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ICCC-12 Conference 2010

Biological Resource Centers: gateway to biodiversity and services for innovation in biotechnology

***National Plan for
Accreditation of
Biological Resource
Centres in Brazil***

*Elizabeth Cavalcanti, Waldemar Souza e Ricardo Nóbrega
Florianópolis/SC - Brazil - September 28th, 2010
Inmetro/Cgcre*



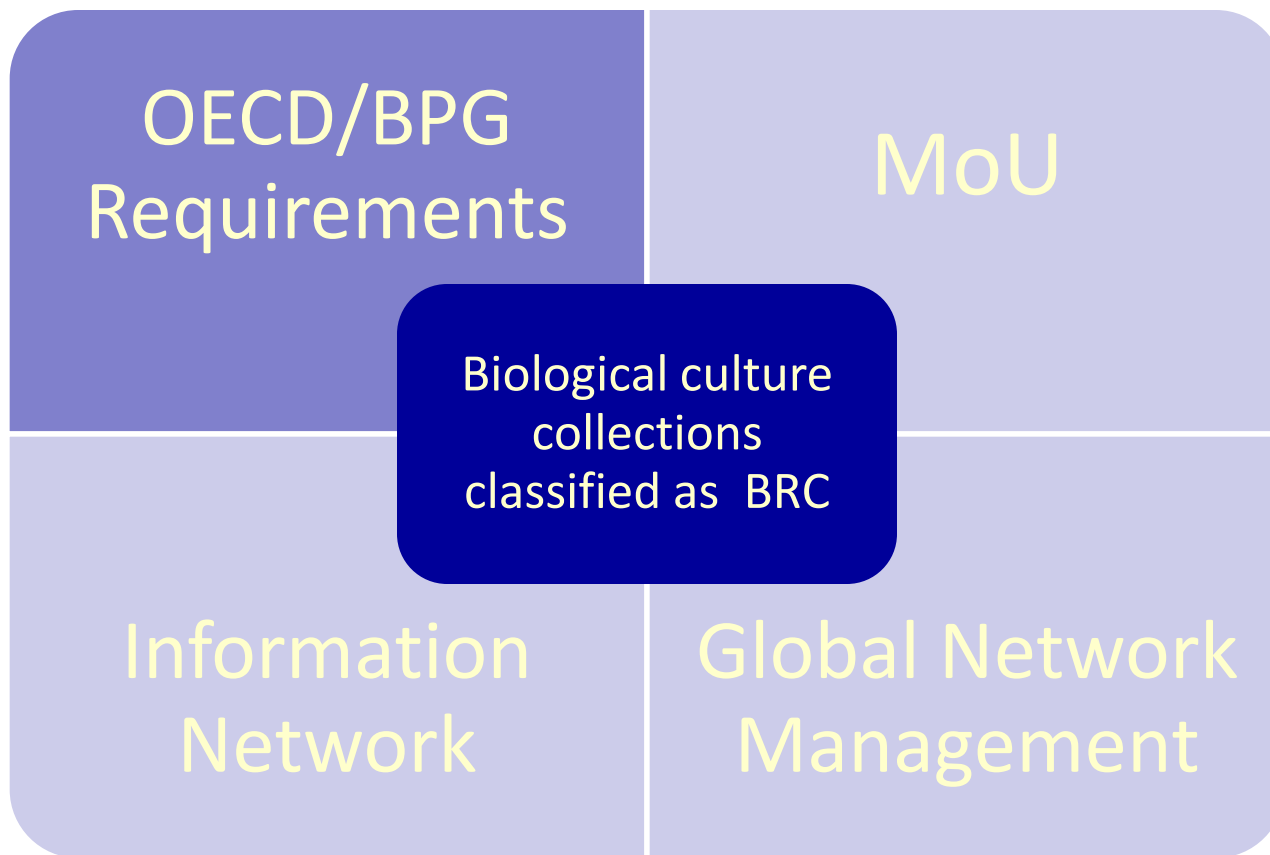
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This work focus on...





