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Abstract	This document converts the Guidance for the operation of Biological Resource Centres (BRCs) in to an operational standard for consideration for adoption under the International Standards Organisation (ISO). The OECD Guidance for BRCs comprises several sets of best practice guidelines that together provide the basis for best practices in the management of BRCs. Two sets of general best practice guidelines address all Biological Resource Centres, no matter what type of biological material they hold and supply. These are: General Best Practice Guidelines for all BRCs and it is supplemented by and Best Practice Guidelines on Biosecurity for BRCs. Further best practice guidelines provide additional best practices for those BRCs that hold and supply biological material within specific domains. Best practice is achieved when BRCs comply with all sets of general best practice guidelines applicable to the specific domain that the biological materials they hold and supply belong to. Currently two sets of such OECD best practice guidelines exist; Best Practice Guidelines for the Micro-Organism Domain, and Best Practice Guidelines for Human-Derived Material. Further domain-specific best practice guidelines for animal and for plant material are regarded as necessary, and might be developed under the auspices of a future global BRC network.
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Revision table			
Date	***Version***	***Revised by***	***Main changes***

Contents

Abbreviation key

BRC	Biological Resource Centre
BTWC	Biological and Toxin Weapons Convention
CABRI	Common Access to Biological Resources Information
CBD	Convention on Biological Diversity
EBRCN	European Biological Resource Centre Network
ECCO	European Culture Collection Organisation
EMbaRC	European Microbial Resources Consortium
EU	European Union
FDS	Full Data Set
GBIF	Global Biodiversity Information Facility
GBRCN	Global Biological Resource Centre Network
IDA	International Depositary Organisation
IP	Intellectual property
IPR	Intellectual Property Rights
ISO	International Standards Organisation
mBRC	microbial domain Biological Resource Centre
MDS	Minimum Data Set
MOSAICC	Microorganism Sustainable Use and Access Regulation International Code of Practice
OECD	Organisation for Economic Community Development
QMS	Quality Management System
RDS	Recommended Data Set
SOP	Standard Operating Procedure
UKNCC	UK National Culture Collection
WFCC	World Federation for Culture Collections
WHO	World Health Organisation

1 Background and Objectives

EMBARC STANDARD Based on ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES

Purpose

This standard provides the basis for a quality management system that will ensure microbial domain Biological Resource Centres are managed correctly to ensure the collection, characterisation and distribution of high quality microorganisms and associated services. The document is based on the standard originally produced by EU project (QLRT-2000-00221) European Biological Resource Centres Network and the OECD Biological Resource Centre Task Force (Focus Group I) and redrafted to include Microorganism domain best practice by the GBRCN demonstration project and EMbaRC consortia. It takes into consideration the French Standard NF S96-900, the GBRCN/EMbaRC self-assessment of implementation of OECD Best Practice Guidelines for BRCs feedback and the introduction of the Biosecurity Code of Conduct for BRCs,

Committees Responsible

This document is adapted from the ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES 2007 by the EU European Microbial Resources Consortium (EMbaRC) project (EU Seventh Framework Programme Research Infrastructures (INFRA-2008-1.1.2.9: Biological Resources Centres (BRCs) for microorganisms (Grant agreement number: FP7- 228310) in consultation with the Global Biological Resource Centre Network (GBRCN) Secretariat.

Foreword

This mandatory guidance provides the basis for best practice in the management of microbial domain Biological Resource Centres (mBRC) and all laboratories maintaining replicable microbiological materials. It draws together the key principles and best practice of quality management systems and operational guidelines prescribed by individual BRCs, national public service collections, and national, regional and world culture collection organisations. It has been designed to meet the needs of the user community through discussion in the OECD Biological Resource Centre Task Force, EBRCN, GBRCN and EMbaRC projects.

This document provides specific guidance on the accreditation of Biological Resource Centres (BRCs) as defined by the OECD in Underpinning the future of life sciences and biotechnology OECD, 2001, for both assessors and producers preparing for accreditation. It is designed as a standalone document for the accreditation of microbial domain Biological Resource Centres (BRC).

This document converts the Guidance for the operation of Biological Resource Centres (BRCs) in

to an operational standard for consideration for adoption under the International Standards Organisation (ISO). The OECD Guidance for BRCs comprises several sets of best practice guidelines that together provide the basis for best practices in the management of BRCs. Two sets of general best practice guidelines address all Biological Resource Centres, no matter what type of biological material they hold and supply. These are: General Best Practice Guidelines for all BRCs and it is supplemented by and Best Practice Guidelines on Biosecurity for BRCs. Further best practice guidelines provide additional best practices for those BRCs that hold and supply biological material within specific domains. Best practice is achieved when BRCs comply with all sets of general best practice guidelines applicable to the specific domain that the biological materials they hold and supply belong to. Currently two sets of such OECD best practice guidelines exist; Best Practice Guidelines for the Micro-Organism Domain, and Best Practice Guidelines for Human-Derived Material. Further domain-specific best practice guidelines for animal and for plant material are regarded as necessary, and might be developed under the auspices of a future global BRC network.

This adapted mandatory guidance brings together the two levels; general criteria for the basis of accreditation of all Biological Resource Centres and specific criteria determined by the microorganism domain into one standard.

