with process owners to analyze nonconformance incidents and identify opportunities for improvements to the Quality Management System. (QMS.)

Competency in this role is demonstrated when the individual:

- Ensures that the process to detect areas of noncompliance is used to document and identify opportunities for continuous improvement.
- Provides tools and training for teams to analyze nonconformance incidents and identify process improvements to implement.
- Ensures that the quality system used provides the organization with documentation of any proposed process changes.
- Collaborates with different process owners to monitor and assess the implementation of process changes and ensure the documentation/measurement of results/impact.

**Knowledge required for competency at this level:**

- Benchmarking techniques
- Force Field Analysis
- Working knowledge of flow charts, Pareto charts, cause and effect diagrams, scatter diagrams, check sheets, control charts

- Working understanding of the Delphi technique
- Knowledge of the Process Capability Index and Ratio

### 3.7.2 Risk Management

Completes a thorough risk analysis of projects/products to identify potential hazards and implement risk management measures to ensure product safety and maintain regulatory compliance.

Competency in this role is demonstrated when the individual:

- Develops an early project risk profile to ensure risk mitigation strategies are built into the project plan and maintains the profile throughout the project lifecycle.
- Educates and coaches project team members on identifying and mitigating potential risks.
- Monitors the impact of implemented risk mitigation efforts to ensure effectiveness of measures and no introduction of further harm as a result.
- Evaluates and understands the insurance requirements, warranties, and maintenance schedules versus potential exposure to guide and approve risk mitigation plans.
- Implements prompt and effective risk mitigation measures, as required.

#### **Knowledge required for competency at this level:**

- Detailed knowledge of ICH guidelines
- Understanding of risk assessment models
- Working knowledge of informed consent processes (ICP) and requirements
- Working knowledge of serious adverse event (SAE) identification and capturing
- Working knowledge of SAE reporting guidelines and requirements
- Knowledge of applicable safety update reports

## 3.8 Personal and professional competencies list for Quality Assurance Manager

### 3.8.1 Fostering Collaboration

Considers the multidisciplinary involvement of quality management and identify the critical stakeholders for collaboration across boundaries and within defined roles and responsibilities to accomplish shared outcomes and greater quality and operational results/achievements.

Competency in this role is demonstrated when the individual:

- Identifies different stakeholders with key contributions in improving quality culture and achievements within the organization.
- Interacts and builds rapport through active listening and support of the different stakeholders' quality goals.
- Establishes formal collaborative relationships with significant contributors by defining potential contributions, roles, and responsibilities and formalize these efforts with the different stakeholders.
- Asks for support, input, and contribution from the stakeholders' groups to drive and deliver improved quality results across all businesses.

#### **Knowledge required for competency at this level:**

- Understanding of teamwork and team dynamics

### 3.8.2 Directing Others

Uses input from others to develop instruction and guidance regarding the achievement of predetermined quality goals in such a way as to motivate multiple stakeholders to work effectively and collaboratively towards the achievement of these goals.

Competency in this role is demonstrated when the individual:

- Consults on a broad basis with process owners to identify quality targets that will be challenging but realistic to achieve.
- Communicates the expected targets and expectations of the responsible individuals clearly and through different modalities, as necessary.
- Clarifies the current state of projects and reasons for specific objectives.
- Describes any expected changes and outlines expectations of commitment to the proposed changes by the various roles.

**Knowledge required for competency at this level:**

- Knowledge of how to set and facilitate directional changes in plans and or targets

### 3.8.3 Professionalism/Emotional Intelligence

Applies emotional and professional sensitivity to become aware of their own emotions and those of the others they interact with in such a way that they can manage personal and professional decorum and maintain productive relationships.