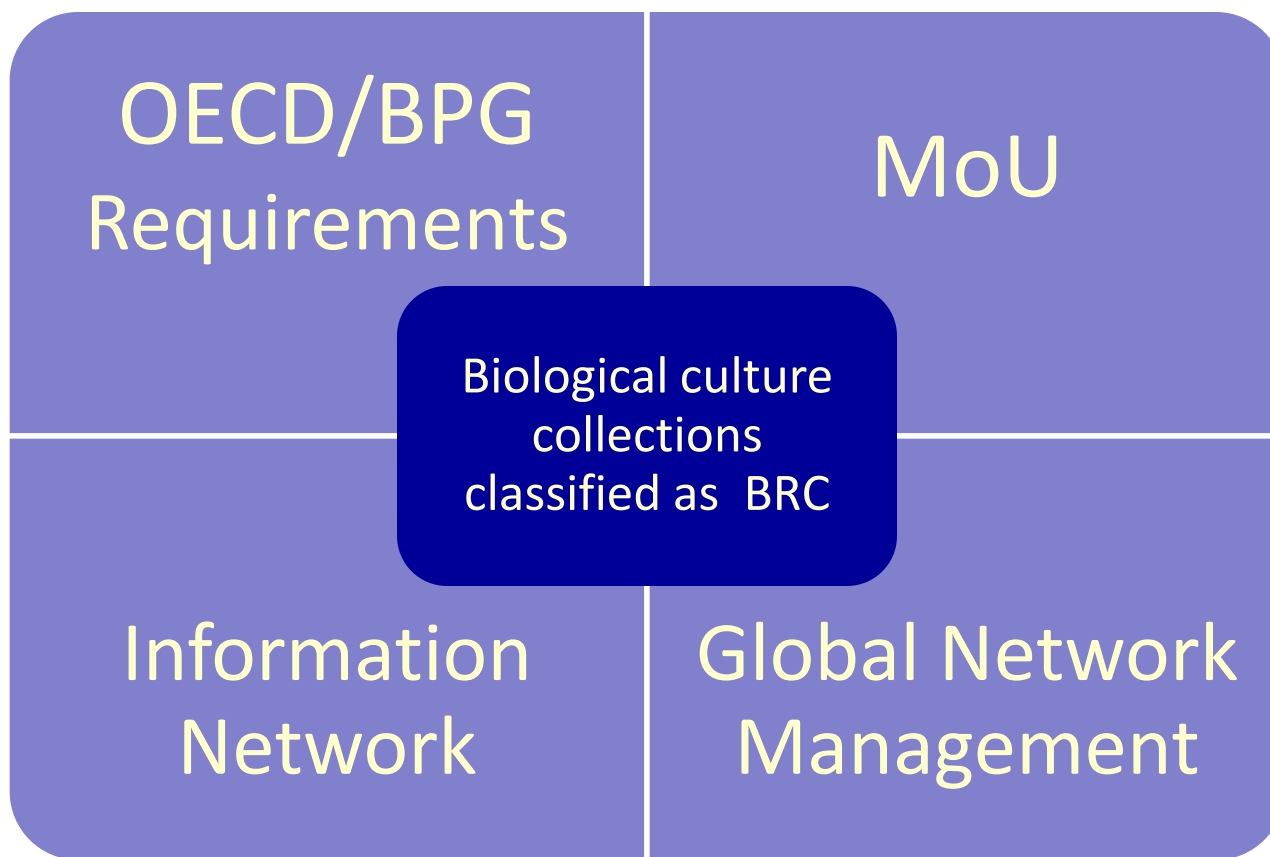
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Main elements of the Global Network