Introduction

Living organisms, their cells or their replicable parts (e.g. genomes, plasmids, viruses, cDNAs,) are the basic elements of the life sciences and biotechnology. They are utilised in large numbers as living reference materials for testing, identification, the production of compounds, fuel and food. They are the tools for knowledge generation and biodiversity conservation. They are grown, maintained and utilised around the world and are key to many research programmes, industrial processes and training courses. These biological resources shall be maintained without change to ensure reproducibility and sustainability.

This standard is based on the OECD Best Practice Guidelines for BRCs and provides specific best practice guidelines for the management of microbial domain Biological Resource Centres (mBRCs) that hold and supply micro-organisms.

Collections of biological materials range from small private centres through to large service centres, and have widely differing objectives, policies and holdings. They are often linked to activities of the parental organisation for example teaching or life sciences research and the organisms they hold may have many different uses. Collections of data (databases) that can be candidates for accreditation shall hold data that is directly linked to biological materials held in an accredited microbial domain Biological Resource Centre (mBRC).

It is the policy of mBRCs to provide their users on every occasion with the products and services they require. These products and services shall be of consistently high quality and fulfil product

claims as defined in their catalogues. At all times appropriate techniques and procedures that comply with relevant national law, regulations and policies shall be in operation. Regular audits shall be carried out to ensure that these procedures are followed and are effective.

In order to achieve best practice in the acquisition, maintenance and provision of biological materials the guidance given in this document shall be followed.

All mBRCs must comply with applicable national and international laws and regulations. These domain specific best practice guidelines provide best practice for managing BRCs and describe the procedures for acquisition, propagation, maintenance and provision of micro-organisms. Best practice requires an mBRC to provide a documented description of the nature of the micro-organism domain biological resources being held and in particular to define the level of hazard and containment in place.

This standard assists the mBRC to put into practice procedures that comply with relevant national law, regulations and policies. Further practical details on the implementation of these procedures may be found in the Common Access to Biological Resources and Information (CABRI) guidelines: (http://www.cabri.org), World Federation for Culture Collections (WFCC) recommendations: http://www.wfcc.info/ or United Kingdom National Culture Collection (UKNCC): www.ukncc.co.uk.

Scope

These best practice guidelines give general best practice for the acquisition, maintenance and provision of biological materials and on the management of microbial domain Biological Resource Centres as defined by the OECD (see definition below, section 3(ii)).

The purpose of these best practice guidelines is to help ensure that biological materials are of the highest standard and authentic. The preservation techniques used shall retain the key features of the biological material and ensure its consistency between centres supplying it. This will help to provide a reliable basis for research and development in different laboratories and to contribute towards protection of the health of laboratory personnel, the public and the environment.

2 Informative references

OECD Best Practice Guidelines for Biological Resource Centres (June 2007), http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

3 Definitions

3.1 Biological materials

The term ‘Biological material’ as used in this refers to microorganisms and their derived materials

from all materials listed in the Organisation for Economic Co-operation and Development (OECD) definition of BRCs given below.

3.2 Microorganisms

“Micro-organisms” comprise all prokaryotes (archaea and bacteria), some eukaryotic organisms (fungi, yeasts, algae, protozoa), non-cellular entities (e.g. viruses), their replicable parts and other derived materials e.g. genomes, plasmids, cDNA.

3.3 OECD Definition of Biological Resource Centres (BRCs)

“Biological Resource Centres are an essential part of the infrastructure underpinning biotechnology. They consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms cells and tissues, as well as data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics. BRC must meet the high standards of quality and expertise demanded by the international community of scientists and industry for the delivery of biological information and materials. They must provide access to biological resources on which R&D in the life sciences and the advancement of biotechnology depends.”

3.4 mBRC – microbial domain Biological Resource Centre

These are BRCs that hold and provide microorganisms as defined in 3(ii) above

3.5 Authentication

Authentication is the process by which biological materials are characterised up to a defined level using appropriate technology to establish a conclusive basis for accepting the material as genuine. This process is defined in the domain specific best practice guidelines for mBRCs.

4 Organisational requirements and quality policy

The mBRC shall meet the OECD definition and must be compliant with appropriate national law and regulations. An mBRC shall describe and document the nature of the biological resources it holds. This information is basic and defines not only the type of organisms/cells held but the level of risk and potentially the sector served. Such a description is needed by a user and it defines the scope of the BRC. It shall define the microbial domain specific criteria that apply to micro-

organisms and define the risk group limits (biological safety level) that apply to the mBRC and describes the types of microorganisms (e.g. bacteria, fungi etc.) the mBRC collects and distributes.

4.1 Long-term sustainability

The mBRC shall develop a strategy for its long-term sustainability. Adequate and reliable sources of funding vary from government support, income from services and private support.

If its future is threatened, the mBRC shall have a plan to ensure that its key holdings remain available.

4.2 Responsibilities of management

Primary responsibility of meeting the standard lies with the mBRC senior management who will define and publish a quality policy, be responsible for the implementation of this standard, regulatory and legislative compliance and relaying the requirements of the mBRC clientele. They will assure delivery of quality products and guarantee measurable quality objectives to improve clientele satisfaction. They will be responsible for holding management reviews.

The mBRC senior management may delegate responsibility for implementation of its policies to named and suitably qualified members of staff and provide them with defined responsibilities and authority. The list of such staff and their specific responsibilities shall be available to all staff of the mBRC and shall particularly be made available to new staff, students and visitors.

