



Is the ISO 9001:2015 a risk or an opportunity for a microbial Biological Resource Centre?



www.mut.unito.it www.unito.it

Iolanda Perugini, Luisella Reale, Isabella Martini, Giovanna Cristina Varese
Department of Life Sciences and Systems Biology, University of Turin - Italy

MUT - MYCOTHECA UNIVERSITATIS TAURINENSIS

The Mycotheca Universitatis Taurinensis (MUT) is the fungal culture collection of the Department of Life Sciences and Systems Biology (DBIOS) of the University of Turin (UNITO). The aims of MUT are: acquisition, identification, characterization, preservation and distribution of fungi to support academic research and bioeconomy. In order to become a reliable provider of biological resources and service MUT decided to undertake the ISO certification in 2006, with the intent of achieving the processes' standardization. While waiting for new standard on Biobanks, ISO/DIS 20387, MUT worked on the transition from ISO 9001:2008 to the new ISO 9001:2015, focusing on the risk analysis of all processes.

ISO 9001:2015

The new ISO 9001 defines the generic requirements for a quality management system that are applicable to any type of organization, including public microbial Biological Resource Centres (mBRCs). The ISO 9001 quality management standards help those who wish to submit their production processes to a quality control in a cyclical manner, starting from the definition of the customer's requirements and ending with monitoring of all phases of the production process. According to ISO 9001:2015, the quality management system can support the organization focusing on the continuous improvement of products and services.

ISSUES OF CONTEXT

MUT identified the internal and the external issues that influence the following elements: **strategic** (products research, market, training), **competitive technological** (human resources and infrastructure) and **legal obligations** (e.g. environment, safety etc.). MUT also defined the **interested parties**, their **needs** and **expectations**, and the **indicators** for monitoring and evaluating each **process** together with internal and external **communication methods**.

INTERESTED PARTIES: THEIR NEEDS AND EXPECTATIONS

Customers (academic, industrial, public service user): Quality, costs and delivery performance of products, trustworthy relations

Suppliers and partners: Mutual benefits and continuity

Employees of the organization: Good work environment, biosafety and biosecurity, transparency

Society: Ethical behavior, Environmental protection, law compliance

MUT Context

PRODUCTS AND SERVICES

Market product:

- Strains
- Services

Research product:

- Publications
- R&D projects

Training:

- Courses for undergraduate and PhD students, technicians
- Tailored courses for companies, public bodies, schools etc.

PROCESSES

Primary processes related to research, performance, training, and services:

- Business/ commercial
- Supplying
- Research design and development

Support processes needed for the management and improvement of the performance:

- Human resources management
- Evaluation of suppliers
- Quality management
- Documents check and legal compliance

For these processes, MUT identified:

- the main objectives and the key performance indicators (KPI);
- the methods for the data collection and management useful to assess the processes' effectiveness.

MUT Quality Management System

MUT applied the QMS to all the activities with the aim of:

- identifying the inputs and outputs;
- ensuring the availability of resources and information necessary to support each step in the processes and their monitoring;
- assigning responsibilities of the different processes within the involved staff, belonging to MUT, DBIOS and UNITO;
- assessing opportunities and risks;
- implementing the analysis of the results in view of a continuous improvement.



Structure of ISO 9001 in PDCA cycle – Number in brackets refer to the clauses in this International Standard

The **QMS** has been defined by MUT on the basis of the **Plan-Do-Check-Act cycle** and the **Risk Base Thinking** in order to:

- guarantee the supply of products and services compliant with customer requirements and with legislation;
- apply the rules of quality assessment and management to basic and applied research.

OPPORTUNITIES

- Accurate planning of activities
- Performance assessment (KPI)
- Continuous evaluation of staff skills
- Planned training
- Traceability of activities
- Internal and external audits
- Improved transparency

RISKS

- Difficulty in applying ISO 9001 to the UNITO administrative staff
- Difficulty in raising awareness of the benefits of a QMS within staff
- Increased time-consuming work for QMS activities the few permanent MUT staff is in charged of
- Increased in management cost due also to the need of temporary fellows.

GOALS

- **Increased quality of products and services**
- **Increased stakeholder community**
- **Increase visibility**

Conclusion

In June 2018, MUT was certified compliant to ISO 9001:2015. This process lead to the identification of strengths and weaknesses of MUT management. Therefore, the regular monitoring of internal and external factors is essential to improve the management and the activities of the collection. MUT is aware that ISO 9001:2015 is an important opportunity to enhance the **quality of products and of the services provided, the stakeholder community, the customer satisfaction, and to bring more profit and society benefits.**