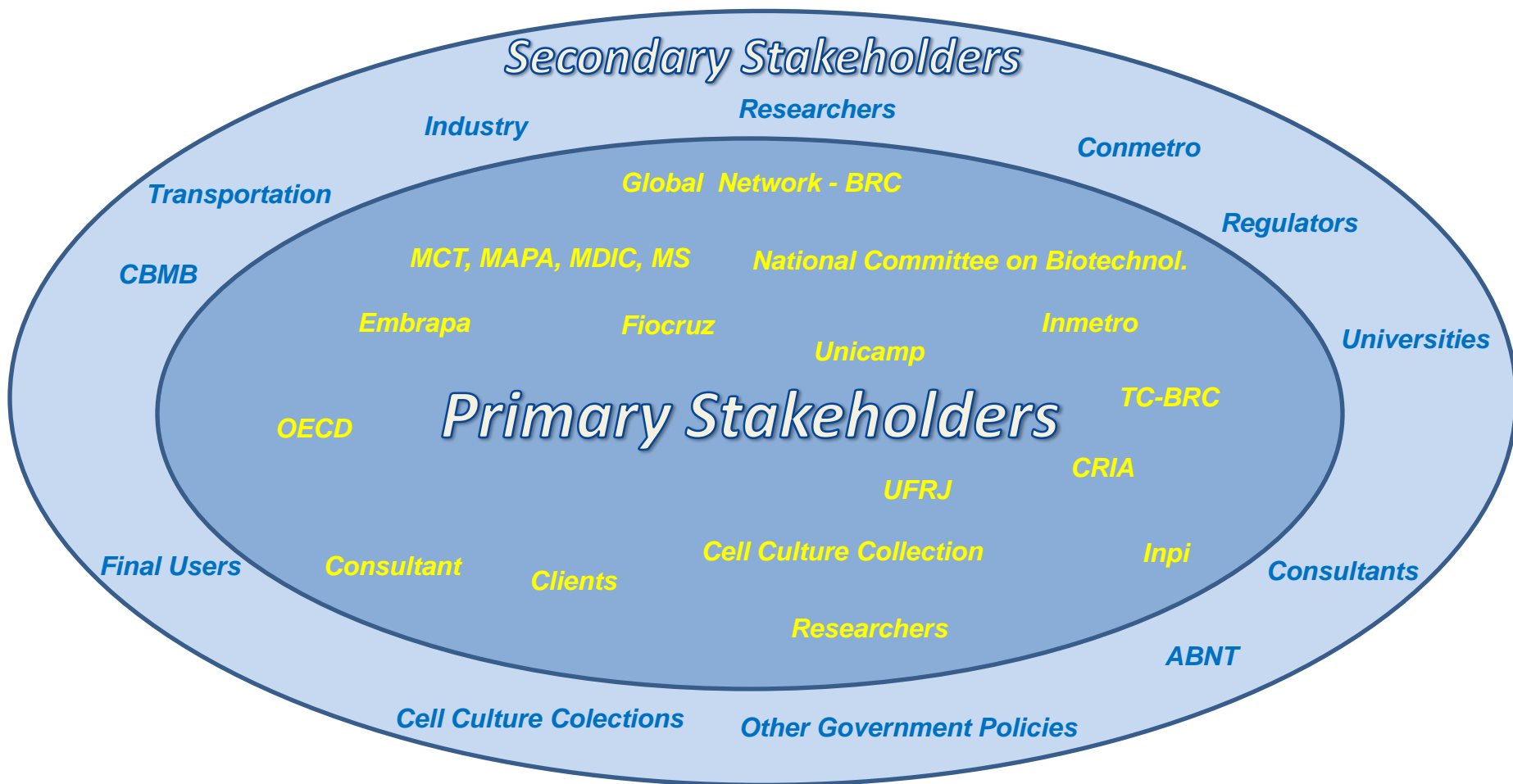
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