Competency in this role is demonstrated when the individual:

- Consistently models ethical conduct such as discretion, personal integrity, and respect for diversity to foster cooperation and collaboration in the achievement of organizational objectives (self-awareness).
- Exercises initiative to proactively address emerging, regulatory, legislative, and technical concerns (self-management and regulation).
- Works cooperatively with multiple stakeholders, demonstrating tact, diplomacy, and a willingness to consider alternative approaches or ideas that achieve results within ethical guidelines (relationship management).
- Navigates effectively through personal and political agendas to avoid or overcome barriers to the organization's progress (social awareness).

**Knowledge required for competency at this level:**

- Working understanding of the principles of emotional intelligence.
- Self-awareness in workplace interactions.
- Social awareness

## 3.9 Essential Skills for Quality Assurance Manager

Essential Skills (ES) are foundational skills required for all types of work. They are not technical skills, but the core skills people need to acquire knowledge and complete workplace tasks and daily activities.

Understanding the ES requirements for a role can allow individuals to compare their skills to those required, assist training/learning providers in developing appropriate supports to ensure ES levels are developed during training, and provide employers with an additional tool for determining who/how to place in particular roles.

Human Resources and Skills Development Canada has defined Essential Skills as follows:

- Reading
- Document Use
- Numeracy, which is further divided into:
  - Money math; Scheduling, budgeting, and accounting math; Measurement and calculation math; Data analysis math.
  - Several different factors related to estimations, including the presence of a set procedure, the number of items being estimated, the consequences of errors in estimation, the amount of information missing, and the accuracy required.
- Writing
- Oral Communication
- Thinking Skills, which are further divided into:
  - Problem Solving
  - Decision Making
  - Critical Thinking
  - Job Task Planning and Organizing
  - Finding Information
  - Significant Use of Memory
- Digital Skills
- Working with Others
- Continuous Learning

Most of the ES have levels based on complexity, and a role can be analyzed to determine the appropriate levels of ES. The exceptions are noted below:

- "Working with Others" does not have a complexity rating: it simply describes the ways in which the role would be required to interact with other people, either internally within the organization or externally (i.e., with clients, customers, or the public).
- "Continuous Learning" does not have a complexity rating: it describes the types of learning expected in the context of the role (e.g., on the job, being mentored by others, formal training as part of the job, etc.).

*NOTE: as of January 2020, ESDC was undertaking a comprehensive review of ES with the intent of adding additional skills, refining existing ones (particularly digital skills), and better aligning ES with similar approaches used in other countries. However, the detail was not finalized in time to be used, therefore the profiles developed for this project follow existing standards as of December 2019.*

### 3.10 Canadian Language Benchmark for A Quality Assurance Manager

Canadian Language Benchmarks (CLB) are a 12-point scale for task-based language proficiency descriptors which were originally developed as a guide for measuring the teaching and assessment of English as a Second Language (ESL) learners in Canada. Since they were originally developed, the Canadian Centre for Language Benchmarks (CCLB) has continued to refine CLB, and it now includes scales for both English and French language proficiency.<sup>1</sup>

The CLB has been validated against both the Common European Framework for Language (CEFL) and the American Council for the Teaching of Foreign Languages (ACTFL) benchmarks and is considered accurate for high-stakes evaluation<sup>2</sup>.

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<sup>1</sup> Centre for Canadian Language Benchmarks. Theoretical Framework for The Canadian Language Benchmarks and *Niveaux De Compétence Linguistique Canadiens*. CCLB. Ottawa 2015. p8

<sup>2</sup> Centre for Canadian Language Benchmarks. Canadian Language Benchmarks: English as a Second Language for Adults, CCLB. Ottawa 2012 p.II

The ES levels for Oral Communication were developed with reference to the Canadian Language Benchmarks<sup>3</sup>. Comparative work to determine the alignment between the CLB and other Essential Skills has been ongoing, with recent work providing additional alignment with the ES for Oral Communication in both spoken and listening domains, Reading, Writing, and Document Use.<sup>4</sup>

CCLB has developed a set of crossover tables that align CLB ratings with ES ratings for reading, writing oral communication and document use.

