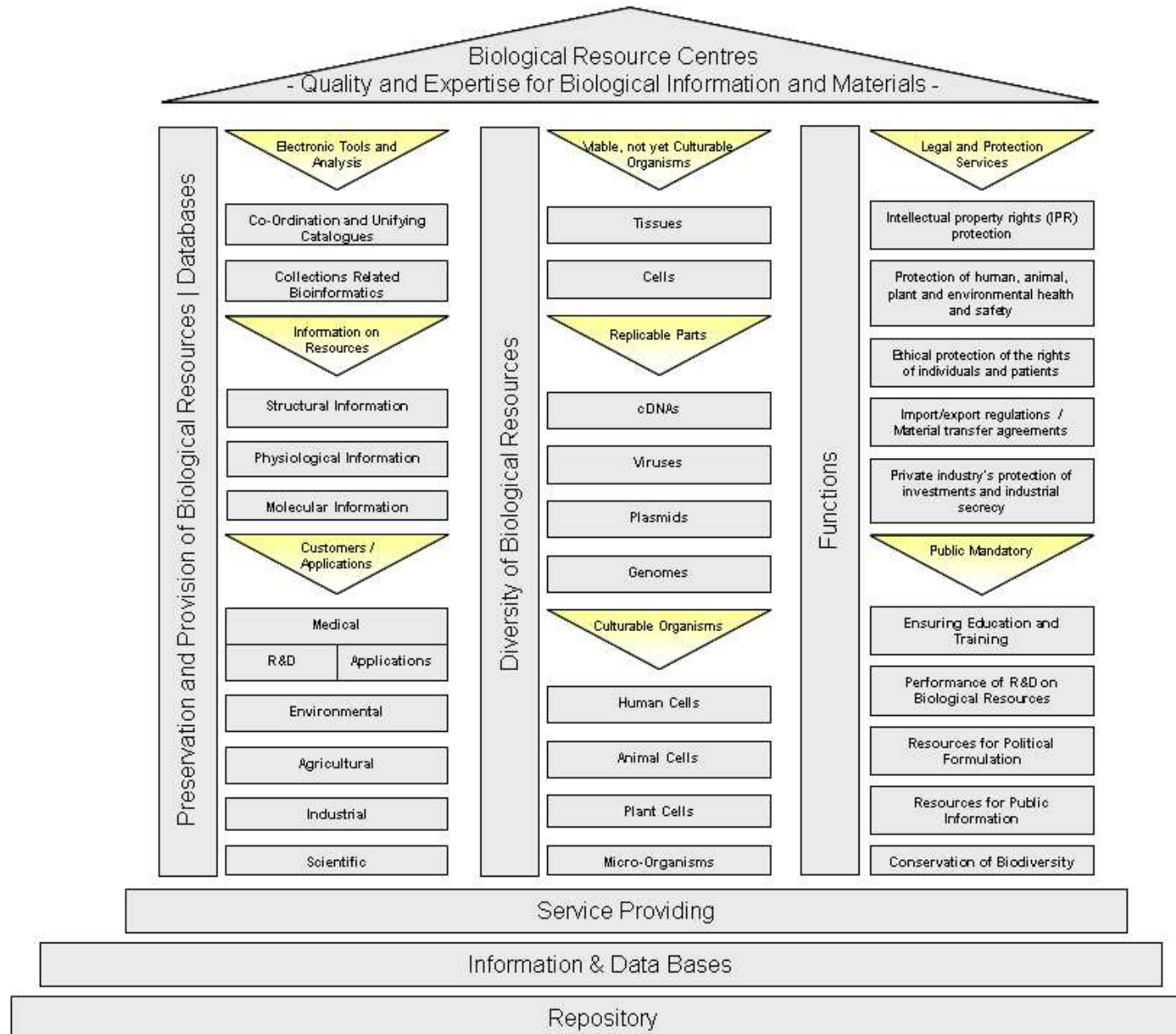


Session V: Implementation of best practice GBRCN Demonstration project activities

**Key Aspects of Quality Management in BRCs
and
Self-Assessment Exercise and Analysis**

Dunja Martin, Joint human & microbial domain GBRCN
pilot phase meeting, 29th – 30th November 2010, Vienna

Definition of a modern BRC according to OECD



Key Aspects of Quality Management

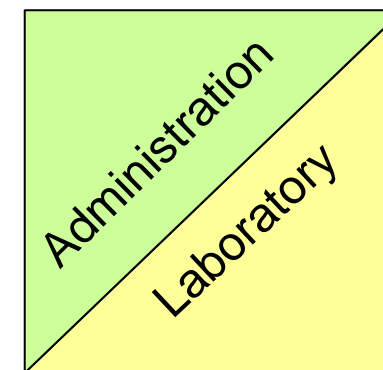
Issues, which impact significantly the implementation and maintenance of quality management in culture collections:

Laboratory perspective:

- documentation,
- long term perspective (preservation, stocks)
- data collection (comprehensiveness, quality, availability)
- laboratory safety and hygiene
- core processes in the laboratories
- continuous improvement,

Administrative perspective:

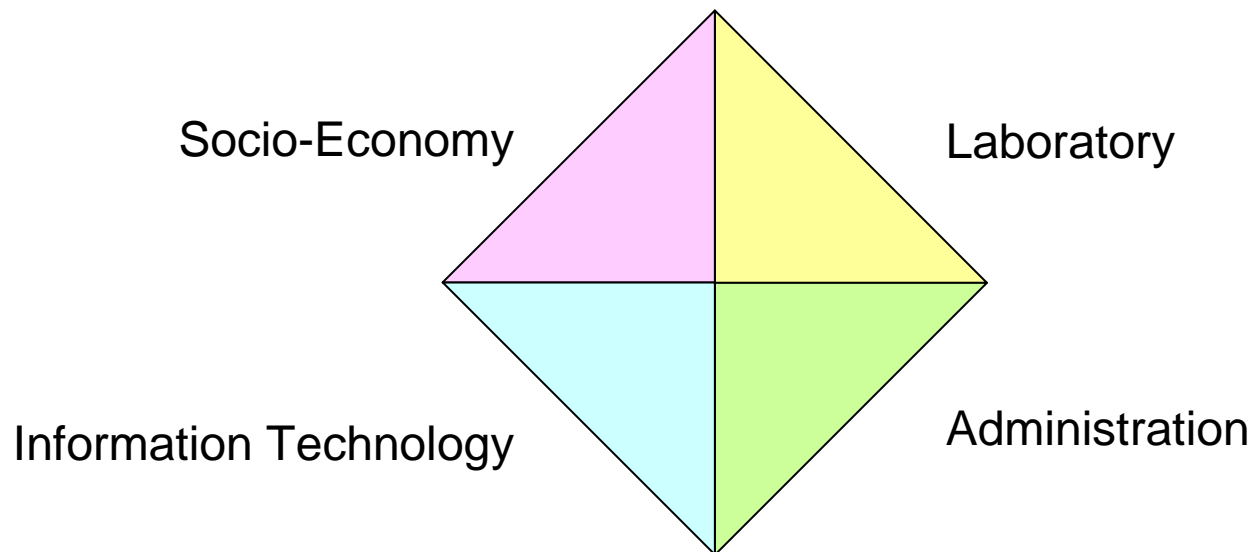
- organizational behaviour,
- human resources management,
- financial condition,
- customer relations and
- evaluation / revision.