The Senior Management of each individual mBRC shall ensure that appropriate resources are available for staff members to discharge its responsibility towards this policy. The mBRC shall appoint a Quality Manager whose duties include:

- Administering and monitoring an efficient up-to-date quality management system.
- Reporting and advising on quality matters.
- Representing the mBRC on quality matters when dealing with users, suppliers and outside bodies.

Where possible a deputy shall be appointed to serve in the absence of the quality manager. The Quality Manager has direct access to the Senior Management of the mBRC on matters concerning quality.

The mBRC shall designate a biosecurity officer, at operational level within the mBRC, whose responsibility it is to ensure internal compliance with the Biosecurity code of conduct (paragraph 13.5) and implement as far as possible Best Practice Guidelines on Biosecurity for BRCs (Appendix 2).

4.3 Quality policy

The mBRC quality policy expresses the quality objectives of the organization, the acceptable level of quality and the duties of specific departments to ensure quality. It also demonstrates how the mBRC will ensure continuous improvement of clientele satisfaction. The quality objectives shall wherever possible be measurable and generally based on performance indicators.

The policy will reflect the mBRC's specific purpose, conform to legislative and regulatory requirements, commit to a philosophy of continuous improvement, set a framework for setting and reviewing quality objectives and be regularly reviewed.

4.4 Quality management system

The quality management system (QMS) is a set of measures to control identified processes to provide compliant microbial resources enabling the mBRC quality policy to be applied. The mBRC shall establish, document, implement and maintain a quality management system and continuously improve its efficiency in compliance with the requirements of this standard.

The mBRC shall:

i. Identify the processes that enable the provision of compliant microorganisms

ii. Determine process sequences and process interactions

iii. Monitor, measure and analyse the performance levels of the various processes

iv. Publish information on the development, deployment and updating of the QMS

v. Regularly evaluate and update the mBRC QMS whenever necessary in order to guarantee that it reflects the entity's operations and incorporates the most up-to-date information

vi. Implement a continuous improvement system.

The mBRC will establish a controlled set of documents (see section 7 for document control system) that include:

i. A quality policy and quality objectives

ii. A quality manual

iii. Technical procedure documents i.e. Standard Operating Procedures (SOPs) and records as required by this standard

iv. Planning, operational and control documents as required to run an efficient QMS

v. Texts stipulating the legal and regulatory requirements governing mBRC activities

vi. Formal statements of the requirements of the various stakeholders and users

The quality manual is the mBRC's master document, its content description is given below and a generic example document is available from the EMbaRC web site.

Presentation of the scope and nature of the mBRC including types of microorganisms

Quality Management System

- Aims and Form of Quality Management System
- Quality Manual
- Quality Management
- Documentation
- Justification of any exclusions concerning the requirements of this standard

Organisation and Management

Management

General Management

- Laboratory Environment
- Accessions to the MRC
- Preservation
- Stock Control of the Preserved Organisms
- Supply
- Confidentiality
- Staff - Qualifications and Training

Quality Audit and Quality Review

- Purpose
- Responsibility
- Implementation
- Planning and Documentation
- Quality Control System

Equipment

- Calibration, Testing and Maintenance of Equipment
- Authorisation for Use
- Monitoring

Measurement Traceability and Calibration

- Policy
- Calibration Methods and Procedures
- Policy and scope
- Availability
- Documentation of Methods and Procedures

Laboratory Accommodation and Environment

- Accommodation and Conditions
- Access
- Housekeeping

Receipt and Handling of Organisms for Deposit

Record system

- Strain Information Recorded
- Protection
- Retention

Handling of Complaints and Anomalies

- Policy and Procedures
- Records
- Audits

Outside Support Services and Supplies

- Policy
- Records

Site Security

4.5 Management review

Senior management shall review the quality management system at regular intervals in order to ensure it remains well-focused, adequate and efficient. It includes an assessment on possibilities for improvements and records kept.

The review must track all previous actions, analyse results of monitoring operational process, monitor change, review improvement actions, analyse impact and needs from clientele feedback

and review audit outcomes. The goal is to ensure the achievement of the mBRC quality objectives.

4.6 Health and safety (biosafety)

All staff shall follow the procedures laid down under the appropriate level of containment for the microorganisms being handled, as defined by the World Health Organisation (WHO, 2004) and as interpreted by national law, regulations and policies, to avoid contaminating samples, risk of infection and environmental dispersion.

4.7 Staff qualifications and training

Staff may be engaged at many levels of experience and qualifications but they shall not be allocated to any piece of work without expert training, or until training appropriate to the job is completed and they are proved competent. Each member of staff shall have documented job descriptions with specific delegated tasks and defined responsibilities.

Staff must be trained according to documented protocols in skills specific to the job and shall receive training as new technologies or practices are introduced. Such training shall be reviewed annually. All mBRC staff has a responsibility towards the main objective of an mBRC that is to provide high quality, biological resource services to the public.

Authorisation to use specialist equipment shall be documented in training records. For example new staff shall not be allowed to use autoclaves, centrifuges, freeze-drying equipment, cryopreservation facilities, safety cabinets until they have been trained in their use and are proved competent.

All staff involved in providing a product or service contribute to the achieved quality. The role of the quality management system is to guide and advise staff on quality matters and to provide independent assurance of quality to the Senior Management.

It is the responsibility of all staff to familiarise themselves with documented protocols and comply with the policies and procedures laid down in the mBRC Standard Operating Procedures and associated documentation at all times. It is the management's responsibility to ensure that staff has access to the Quality Manual and they understand its requirements and are kept informed of any amendments.