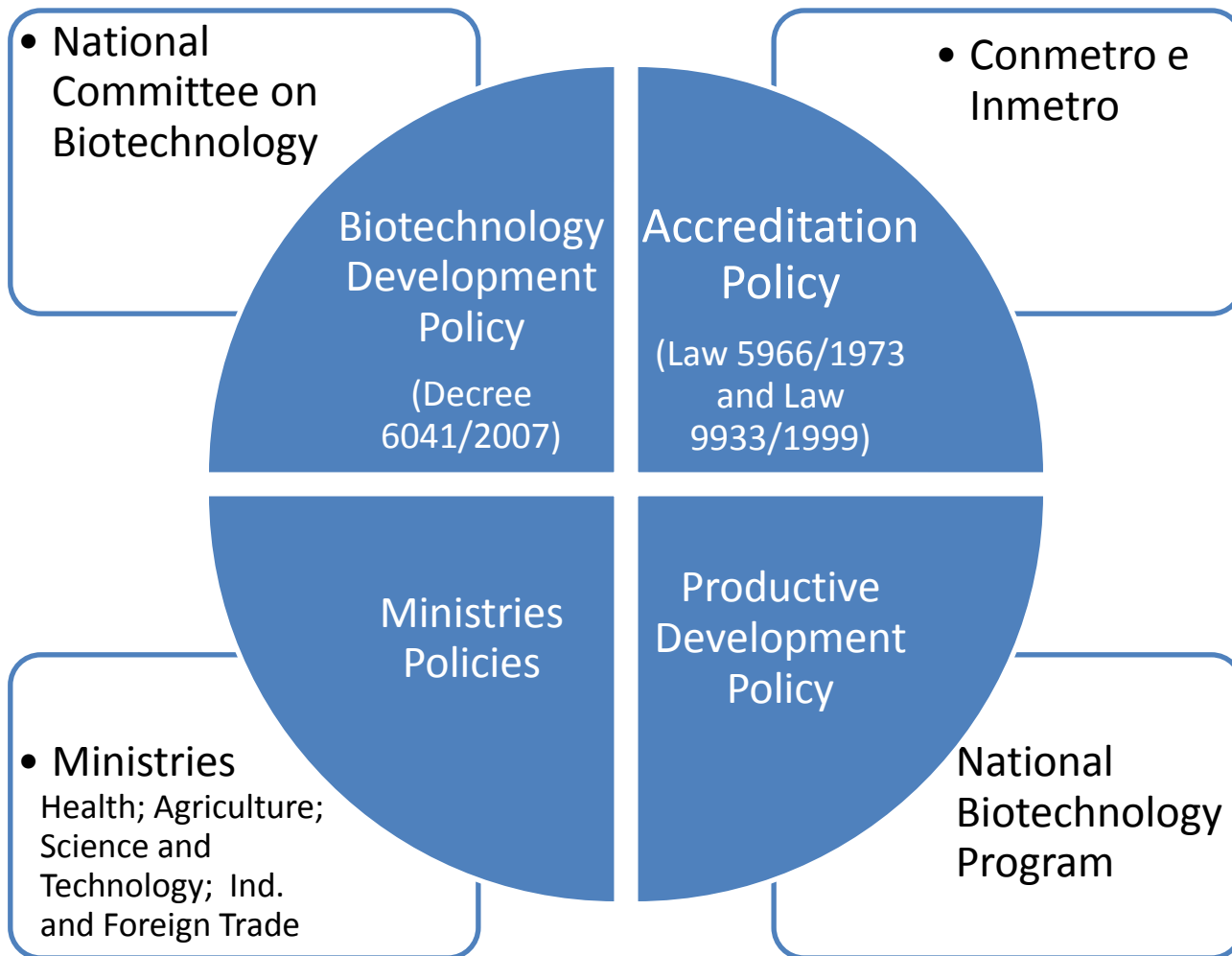
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Stakeholders