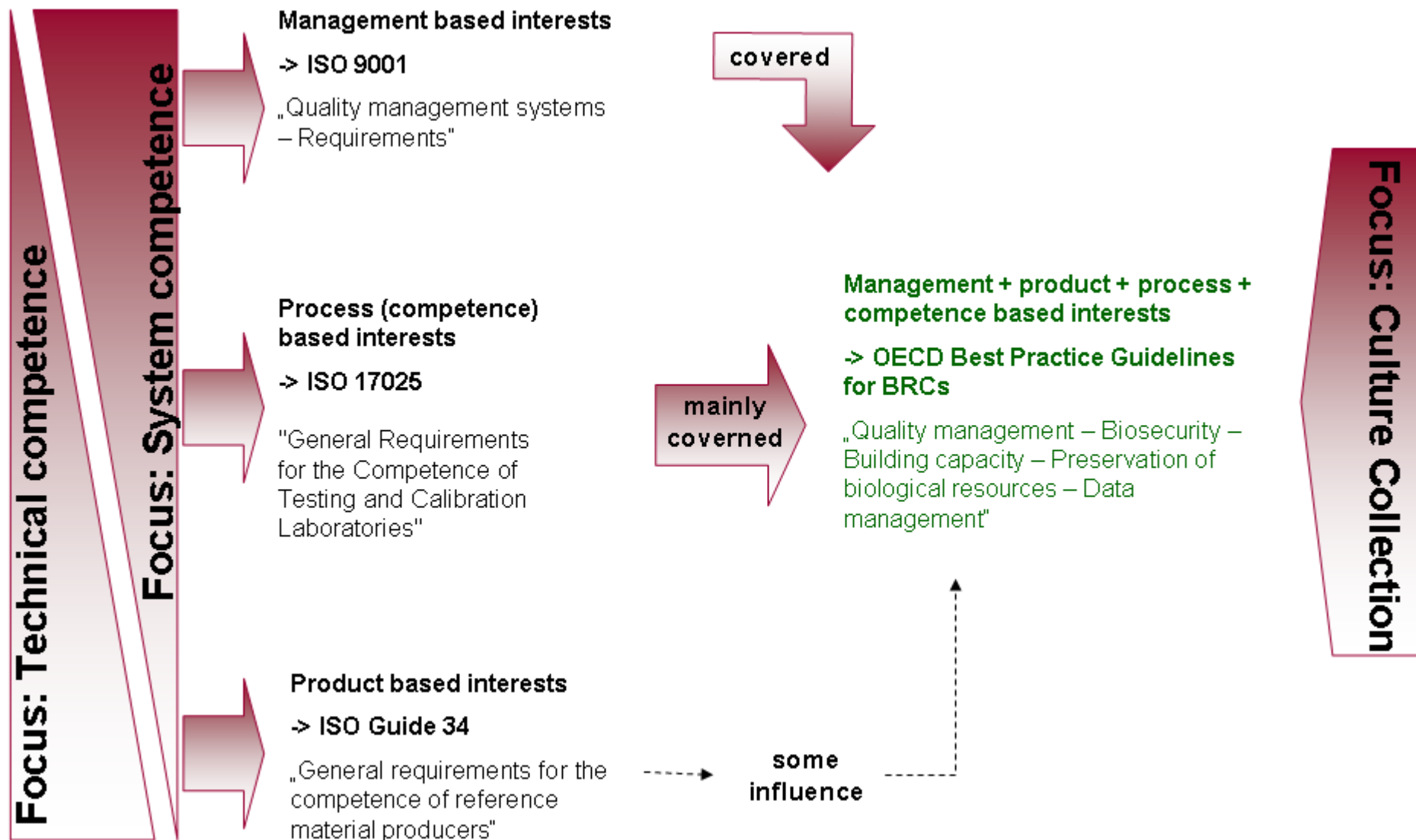
Key Issues in Quality Management

There are even **far-reaching issues according to** the definition of the **OECD** for Biological Resource Centres (BRC):

- social and socio-economic tasks,
- sustainable financial management,
- balancing of commercial and scientific interests as equitable stakeholders,
- linkage to modern respective innovative information technologies and
- realisation of governmental and cross-national legislation in the fields of biotechnology and security interests.



OECD BPG: a Special Tailored Guideline for BRCs



Key Issues for BRCs Addressed by OECD

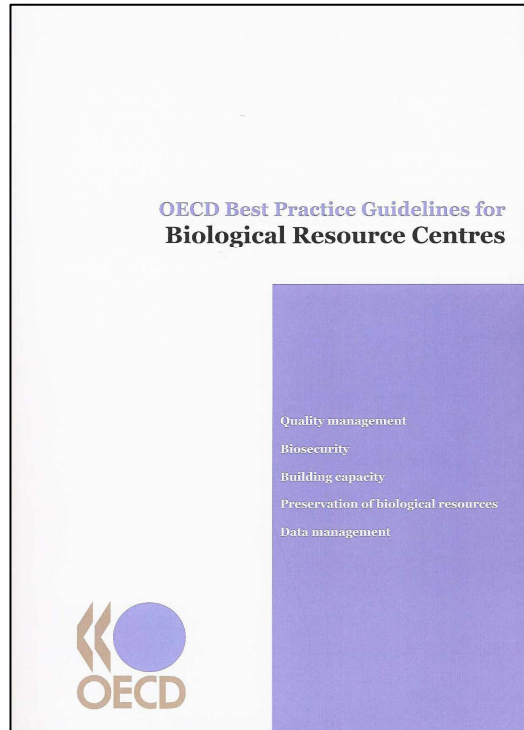
But although having a high coverage of all requirements in one single guideline, there are **still unsolved problems left to the individual BRCs** and their quality managers.

- > transition of the guidelines into the own organization,
- > handling of increasing coeval requirements
- > diminishing financial support and
- > exposure to regulatory compliance.

A golden rule is difficult to set up, as **BRCs themselves mirror the diversity of the biological material** by having different organizational structures of small, large, complex, independent or dependent, profit or non-profit and state-run organizations or commercial enterprises.

OECD Best Practice Guidelines have **synthesized basic rules** and critical factors **for a successful implementation** of an individual quality management in a chain of reasoning **to gain a sustainable quality management** being manageable.

Effects of Implementing the OECD BPG

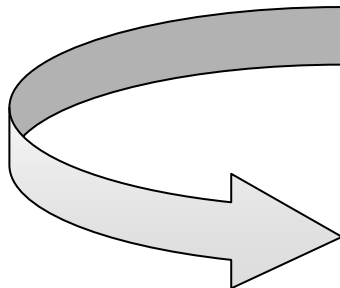


Aligning culture collections to

- deliver authentic biological material,
- preserved by state of the art techniques with
- validated information and
- published with shared protocols.

Transition culture collections into modern BRCs by approving compliance through a independent, third party assessment.

Pre-conditioning for culture collections to comply with OECD Best Practice Guidelines to become a member of the GBRCN.



GBRCN must configure the compliance process

- to guarantee the above requests
- to allow culture collections an appropriate transition and
- to be inclusive to the world community of culture collections.