### Quality Assurance Manager ES/CLB Profile

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Reading	Reading 9–10	1	2	3	4	5
Document Use	Reading: 11–12 Writing: 9–10	1	2	3	4	5
Writing	Writing 9–10	1	2	3	4	5
Oral Expression	Speaking: 11–12 Listening: 11–12	1	2	3	4	5
Numeracy	n/a	1	2	3	4	5
Thinking Skills – Problem Solving	n/a	1	2	3	4	
Thinking Skills – Decision Making	n/a	1	2	3	4	
Thinking Skills – Job/Task Planning and Organizing	n/a	1	2	3	4	
Thinking Skills – Significant Use of Memory	n/a	Types 1,2,3				
Thinking Skills – Finding Information	n/a	1	2	3	4	

<sup>3</sup> Essential Skills Research Group. Readers Guide to the Essential Skills. ESDC. Ottawa ND. p57

<sup>4</sup> Canadian Centre for Language Benchmarks. Relating Canadian Language Benchmarks to Essential Skills: A Comparative Framework. 2015, p3

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Digital Skills	n/a	1	2	3	4	5
Working with Others	n/a	See Below				
Continuous Learning	n/a	See Below				

### Explanation of the Essential Skills and the Canadian Language Benchmark for a Quality Assurance Manager

#### Reading: ES: 4 CLB: 9–10

QA Managers read and understand a variety of technical and scientific documents related to production, the QMS in use, regulations, and corporate procedures. These include testing protocols, regulatory requirements, audit plans, a variety of internal quality system reports, and technical/professional documentation related to best practice and professional standards in quality assurance.

#### Document Use: ES: 4 CLB: Reading: 11–12 Writing: 9–10

QA Managers access and gather information from a variety of paper and electronic documents, including the creation and interpretation of data representations such as flow charts, scatter diagrams, cause/effect diagrams, etc. to solve problems, make decisions, or develop reports used by others. Information is accessed in standard formats, with interpretation/translation required to use the information for other purposes.

#### Writing: ES: 4 CLB: 9–10

QA Managers are responsible for writing QMS performance reports for management and other internal and external documents related to the quality assurance/quality control function. They produce a written analysis of the results of quality control testing, quality audits, and mitigation/improvement activities. They also develop documentation to provide guidance to others (generally from the production function) on quality program processes.

**Oral Expression: ES: 4 CLB: Speaking: 11–12 Listening: 11–12**

QA Managers communicate internally with production and engineering staff and senior management to relay information on quality system performance, quality variances, and mitigation procedures. They engage in technical discussions with process owners and quality system personnel to troubleshoot and resolve quality issues. They also instruct, coach, and mentor their own staff, providing verbal instructions on correct quality assurance processes and critical quality management system protocols to ensure the performance of the overall quality system.

**Numeracy ES:4 (Money Math: 3, Scheduling, Budgeting and Accounting: 3, Measurements: n/a, Data Analysis: 3)**

QA Managers are responsible for departmental budgets, expense management and reporting for department operations, and contributions to forecasts for future profitability of the production function. They are involved in the scheduling and organization of department work, assigning tasks to others, and monitoring performance. They also oversee the collection and analysis of quality data from current processes and develop and deploy statistical modeling processes for the analysis of quality data.

**Thinking Skills:**

Thinking skills are subdivided into five domains:

- Thinking Skills — Problem Solving
- Thinking Skills — Decision Making
- Thinking Skills — Job/Task Planning and Organizing
- Thinking Skills — Finding Information
- Thinking Skills — Significant Use of Memory
- **Thinking Skills — Problem Solving: ES 4**

QA Managers solve complex, multi-variate problems in the course of their work. They deal with problems of a scientific and technical nature where the interactions of variables may be unknown or unpredictable, and they must develop a process for solving these problems to optimize the outcomes.

- **Thinking Skills — Decision Making: ES 3**

QA Managers analyze, synthesize, and evaluate arguments, information, and data and must exercise sound judgement in deciding between alternative courses of action. The decisions they make can have significant financial consequences for their organization; these decisions can be reversed, but not without cost and inconvenience.