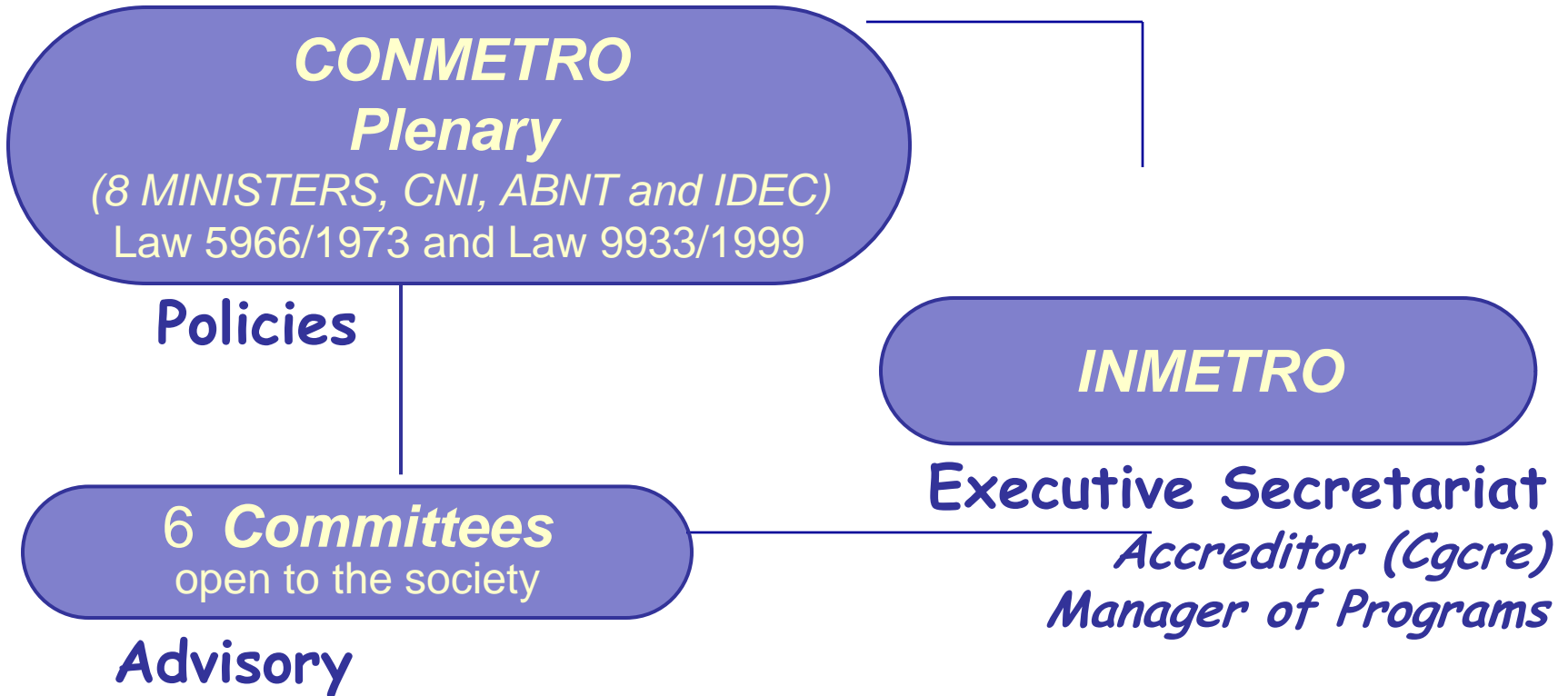
Political support





National Accreditation Policy

Brazilian System for Conformity Assessment





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Cgcre

GENERAL COORDINATION FOR ACCREDITATION (Cgcre)

**❖ Cgcre is the accreditation body recognized by the
Brazilian Government**

→ Decree n° 6.275, November 28th 2007

**❖ Brazilian Monitoring Authority of the Compliance to OECD
GLP Principles**

→ Inmetro s Administrative Rule n° 220, de July 23th 2009



Definition of accreditation

Accreditation

“Accreditation is third-party attestation related to a conformity assessment body – CAB (laboratory, certification body or inspection body) conveying formal demonstration of its competence to carry out specific conformity assessment tasks.”