5 Premises

It is the responsibility of the entity which comprises the mBRC, or, within which the mBRC is located, to provide an environment that is conducive to handling micro-organisms, for example, free from contamination. These premises shall facilitate the acquisition, maintenance and

provision of biological materials and its services.

It is the responsibility of the member of staff allocated to a task to check that the accommodation is clean and well lit and that usual aseptic techniques are followed. Appropriate protective clothing shall be worn and safety procedures followed.

Appropriate arrangements, in accordance with national and international regulations, for site security shall be made to ensure hazardous organisms cannot be released to unauthorised users.

The mBRC shall describe the premises and processes (including all areas under the responsibility of the mBRC) used for the specific operation of the mBRC. These areas, as well as the environment and equipment in the premises, shall be in conformity with all relevant national and international standards and regulations.

The safe operational level or safety limit for the resources available shall be justified and documented and the mBRC shall not operate beyond these limits.

5.1 Biological Resource Centre operations

Appropriate areas are required for the specific operation of an mBRC as appropriate to the domain of the biological materials. The activities that shall be accommodated are as follows:

- Receipt and storage of the initial sample.
- Preparation, regeneration, handling and processing of samples.
- Biological material storage area and back-up or safety duplicate collection. Duplicate collection shall be preferably in a remote building or alternative site.
- Supply, delivery/sales (kept separate from incoming accessions).
- Decontamination and cleaning of equipment and processing of wastes.

There are several ways to achieve the above as an alternative to having separate areas. For example: (a) to construct the laboratory on the ‘no way back’ principle, (b) to carry out procedures in a sequential manner using appropriate precautions to ensure sample integrity (e.g. use of sealed containers), (c) to segregate activities by time and space.

Other areas associated with the mBRC shall be structurally sound, unobstructed, clean and free from laboratory materials.

5.2 Construction and operation

Construction shall respect the containment level appropriate for the risk group of the micro-organisms worked with and shall meet appropriate national law, regulations and policies. If major building, renovation or repair work, or other work that is likely to compromise containment or clean

conditions, is necessary in Biological Resource Centres, normal activities shall be suspended until the building renovation or repair work is completed.

5.3 Access

The minimal requirement is to restrict access to the mBRC to authorised staff or those accompanied by them. mBRCs housing hazardous biological materials shall pay particular attention to security and where appropriate be fitted with security devices (see Best Practice Guidelines on Biosecurity for BRCs).

5.4 Maintenance and inspection

Cleaning of laboratory benching and equipment shall be performed by authorised and trained staff using appropriate personal protection equipment and following documented procedures. A contamination monitoring programme shall be in place to include environmental monitoring of laboratory air and surfaces. If a major contamination problem arises in the mBRC, the mBRC manager shall be responsible for implementing a cleaning programme and an investigation of the source of contamination. Details of decontamination procedures shall be located in a Procedures Manual or relevant Standard Operating Procedures (SOPs). Quality audit and quality review shall be carried out.

5.5 Outside support services and supplies

Any support services used by the mBRC shall be of adequate quality to sustain confidence in its activities. Supplies shall be sought from reputable companies with, where possible, proven quality of products. Preference shall be given to services and supplies covered by certification schemes. Where no independent assurance of quality of support services is available, the mBRC shall be responsible for confirming the quality of vital supplies. Copies of purchase orders shall be held on file and records of suppliers, standing orders etc. shall be maintained for a minimum period of five years.

6 Equipment use, calibration, testing and maintenance records

Equipment management procedures including use, control of performance, maintenance and calibration shall be laid down in a predefined schedule. Instructions for these activities shall be laid down in the manufacturer's handbooks/manuals or in the mBRC procedure. Service records shall be maintained and copies of key documents shall be held in the mBRC Equipment Maintenance and Calibration Log books in the care of the Quality Manager.

Appropriate maintenance and calibration procedures for common items of equipment used in microbial domain BRCs are summarised in Table 1 of the Appendix 1.

7 Documentation management

The mBRC Quality Manager shall be responsible for ensuring that all documentation is correctly updated. Alterations to any operating documents shall not be allowed unless agreed to by the Quality Manager. Amendment sheets shall be issued to all holders. Short-term sanctioned alterations shall be made in ink by scoring through existing wording so that it is still legible – scribble, correction fluid or tape shall not be allowed. The alterations shall be signed and dated by the Quality Manager. Copies of the quality manual and, if appropriate, specific procedures shall be such that they can be made available to enquirers, course participants and staff through the mBRC Quality Manager. In such cases, they shall be provided with copies clearly marked as uncontrolled copies and such copies shall not be updated.

7.1 Compliance with internal documentation

All staff shall adhere to the prescribed policies and procedures. Any departures from documented procedures shall be agreed by senior management prior to deviation. Written permission and justification shall then be included in the relevant records.

In the case where a procedure is not followed a deviation report is required outlining the specific error and corrective actions that will be taken. If failure has been brought about by a misunderstanding or misdirection, the error shall be investigated, rectified and retraining implemented if necessary.

8 Data and informatics

The mBRC shall manage and store data and produce electronic catalogues based on authenticated and validated information.

8.1 Data management

Depositors are responsible for assuring the quality of data associated with the biological material. The mBRC may require evidence to assure the validity of the data.

The authentication of data may differ from centre to centre, but a mBRC shall:

- Provide traceability of data through a history of modifications (dates and signatures of inputs, validations, modifications and deletions).
- Give signature for data entry, validation, modification or deletion.