Self-Assessment Exercise and Analysis

OECD Best Practice Guidelines for BRCs



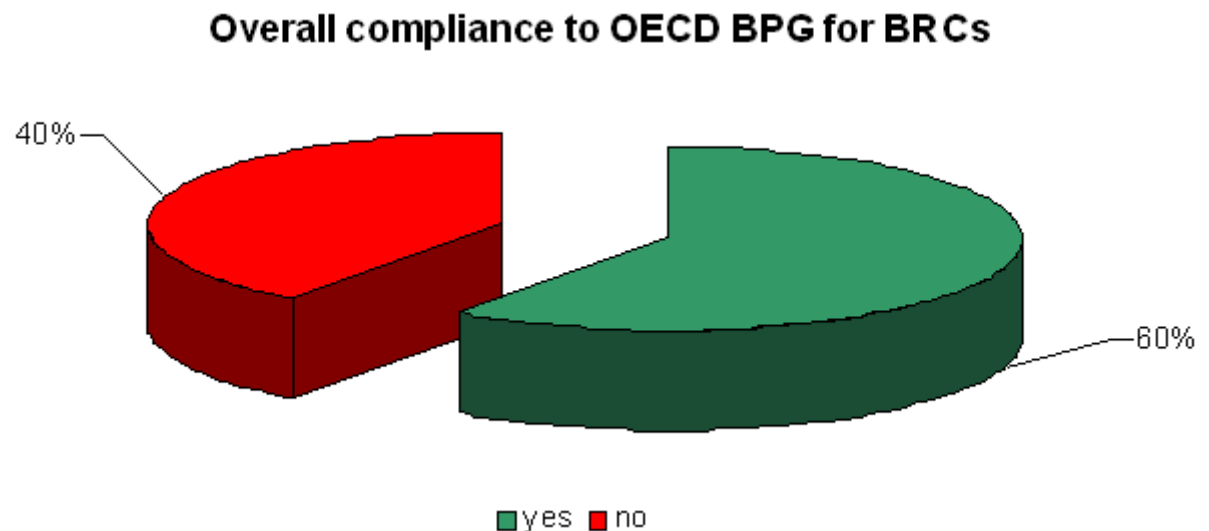
9 GBRCN Pilot Project Partners performed an Internal Audit according to the OECD BPG checklist:

Belgium	BCCM
Brazil	CBMAI
Finland	VTT
France	CIP
Germany	DSMZ
Netherlands	CBS
Portugal	MUM
Spain	CECT
UK	CABI

in preparation

Russia	VKM
Taiwan	FIRDI
UK	NCIMB

Overall result of the self-evaluation:



Self-Evaluation Based on an Audit

Checklist

To ensure that the conformity to the specific requirements is succeeded an **internal audit is performed following a matrix** comprised by six columns:

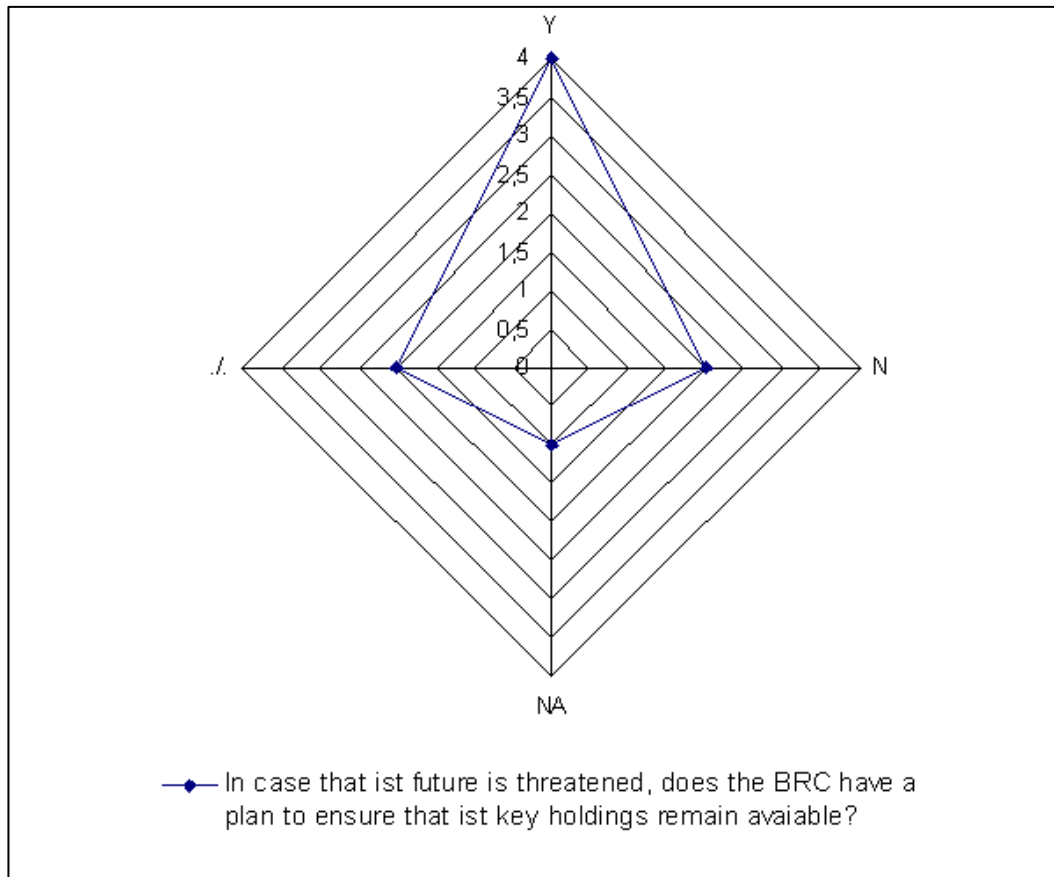
- Chapter of the guide
- Requirement
- Procedure in Place
- Compliance
- Comments
- Score