(ISO/IEC 17000:2004)

“ Impartial, independent assessment of competence against international standards”

**ACCREDITATION:
provides confidence in conformity
assessment!**

Global
Acceptance



World Accreditation Day
9 June 2010





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CGCRE Accreditation Programs

Laboratories			Reference Materials	Proficiency Test
Calibration and Testing	Good Laboratory Practices	Medical Laboratories	Reference Materials Producers	Proficiency Test Provider
ISO/IEC 17025	OECD GLP PRINCIPLES	ISO 15189	ISO Guide 34 + ISO/IEC 17025 (in near future)	ILAC G13 (in near future)

Inspection Bodies	Certification Bodies		
Inspection	Management Systems	Persons	Products
ISO/IEC 17020	ISO/IEC 17021	ISO/IEC 17024	ISO/IEC Guide 65



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International Recognition of Cgcre

- *IAF (International Accreditation Forum): QMS, EMS, Product.*
- *ILAC (International Laboratory Accreditation Cooperation)*
- *EA (European Accreditation)*
- *IAAC (InterAmerican Accreditation Cooperation)*
- *PEFC (Program for the Endorsement of Forest Certification Schemes)*



GLOBALG.A.P.
The Global Partnership for Good Agricultural Practice





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Timeline

Brazil's attendance at OECD	2001
Ministry of Science and Technology creates TG	
TG: Green Book - ISO (17025) approach	2002
SICOL 3 – Financial Resources - Structuration of Brazilian Collections. FINEP Project - Funds for Collections compliance to ISO 17025	2005
Guidelines for BRCs	
SICOL 4 – Financial Resources - Guidelines for BRCs - Funds for Collections to implement OECD/BPG for BRC	2007
GBRCN Demonstration Project	2008
TC-BRC identifies accreditation programs, ISO 17025 and includes ISO Guide 34	2010



Roles played by BRCs:

- ***Preservation and provision of biological resources for scientific, industrial, agricultural, environmental and medical R&D applications;***
- ***Performance of R&D on these biological resources***
- ***Conservation of biodiversity***
- ***Repositories of Biological Reference Material***
- ***Repositories of biological resources for protection of intellectual property***
- ***Resources for public information and policy formulation***



Accreditation options

What Cgcre can offer as the brazilian accreditation body?

- ***An accreditation body accredits conformity assessment activities***

- ***What activities performed by the CRBs can be considered as conformity assessment?***
 - ✓ ***testing for the determination or confirmation of some characteristic of the biological material***
 - ✓ ***provision of biological resources for scientific, industrial, agricultural environmental and medical R&D applications***
 - ✓ ***repositories of biological reference material***

- ***Since the activities of Testing and Reference Material Production are considered to be conformity assessment activities, they can be accredited according to the ISO/IEC 17025 (testing) and ISO Guide 34 in combination with ISO/IEC 17025 (RMP).***



ILAC Resolutions on RMP

8th ILAC General Assembly (2004):


- ✓ **ILAC Resolution GA 8.11:** *assessing the technical competence of bodies producing reference materials with assigned values is accreditation of a conformity assessment activity.*
- ✓ **ILAC Resolution GA 8.12:** *accreditation of technically competent bodies producing reference materials with assigned values will be conducted against harmonized criteria based on ISO Guide 34 and ISO/IEC 17025 in combination.*

9th ILAC General Assembly (2005):

- ✓ **ILAC Resolution GA 9.28:** *Following 2004 ILAC GA resolutions 8.11 and 8.12 relating to accreditation of Reference Materials Producers, the General Assembly resolves that the accreditation to ISO Guide 34 in combination with ISO/IEC 17025 be included under the current ILAC Arrangement when appropriate procedures for this activity are developed and agreed by ILAC.*