The mBRC shall use a standard terminology and formats for data management and exchange and standard protocols for data transmission to networks (domain, regional or global networks):

i) Select data format, data representation and data transportation taking into consideration existing standards for data processing, e.g. DarwinCore/DiGIR and ABCD schema/BioCASE for strain data, CCINFO for the organizational information of mBRCs.

ii) Check vocabulary against standard reference lists or thesauri.

iii) Keep consistency among mBRCs for searching and retrieving of information from catalogues and databases:

- Each biological material record shall contain a Minimum Data Set, a Recommended Data Set and/or a Full Data Set in accordance with domain specific criteria.
- Spell checking for every field shall be a basic requirement.
- International English shall be chosen as a preferred language of data (in addition to local language if different).
- A standardised approach shall be adopted to certain scientific symbols (to avoid any errors due to incorrect reading of a character set, standard ASCII alternatives to symbols shall be used: e.g. Greek letters cannot be used, they shall be fully spelled (write alpha, gamma, beta...); the °symbol for temperature is to be omitted entirely (e.g. 37C replaces 37°C); no subscripts or superscripts are allowed (e.g. cm3 replaces cm3 and CO2 replaces CO2).

mBRCs shall adopt procedures to detect errors in data to improve their quality and consistency. This is an essential part of information management and shall be both applied to the input of new data as well as to pre-existing information in current databases:

- For existing data, a series of checks shall be carried out to ascertain their validity and completeness. As more mBRCs become associated, more searches shall be made for common classes of error to allow more efficient error correction.
- For new data, wherever possible, inputting shall be checked against authorised lists of not only scientific names but also thesaurus/ontology to prevent errors such as mistyping.
- mBRCs shall present evidence that they have applied a recognised protocol appropriate for each data element.

There shall be a minimum amount of information available for each accession in the collection (Minimum Data Set (MDS). Additional data may be included in the Recommended Data Set (RDS) and Full Data Set (FDS). The MDS and RDS are listed in Table 2 of the Appendix 1. The MDS comprises essential information to identify a unique item in the mBRC. The RDS includes useful

information for an improved description of the material. The FDS provides all remaining information that is available at the mBRC for any given biological materials. The MDS shall always be recorded and made available whereas the RDS is recommended, and the FDS is additional optional information.

8.2 Data processing

The informatics system employed by mBRCs shall provide appropriate facilities for information management, linkage and exchange of the mBRC.

The databases shall contain either information relating to strains held by a mBRC (which at least, shall be retained as long as a strain remains viable), or other relevant data items or composite data needed by the mBRC (e.g. users records). On the loss of a strain the database record shall be either printed and stored on file or copied to a digital archive before the entry is removed from the working database, placed in reserve or annotated to indicate that it is no longer available as living material.

The mBRC shall preferably choose standard data schema and protocols to make the databases distributed and interoperable. Confidential data shall be clearly identified in relation with user authentication capability, encryption techniques and other related information security tools.

The informatics system shall ensure regular data back-up. Off-site storage of data is desirable. Data archives shall be maintained in accordance with the maintenance of the biological resource storage policy. The support of these archives shall be regularly updated according to its physical characteristics (obsolescence) and to software compatibility.

mBRCs shall introduce appropriate measures (protocols, tools and standards) in their own informatics systems to assure reasonable security of information. There are existing systems, e.g. authentication by user ID and password, encryption, encryption of messages and restriction of IP addresses that may provide the basis for such measures. Backup-files shall be stored in secure cabinets.

8.3 Access to data and publication

The mBRC shall make available data describing the biological material and its origin and provide electronic catalogues to users through their own facilities (e.g. website) or through focused, national, regional or global networks. Data shall also be retained for traceability in compliance with relevant national laws and regulations.

The mBRC shall respect a defined update frequency for data publication (on-line or not), in accordance with the flow of available biological resources.

mBRCs shall ensure the quality and consistency of data sets and provide data to users while

ensuring information security, bio-security, protection of IPRs, client information and human dignity. National data protection regulations shall be adhered to.

Exchange of information shall be in line with the OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal data.

mBRCs shall restrict access to the electronic catalogues where appropriate.

Users shall be authenticated. Specific identities and passwords shall be provided by mBRCs to users to access different categories of information and services. The validity of identifiers and passwords shall be checked.

9 Preparation of media and reagents

The mBRC shall define standards for all preparations used in the growth and/or maintenance of the living biological materials held; these shall be documented with the appropriate mechanisms in place to allow changes to procedures.

Accurate preparation and storage conditions of culture media, one of the fundamental steps in the growth and maintenance of biological materials, shall be given special attention. The mBRC shall have defined standards for all preparations; media formulae shall be documented and procedures put in place to make changes to procedures and for their approval and adoption. Media batches shall be clearly labelled and expiry dates (date after which media and reagents are not to be used) defined and clearly indicated.

Supplies of materials for use shall be of high standard and shall not be contaminated.

10 Accession of deposits to the mBRC

10.1 Receipt and handling of biological materials

The mBRC shall document and implement safe procedures for receipt and storage appropriate to the type of biological materials handled. All incoming parcels that contain known or unknown micro-organisms shall be opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological materials.

The depositor shall provide assurance that biological materials were obtained legitimately. Conditions of deposit shall be determined and agreed e.g. laid down in a material transfer agreement (MTA), for example to protect assigned intellectual property rights (IPRs). Where deposits are outside the expertise of the mBRC, alternative suitable mBRCs shall be recommended.

