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5.4 Proactive approaches to quality management

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The publication of the *ISO 20387 - Biotechnology - Biobanking - General requirements for biobanking* standard – planned for the end of 2018 - can broadly impact the manner of culture collections - also known as biobanks from microbial domain (mBb) - work and interact with each other and society. It is currently going through its public consultation stage providing mBb with an (almost unique) opportunity to comment and improve the standard's appropriateness to the mBb needs. ISO 20387 is intended to ensure competence and a consistent biobanking operation by conveying general provisions including quality control requirements.

Quality control is related to Quality by Testing, the current paradigm to manage quality (concerning the microorganism testing) in mBb. It is a reactive approach where consistency relies on extensive testing throughout the *microorganism preservation lifecycle*.

Through process design, qualification and continual improvement - using proactive and knowledge based approaches such as Quality by Design and Knowledge Management, consistency can be efficiently achieved and process capability improved. Besides microorganism testing for viability, identity and purity, process validation can ensure consistency in preserving the microorganisms for the long term.