Chapter ^o	Requirement ^o	Procedures in place ^o	Compliance ^o			Comments ^o	Score ^o
			Yes ^o	No ^o	N/A ^o		
BRC general criteria^o							
	Certified BRCs must comply with: ^{ff} <ul style="list-style-type: none"> • Their national and international legislation, regulations and policies concerning acquisition, conservation, utilisation, including the fair and equitable sharing of benefits arising from utilisation of genetic resources, and distribution of biological resources and data related thereto.^{ff} • The regulations of the relevant countries when moving biological materials across national boundaries.^{ff} • The relevant national and international agreements, regulations, policies, frameworks and recommendations.^{ff} 						
	Certified BRCs have in place a mechanism that updates their knowledge of the above. ^o						
Organisational requirements^o							
	The BRC should meet the OECD definition and be compliant with appropriate national law, regulations and policies. The application for certification must describe and document the nature of the biological resources being held and for which certification is being sought. It must define the biological domain and therefore the domain specific criteria that apply e.g. micro-organisms or human materials. ^o						
4.1 ^o	Long-term sustainability^o						
4.1.1 ^o	The BRC should provide evidence of a strategy for its long-term sustainability. Adequate and reliable sources of funding vary from government support, income from services, and private support. ^o						

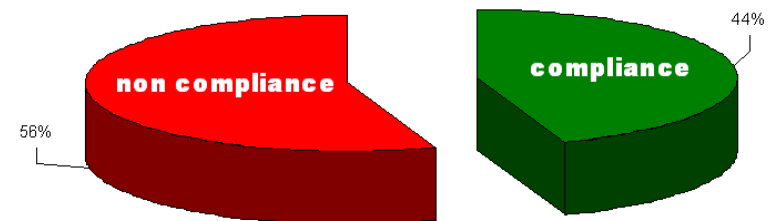
Score:

- full compliance = 2
- Compliance with minor rework = 1
- non-compliance = 0

Selected results: management of BRC

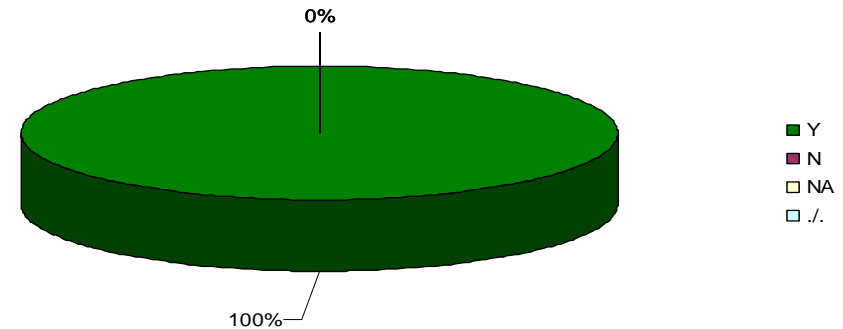


Why is an emergency plan for saving the biological material not applicable?

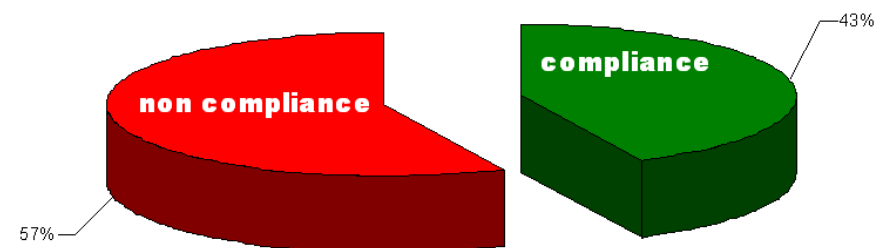
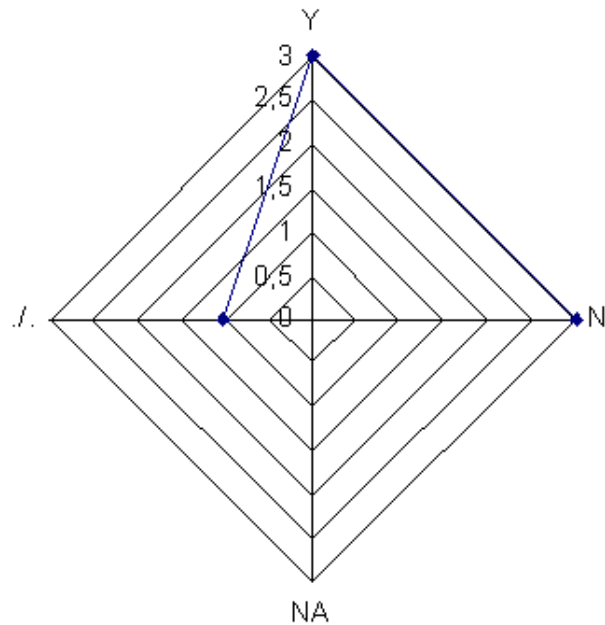


Selected results: biosafety and monitoring programme

Receipt and handling of biological materials:
Is a risk assessment being carried out on the biological material?