Quality control procedures shall be carried out upon receipt of biological material to confirm its

purity, identity and viability. The recommended procedures that shall be carried out are in Table 3 of the Appendix 1.

Before accepting a deposit, the mBRC shall check against risk group lists and other lists to make sure that the biological material does not exceed the laboratory's biological safety containment level.

A risk assessment shall be carried out on the biological material and the methods recorded to determine, as far as possible, the potential of harm to personnel, the public and the environment. The risk assessment shall be reviewed and updated regularly.

A unique collection number is allocated to the biological material, which is never reassigned if the biological material is later discarded.

10.2 Accession

The mBRC shall document its acquisition policy defining the biological material to be maintained and the criteria on which the acceptance of new biological material offered to the collection is based. This policy shall balance capability, capacity with scientific and user's needs.

mBRCs shall only accept deposits of biological material that meet its acquisition criteria and fall into the groups of its specialist expertise.

The biological material received shall have the following information:

a) Name (where one can be applied), other identifier or cell culture description.

b) Depositor's name and address.

c) Source, substrate or host from which the biological material was isolated or derived (where identified) and date of isolation.

d) Geographical origin of material (the minimum requirement is the country of origin or the furnisher of the source, substrate or host). In the case of a plasmid this would be information on who and where it was constructed.

e) Depositor's biological material number or other collection number(s), if deposited elsewhere.

f) Growth media and conditions, cell preservation or storage conditions where known.

g) Hazard information e.g. in the form of a safety data sheet.

10.3 Quality checks on the biological material

The mBRC shall perform authentication tests as well as determine the stability of some key features, growth requirements, and methods of maintenance and/or preservation as appropriate to

the biological material maintained, using appropriate technology. This information shall be recorded. These records shall be retained and can be used as a base line when in-storage maintenance checks are performed or for validation after preservation restocking.

Where possible the identity of the biological material shall be confirmed after receipt by a competent person (employed or contracted by the mBRC or its parental organisation). The biological material shall be checked again by these competent persons before (if there are additional transfers of the biological material before it is preserved) and after preservation. This step may include identity, purity or property check of the biological material performed by the depositor.

A “maintenance plan” (i.e. a scheme for periodic control of the preserved material) shall be in place for each item stored. Several aspects determine the frequency of the maintenance checks (e.g. the type of biological material, the preservation method, turnover of the material, etc.). The maintenance check shall be appropriate to the biological material and be laid down in the domain specific criteria.

See domain specific recommendations for specific details of quality controls.

11 Preservation and maintenance

The mBRC shall select preservation and maintenance methods according to recommendations from the depositor and/or previous experience. The mBRC shall document these preservation procedures to ensure they are reproducible and that key parameters of the process are recorded and monitored.

The biological material shall be preserved by at least two methods (where two distinct methods are not applicable to the biological material, cryopreserved stocks shall be maintained in separate locations) and as master cell banks and as stocks for distribution. The labels shall include at least the batch date or number and the mBRC accession number. Where possible an indication of expiry date shall be provided to the user of the biological material. Biological materials with specific hazards shall be clearly differentiated.

11.1 Long-term preservation

The commonly used approach for sustainable preservation of microbial cultures is long-term preservation employing liquid nitrogen, deep freezing, freeze-drying or L-drying methods. These methods allow high quality long-term storage, recovery and use of the micro-organism. For each micro-organism culture, an appropriate preservation method(s) shall be chosen by the mBRC based on its own experience or on the recommendations of the depositor (see section 10.2). The methods used shall be equivalent to those cited above and shall ensure:

High viability/recovery of the preserved culture.

No contaminant in the preserved culture (this does not include any recognised co-culture e.g. symbiotic micro-organisms), which are not regarded as contaminants so long as the constituents are correctly specified and checked by microbiological and molecular analysis, as applicable).

Authenticity of the preserved culture and genome integrity (molecular, phenotypic analysis), where applicable.

The recommended methods for the storage and preservation of biological materials and the form in which it is distributed are set out in Table 4 of the Appendix 1.

11.2 Validation of methods and procedures

Validation of the methods and procedures used for preservation shall be carried out to ensure their reproducibility and reliability, and general compliance during the quality control of biological material. Performance of the method(s) shall correspond to the criteria listed in Section 10.1.

In addition to the requirements laid out in the General Best Practice Guidelines for all BRCs, the validation of quality check, characterisation and preservation methods shall be carried out by using at least one of the following approaches:

Performing blind tests.

Comparing the results of the same method performed at different times (reproducibility).

Comparing results obtained with different methods (reliability).

Comparing the results obtained for the same method performed by different persons.

The results of quality checks and the procedure used shall be recorded.

11.3 Stock control of the preserved biological materials

To ensure a minimum number of transfers or generations from the original biological material, where this is appropriate, the mBRC shall use master (or seed) and distribution stocks.

The mBRC shall produce the master stock from the original biological material. This master stock shall be used to generate the distribution stock. The mBRC shall use the distribution stock to supply biological materials.

The mBRC shall adapt the size of these masters and distribution stocks to the anticipated distribution rate.

11.4 Storage of preserved biological materials

The biological material shall be stored under environmental parameters that assure the stability of

its properties (see domain specific obligations).

Details of the inventory control, lead times and re-stocking practices shall be documented.

A duplicate collection shall be maintained, preferably on another site as a ‘disaster’ protection measure and to avoid accidental loss.