RMP pilot programme in Brazil

- ***Reference Material***  ***Key Factor affecting laboratories***

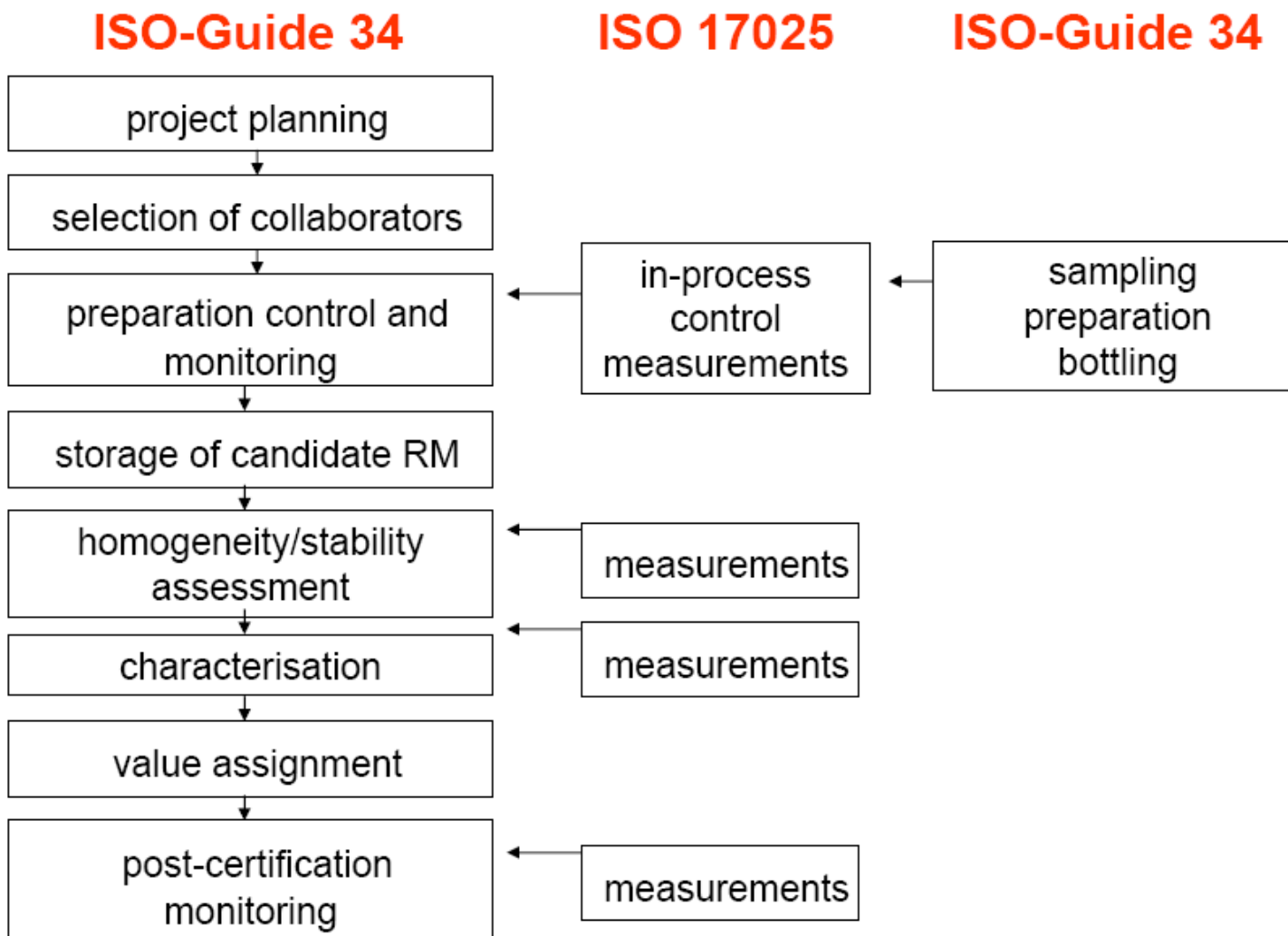
- ***Third party assessment of the reference material producer:***
 - ✓ *assessment of the quality of materials involved on the production of reference materials;*

