Thoughts about elements in a quality management system

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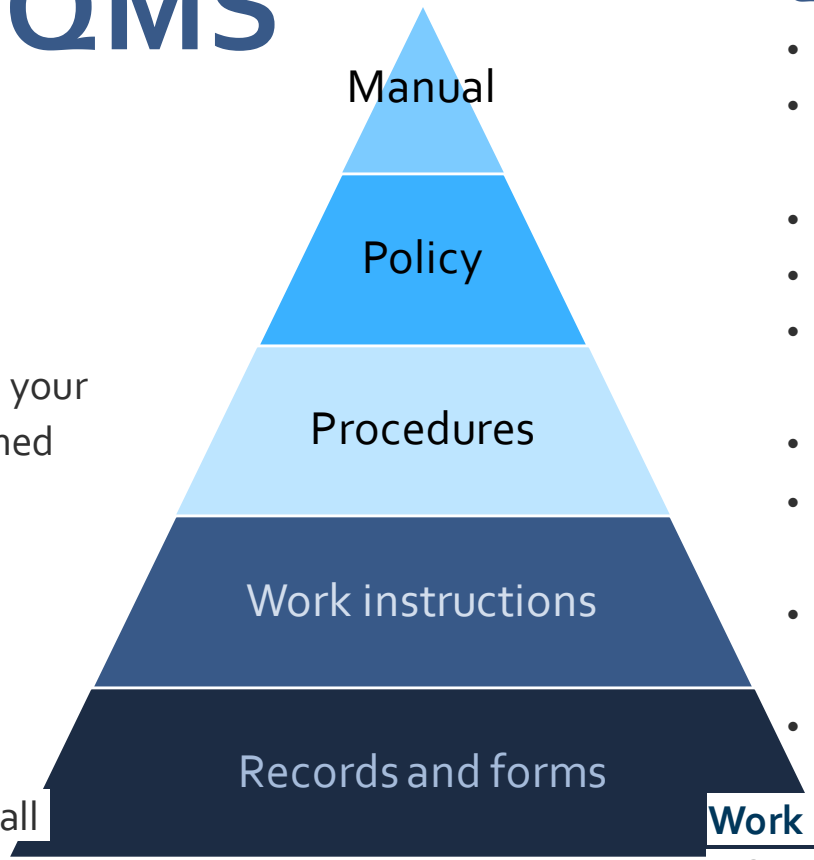
QMS

Q= Quality
M= Mangement
S= System

Quality Management System (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

A QMS ensures that products or services are consistently in compliance with customer, standards and regulatory requirements.

Elements in a QMS



The **Quality Policy** is the organizations commitment to quality, to continual improvement, and to fulfilling its legal and regulatory obligations. Basically, it outlines your organization's quality goals, which are defined by quantifying its quality objectives.

Quality procedures. The backbone of an organization's QMS. Their purpose is to establish processes that will ensure the company's activities conform to requirements. Quality procedures come in all shapes and sizes. They can be descriptive, such as in narrative form; they can be in a more structured format, like tables; they can be more illustrative, such as a flow chart; or they can be a combination of any or all of the above.

Records and forms Documents that provide evidence that a process is in place and performed according to the procedure or work instruction. For example, inspection records show that an inspection was performed, along with some specific findings.

Quality Manual. Would typical include:

- title and table of contents
- information about document version and approvals
- a description of the QMS
- the scope of the QMS
- Including any standards or systems to follow or why not
- business model and organisation
- roles and responsibilities of management and staff
- references to additional relevant documents and appendices
- the Quality Policy and objectives

Work instructions. Can be a part of a procedure, or a reference to in the procedure. Work instructions are typically structured in the same way as the procedures, and cover the same elements; BUT, the work instructions provide greater detail about the activities that need to be performed, with an emphasis on the sequence of steps to be taken, the tools and methods to be used, and the accuracy requirements.