11.5 Validation of methods and procedures

The mBRC shall document all methods and procedures used in validation (see domain specific criteria).

The results of method and procedure validation shall be recorded.

12 Supply

12.1 Order placement

The materials shall be distributed according to the policy of each depository. This policy shall take into account the nature of the biological materials and meet all relevant national and international regulations and policies.

To the extent that it can be determined, mBRCs shall supply micro-organisms only to laboratories and only to those individuals who are trained in microbiology and have access to properly equipped laboratories, unless otherwise justified and documented. The recipients facilities shall meet the specific requirements as required by relevant national and international regulations and policies.

First orders from new clients shall be received on an order form with the client’s official letterhead and signed by an authorised person. The mBRC shall accept fax and mail orders with an official user order number unless signature and/or permits are required for release of particular biological materials. E-mail and telephone orders could be accepted from known or registered users where signatures of authority are not required.

An order shall only be accepted when the required accompanying documentation is completed, signed and returned.

12.2 User validation

To ensure that only authorised users may access biological material that is pathogenic or toxic to humans, animals and plants, the mBRC shall implement any national and international requirements and, as applicable, the following measures for the respective hazardous material:

- Comply with the measures set out in Best Practice Guidelines on Biosecurity for BRCs.

- Check that the name and signature of the head of department/division match against those registered in the mBRC's list of authorised institutions.
- Check that the name and signature of the user match against those registered in the mBRC's list of authorised users.
- Have written and signed documentation proving that the user has the appropriate containment facilities and the authorisation to import and handle such biological material.

An order shall only be processed when the required accompanying documentation is completed, signed and returned.

12.3 Availability of the biological material ordered

Freeze-dried or cryo-preserved (when supplied frozen) material shall be dispatched as soon as possible once necessary licenses and/or documentation are provided. Dispatch for such materials shall be according to the laid down procedures and conditions. Where materials cannot be delivered within three working days (e.g. actively growing cultures), then the client shall be informed of the delay within three working days.

If a biological material cannot be delivered within the specified delivery time, the mBRC shall contact the user with an estimated supply date. The mBRC shall recommend where possible other national or foreign mBRCs to supply biological materials not held.

12.4 Packaging and Transport

The packaging of biological material and its transport by postal and other transport services is controlled by international and regional agreements and national laws.

To ensure safe and secure packaging and transportation of biological material, mBRC shall follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances. These best practice guidelines provide practical guidance to facilitate compliance with current international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally.

Those materials exempt from the WHO guidelines (non-infectious micro-organisms allocated to Risk Group 1 may be sent by (air) mail or other means of transport according to the Universal Postal Union (UPU) requirements.

The International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) are legally binding for shippers and carriers of dangerous goods (including infectious substances) to be transported by air. For transportation via road, rail and waterways, regional and/or national regulations exist. mBRCs shall follow the IATA DGR and other respective regulations, to ensure that all applicable requirements for packaging and shipping dangerous goods on ground and air

are met.

mBRCs shall ensure that staff responsible for the distribution of biological material have the necessary knowledge and training.

Staff responsible for the distribution of dangerous goods (including infectious substances) via air shall have the shipper's training certificate as required by IATA.

12.5 Traceability of hazardous biological materials

The mBRC shall keep records of all requests for biological materials – including those requests refused for any reason – showing the biological material, method and date of shipment, and name and address of the person to whom sent. Where recorded delivery, courier or similar shipping mechanisms are used records of shipment receipt shall be maintained. The records shall be maintained to meet national law, regulations and policies.

12.6 Information provided with the biological material supplied

The mBRC shall provide at least the following information to the user:

- Biological material identifier, accession number and batch number.
- An estimate of shelf-life, storage conditions, storage instructions and if appropriate, conditions of growth.
- Instructions for opening ampoules or vials (when appropriate and in all cases where materials are being provided to new users).
- A safety data sheet including the containment level required for handling the biological material, disposal measures and measures to take in case of spillage.
- A Material Transfer Agreement: an essential requirement to protect IPR and mandatory where they are required by national law. They are used to relay the depositor's and/or country of origin requirements on use of the biological material.
- Fax-back sheet to acknowledge receipt of materials may be desirable.

12.7 Invoicing for supply charges

Invoices shall normally be despatched at the same time as the material unless otherwise instructed or where pro forma invoices have been paid in advance.

12.8 Meeting stakeholder needs and expectations

The success of the mBRC depends upon a thorough understanding and the meeting of present

and future needs of its current and future clientele.

The mBRC shall:

- Identify its stakeholders according to their activities
- Determine their needs and expectations
- Identify those needs the mBRC can meet

12.9 Handling complaints, anomalies and refunds

The mBRC shall record all user queries or complaints and acknowledge as soon as possible (preferably on the same day) by fax, telephone or e-mail.

The mBRC shall investigate the complaints as soon as received and implement the necessary corrective actions. All complaints shall be included in regular trend analysis.

Records of responses/solutions shall be stored.

Despite rigorous quality control and standard procedures being followed, it may be possible that the biological material provided may not have the property stipulated in the order or that is reasonably expected of it on receipt. If the user is not deemed at fault it is normal policy to provide the user with a replacement free of charge where this is possible. If refunds are considered appropriate they shall be given.