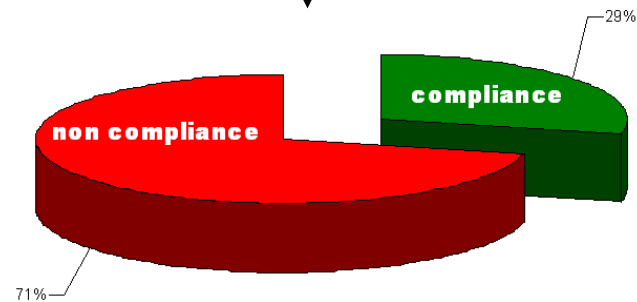
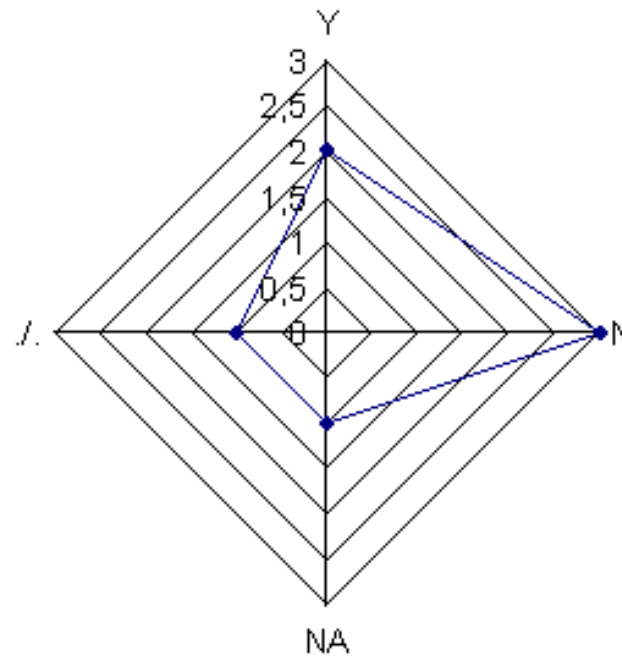


Is a contamination monitoring programme in place to include environmental monitoring of laboratory air and surfaces?



Selected results: biosecurity

Is the level of biosecurity risk of biological material determined according to the best available information on its potential for malicious misuse as well as its virulence?

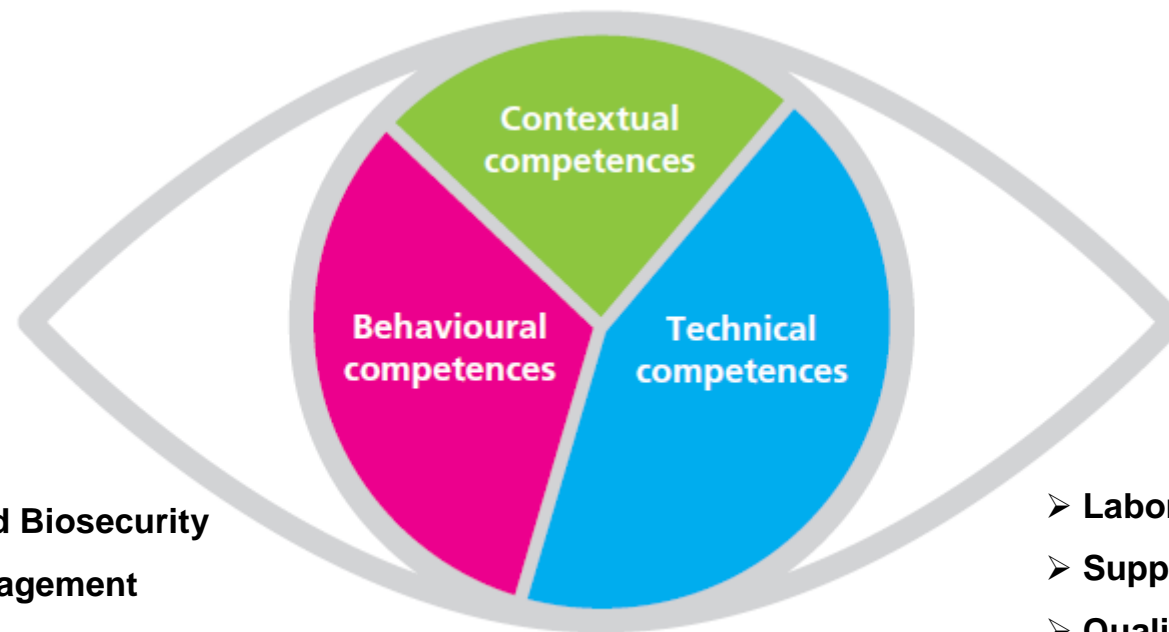


Conclusion: Competence as Major Key to OECD BPG

Competence is the ability to get things done - **the challenge for performance is to develop excellence in performing.**

Due to the three characteristics of competence, the competences can be identified as follows:

- **BRC as a Role Model**
- **Capacity Building**
- **Public Responsibility**

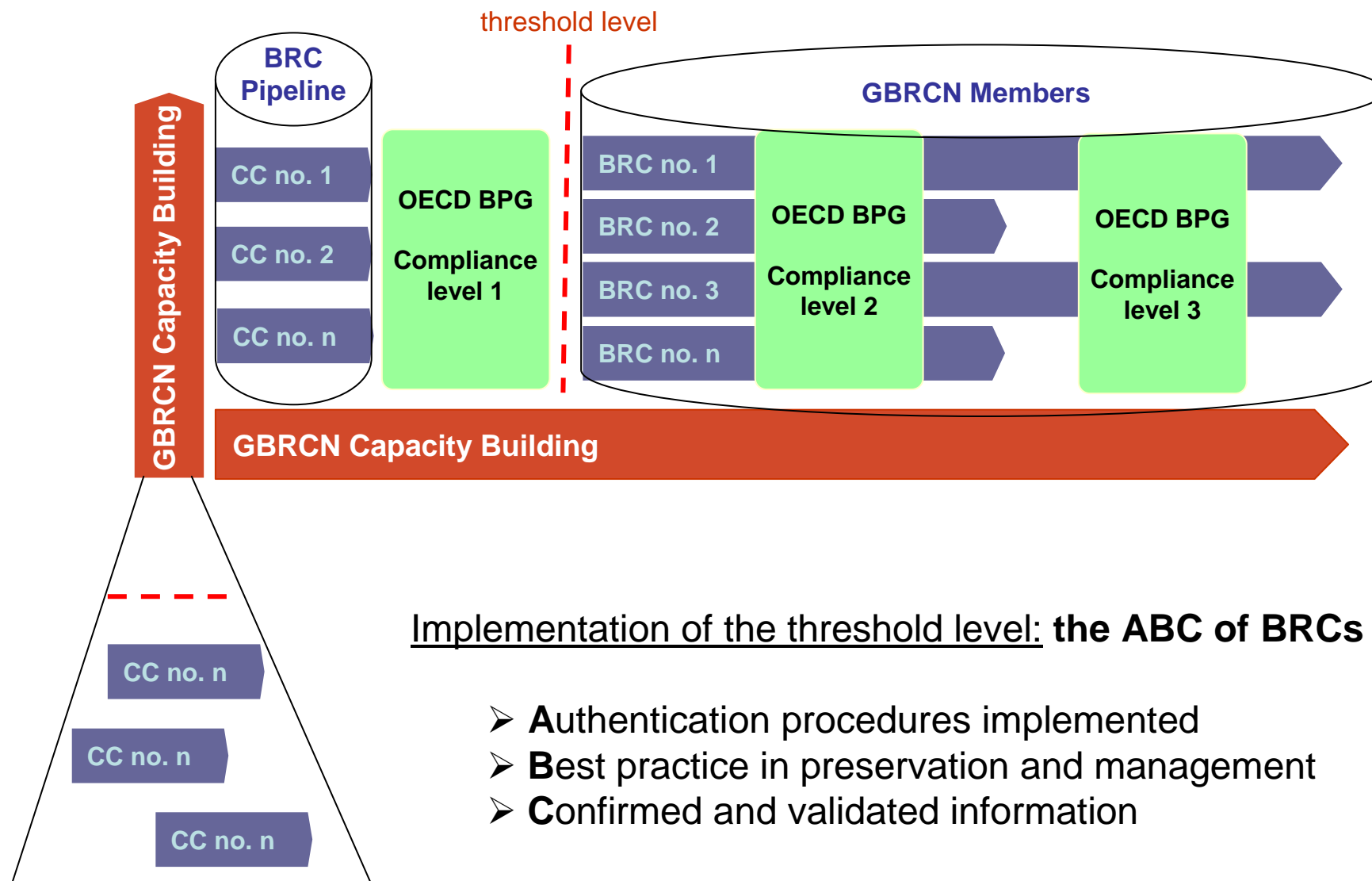


- **Biosafety and Biosecurity**
- **Incident Management**
- **Sustainability Efforts**