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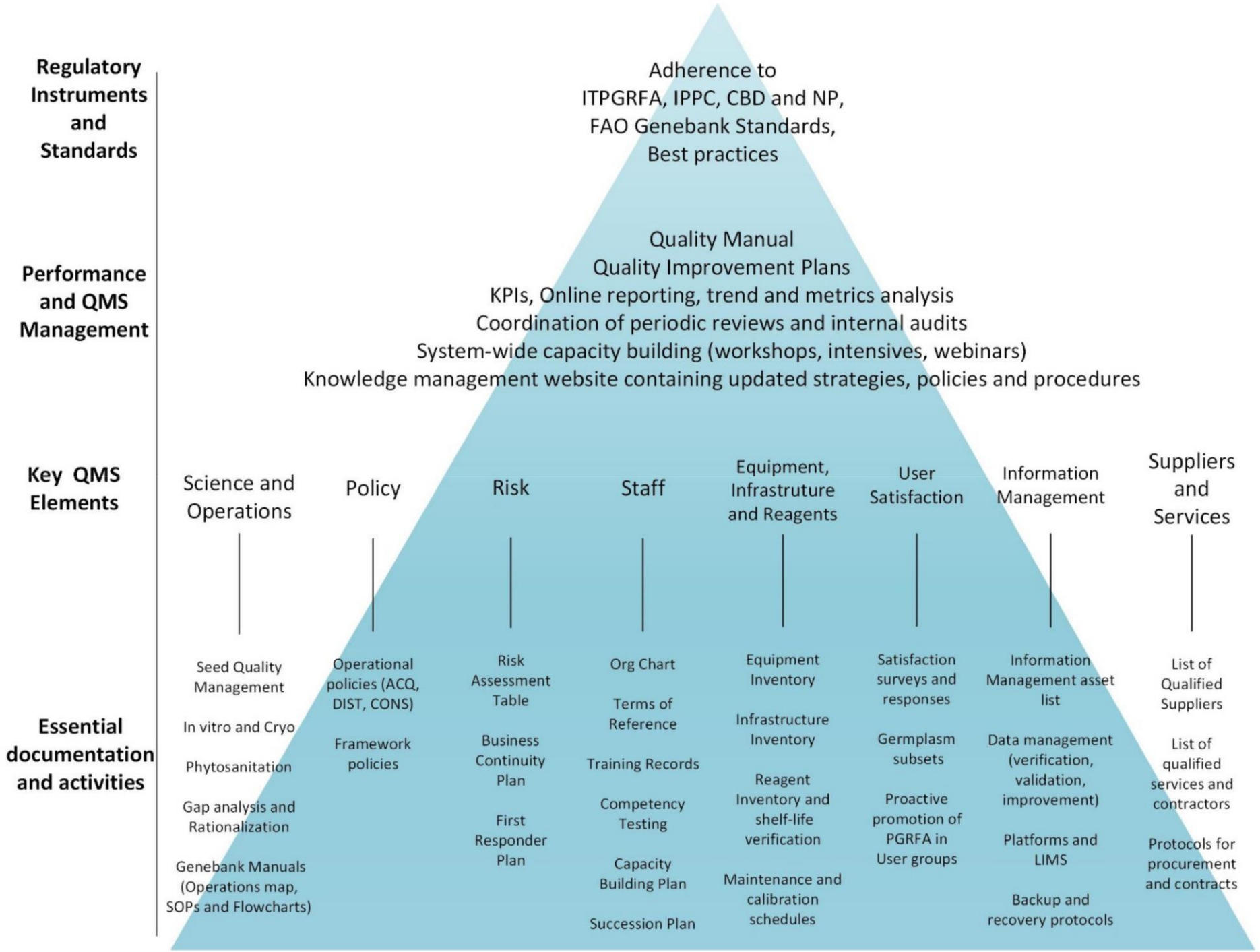
Quality Management Systems and standards - Different elements in different QMS regulations

ISO 9001 ISO 9000

AEGIS Quality System (AQUAS)

ISTA
Seed Quality Assurance

CGIAR



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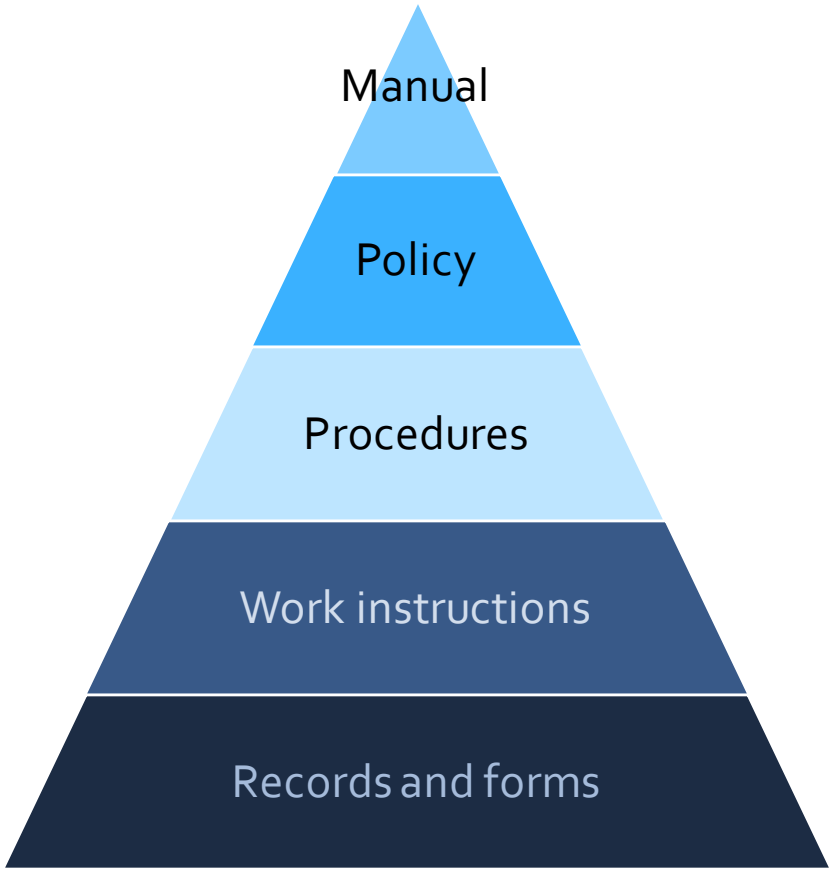
What elements – what can be relevant ?

System



Standards

ISTA
Seed Quality Assurance

Organisational capacity and ambition

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Thoughts

There is no QMS system and standards that can stand alone today for genebanks.

Use the elements that fit your purpose and ambitions

The QMS is only as good as the internal ownership of your system and its procedures. Involve everyone, make internal audits, learn from your non-conformities, improve and learn.

Recap

- Did we meet the expectations?
- What has been useful?
- What could be better?

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European Cooperative Programme for Plant Genetic Resources

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Next meeting

- Topics
- Engagement

- Physical meeting 2025

  Crop Research Institute in the Czech Republic

  Host: Dagmar Janovská

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