- **Thinking Skills — Job/Task Planning and Organizing: ES 3**

QA Managers plan their own work, considering the availability of shared resources and the potential scheduling conflicts with others. They plan and direct the work of their departments, setting priorities and allocating and managing limited resources to optimize their value. They have wide discretion over what and how of their work and are expected to manage their time to meet specific milestones and corporate performance targets. They work within an interdisciplinary team to execute projects that impact the future profitability of the organization.

- **Thinking Skills — Finding Information: ES 3**

QA Managers collect, analyze, and interpret data from a variety of different scientific and technical resources in the course of their work. Some information is directly useable, while other components must be synthesized and interpreted/translated for use in other contexts.

- **Thinking Skills — Significant Use of Memory: Types 1, 2, 3**

QA Managers must memorize, retain, and use information through one or all the following methods:

- Purposeful memorization of procedures, codes, parts numbers, memorization through repetition (Type 1)
- Remembering information for brief periods, e.g., minutes or hours (Type 2)
- Unique events in which learning occurs from exposure (Type 3)

**Digital Skills: ES: 3**

QA Managers utilize standard office productivity software tools (Word processing, spreadsheets, presentations, etc.) and electronic communication tools (email, text, instant messaging, video conferencing, etc.), and set up and use specialized data capture and analysis tools/software in the performance of their duties.

**Working with Others: Contexts 2, 3 & 4**

The following work contexts and functions are relevant to the QA Manager role:

- Works independently (Work Context 2)
- Works jointly with a partner or helper (Work Context 3)
- Works as a member of a team (Work Context 4)

**They may also be involved in supervisory or leadership activities, as follows: Functions 1–5 & 8–12**

- Participate in formal discussions about work processes or product improvement (S/L Function 1)
- Have opportunities to make suggestions on improving work processes (S/L Function 2)
- Monitor the work performance of others (S/L Function 3)
- Inform other workers or demonstrate to them how tasks are to be performed (S/L Function 4)
- Orient new employees (S/L Function 5)
- Select contractors and suppliers (S/L Function 8)
- Assign routine tasks to other workers (S/L Function 9)
- Assign new or unusual tasks to other workers (S/L Function 10)
- Identify training that is required by or would be useful for other workers (S/L Function 11)
- Deal with other workers' grievances or complaints (S/L Function 12)

**Continuous Learning: Types of Learning: 1, 2, 3 How Learning Occurs: 1, 2, 3, 4, 5, 6**

QA Managers are expected to continuously learn as a requirement of the role.

**Type of learning may include:**

- Training in job-related health and safety (Type 1)
- Obtaining and updating credentials (Type 2)
- Learning about new equipment, procedures, products, and services (Type 3)

**The learning may occur:**

- As part of regular work activity (Context 1)
- From coworkers (Context 2)
- Through training offered in the workplace (Context 3)
- Through other forms of self-study (Context 4):
  - At work
  - On worker's own time
  - Using materials available through work
  - Using materials obtained through a professional association or union
  - Using materials obtained through worker's own initiative
- Through off-site training (Context 5):
  - During working hours at no cost to the workers
  - Partially subsidized
- With costs paid by the worker (Context 6)

## 4 REFERENCES

### Gathering the data

The development of the National Occupational Standards started with a review of existing information for the role. This review process included: referencing books, job postings, websites, articles, and BioTalent Canada's existing skills profiles to create the first draft. After several iterations via written feedback, focus groups and a national survey with subject matter experts, the National Standards were developed. The following are sources consulted during the creation of the **Quality Assurance Manager** profile:

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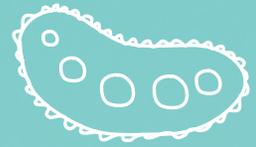
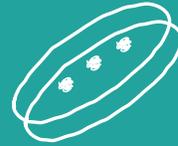
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During the research period, several job posting boards were reviewed for this profile.

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