 - ✓ *assessment of the quality system, involving aspects related with personnel performing specific tasks (qualified on the basis of appropriate education, training, experience and/or demonstrated skills), material preparation, homogeneity and stability testing, characterization and assignment of a property value and the authorization of property values and issue of certificate;*

- ***Develop a suitable programme considering ILAC Resolutions.***



ISO Guide 34 approach





Decision on the accreditation program

- *A technical committee (CT-CRB) was created as an advisory group to help Cgcre in the choice of the type of accreditation for the BRCs.*
- *This committee is formed by representatives from four potential candidates Culture Collections and also from Inmetro, Cgcre, INPI, MCT, CRIA and TECPAR.*
- *With the aim of identify the type(s) of accreditation most suitable, the Collections were asked to list their main activities taking in account what is described in the OECD Guideline for BRCs, in order to compare with the accreditation programs run by Cgcre.*



Decision on the accreditation program

<p>ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)</p>	<p>ISO Guide 34 in combination with ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)</p>
<p>- Protozoa serotyping by enzyme electrophoresis or PCR followed by RFLP or PCR followed by DNA sequencing</p>	<p>- Biological reference materials: protozoa</p>
<p><u>Activities related to both types of accreditation:</u></p> <ul style="list-style-type: none"> - Samples deposit - Handling, storage, maintenance and preservation of cell cultures 	



Decision on the accreditation program

ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)	ISO Guide 34 in combination with ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)
- Isolation and counting of microorganisms	- Biological reference materials - bacteria - filamentous funghi - yeast - clones
- Identification, taxonomic characterization and serotyping of industrial and environmental microorganisms	
<p><u>Activities related to both types of accreditation:</u></p> <p>-Deposit and preservation of microbiological material.</p>	



Decision on the accreditation program

ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)

- Identification of microbiological contaminants;
- PCR and fluorescence analysis for micoplasm presence evaluation;
- Citotoxicity tests;
- Genotoxicity tests;
- "In vivo" and "in vitro" biocompatibility tests;
- Cell lines characterization. Cellular imortalization.

ISO Guide 34 in combination with ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)

- Reference materials
 - Cell lines
 - hybridomas

Activities related to both types of accreditation:

- Deposit, preservation of cell lines
- Development of primary culture



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Decision on the accreditation program

ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)	ISO Guide 34 em combinação com a ABNT NBR ISO/IEC 17025: 2005 (+ OECD Guideline)
- Microorganism strain characterization.	- Reference materials (microorganism strain)



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Decision on the accreditation program

- *Some activities such as handling, storage and transport, are common to both standards and will be evaluated during the process of accreditation*
- *Some activities such as R&D and technical scientific consultancy can not be classified as conformity assessment activity and thus will be not subject, in principle, to the accreditation process. But it can be necessary to check if these activities cause any conflict of interest.*



Conclusion

- *From these results it was agreed by the technical committee that Cgcre will offer two types of accreditation:*
 - ✓ *As testing laboratories using the ISO/IEC 17025 standard as criteria and;*
 - ✓ *As Reference Material Producer using ISO Guide 34 in combination with ISO/IEC 17025.*

- *In both cases, compliance to the Best Practice Guidelines for BRCs will be assessed, as an additional requirement.*



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Final comments

- ***Government policies related to BRC are synchronized***
- ***Brazilian government is spending efforts on the reorganization of the technical foundation of the culture collections***
- ***Funds has been provided for the reorganization of infrastructure and quality management, with the development and implementation of the information system***
- ***We understand that two parallel efforts give support to the participation of a BRC in the Global Network: third part recognition and the Network information system***
- ***Criteria for the accreditation program will encompass the ISO/IEC 17025, ISO Guide 34 and the OECD BPG Guidelines***
- ***Cgcre has already available the ISO/IEC 17025 accreditation. ISO Guide 34 + ISO/IEC 17025 accreditation is in pilot project phase and expected to be fully available in the second semester of 2011***



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Thanks

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