- **Laboratory Methods**
- **Supply of Material**
- **Quality Management**

The Eye of Competence

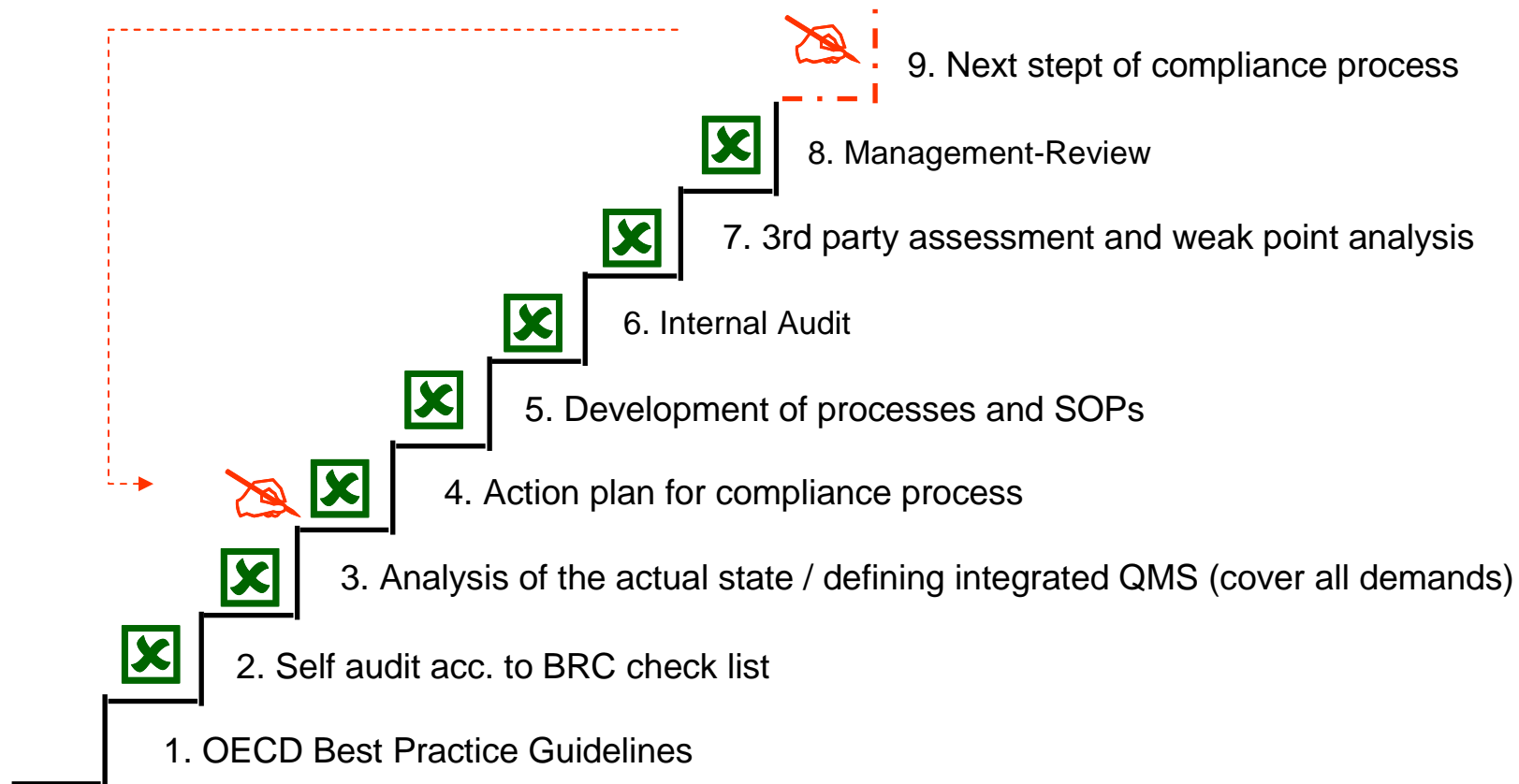
Capacity Building for Excellence in Performance



Implementing the OECD Best Practices

☑ assistance by GBRCN (audits, master processes, checklists, capacity building ...)

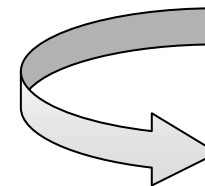
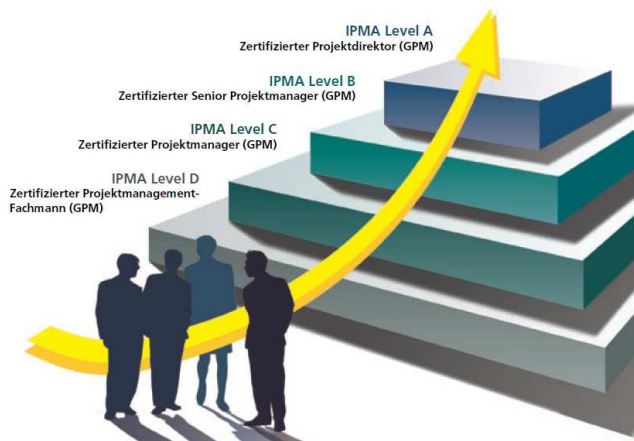
~~✗~~ defining threshold level resp. compliance level



Compliance Proof within an Excellence Model

An excellence Model is based on a **stepwise improvement** with a **minimum compliance** in the first step and increasing performance in compliance for each further steps. Within this model of conformity stages a candidate can **succeed in the efforts to get full compliance and excellence in performance.**

Successful, international recognized examples already exist:



enabling inclusiveness

Thank you very much for your attention!

For further questions please contact:

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c/o Julius Kühn-Institut (JKI)

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info@gbrcn.org

OECD Best Practice Guidelines for BRCs – requirements



☒ **General best practice guidelines for all BRCs**

- Organisational requirements
- Equipment use, calibration, testing and maintenance records
- Documentation management
- Data management, processing and publication
- Preparation of media and reagents
- Accession of deposits to the BRC
- Preservation and maintenance
- Supply
- Quality audit and quality review

☒ **Best Practice Guidelines on Biosecurity for BRCs**

- Assessing biosecurity risks of biological material
- New acquisitions/ re-assessment of inventory
- Biosecurity risk management practices
- Physical security of BRCs
- Security management of personnel and visitors
- Incident response plan
- Material control and accountability
- Supply and transport security

☒ **Best Practice Guidelines for the Micro-Organism Domain**

- Staff-qualifications and training
- Hygiene und biosafety
- Equipment use, calibration, testing and maintenance records
-
- Preparation of samples
- Information provided with the biological material supplied

☒ **Best Practice Guidelines on Human-Derived Material**

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