12.10 Confidentiality

All work carried out for a client shall be treated as strictly confidential to that client unless national requirements apply. This shall apply to all requests for biological materials, safe and patent deposits, information supplied relating to these and to the fact that the product or service was requested in accordance with national law, regulations and policies. Information may be included in statistics produced to show mBRC activities in a way that the customer is not identified.

The names of past or present clients shall only be revealed with the clear permission of the client.

12.11 Preventive actions and improvement

The mBRC shall identify actions for eliminating the cause of non-conformities to prevent their occurrence and continually improve the efficiency of its quality management system.

The mBRC shall establish a documented procedure to:

a. Identify possible non-conformities

b. Assess the need for preventive actions for these possible non-conformities

c. Identify and implement actions

d. Record results of the actions and review impact

13 Micro-organism Biological Resource Centres' compliance with national and **international law**

Micro-organisms are isolated, grown, characterised, preserved for the long-term, stored and transported between laboratories. They are shipped by various means, by postal mail or by courier service, from one laboratory to another within countries, and often across borders or continents. They are sent for identification, reference, research or for production purposes from colleague to colleague, from and to culture collections. All these actions shall be carried out safely and in compliance with the various legislation and regulations that control these matters. The mBRC shall ensure that any changes to applicable legislation and regulations are implemented in their procedures.

The importance of a laboratory's health and safety procedures extend beyond the laboratory to all those who come in contact with substances and products from that laboratory. A micro-organism in transit might put carriers, postal staff, freight operators and recipients at risk, some organisms being relatively hazard free whilst others can be quite dangerous. Safety and shipping regulations shall be followed to ensure safe transit. The mBRC shall adhere to regulations relevant to the distribution of micro-organisms.

A microbial domain Biological Resource Centre (mBRC) shall, for example, comply with:

- Applicable health and safety requirements.
- Classification of micro-organisms on the basis of risk.
- Applicable quarantine regulations.
- Intellectual property rights (IPR).
- Requirement that safety information is provided to the recipient of micro-organisms.
- Applicable regulations governing shipping of cultures.
- Control of distribution of biological material (see paragraph 13.5 addressing biosecurity).
- Provision of appropriate safety information to the recipient of micro-organisms.

In the process of isolation, handling, storage and distribution of micro-organisms, there are many stages where compliance with the law, regulations or voluntary international conventions is required. Table 5 of the Appendix 1 lists some examples of these.

Whether it is compliance with the law, or duties of a caring employer, essential components for a safe workplace are:

- Adequate assessment of risks.

- Provision of adequate control measures.
- Provision of health and safety information.
- Provision of appropriate training.
- Establishment of record systems to allow safety audits to be carried out.
- Implementation of good working procedures.

Best practice requires mBRCs to have and implement a sound health and safety plan.

13.1 Classification of micro-organisms according to risk groups

Various classification systems exist and are implemented nationally. The key references are the definitions for classification made by the World Health Organisation (WHO). The definition and minimum handling procedures of pathogenic organisms are set by appropriate authorities in each country.

The WHO classifies micro-organisms into four groups according to the risk they impose to humans:

Risk group 1: (no or low individual and community risk). A micro-organism that is unlikely to cause human or animal disease.

Risk group 2: (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Risk group 3: (high individual risk, low community risk). A pathogen that usually causes serious human or animal disease but does not ordinary spread from one infected individual to another. Effective treatment and preventive measures are available.

Risk group 4: (high individual and community risk). A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

An mBRC shall ensure that all biological materials are assigned to appropriate risk groups; this includes a positive assignment to Risk Group 1 unless otherwise considered hazardous. Risk group information shall be recorded and made available to recipients of biological material.

13.2 Quarantine regulations

Clients, who wish to obtain cultures of plant pathogens underlying quarantine regulations shall first obtain a permit to import, handle and store from the appropriate authority. Under the terms of such a licence the shipper is required to see a copy of a permit before such strains can be supplied.

Plant pathogens handled by mBRCs that are subject to quarantine regulations shall be registered by an appropriate governmental office. Import and transfer of such pathogens within the country shall be carried out according to relevant law.

13.3 Intellectual Property Rights (IPRs)

On deposit of a micro-organism, mBRCs shall record terms and conditions for its further distribution.

Transparency, retaining the link between the source and all recipients of biological materials, is the preferred practice. Where appropriate, material transfer agreements shall be put in place.

13.4 Safety information provided to the recipient of micro-organisms

Safety information shall be dispatched with a micro-organism indicating which risk group it belongs to and what containment and disposal procedures are necessary. For a micro-organism, a safety data sheet shall include:

- The risk group of the organism being dispatched.
- A definition of the risks and assessment of the risks involved in handling the organism.
- Requirements for the safe handling and disposal of the micro-organism.
- Containment level.
- Opening procedure for cultures and ampoules.
- Appropriate transportation of the micro-organism.
- Procedures in case of spillage.

13.5 Control of Distribution of Hazardous Micro-organisms

mBRCs shall follow the Code of Conduct on Biosecurity for BRCs and where appropriate and practicable implement the Best Practice Guidelines on Biosecurity for BRCs (Appendix 2).

There is considerable concern over the transfer of certain infectious agents capable of causing substantial harm to human health. There is potential for such organisms to be passed to parties not equipped to handle them or to people who may make illegitimate use of them. To reduce the risk a mBRC shall have procedures in place which meet national requirements to check the validity of customers that wish to receive hazardous organisms.

Code of Conduct on Biosecurity for Biological Resource Centres (BRCs)

Accumulated and advancing knowledge on biological systems offers substantial benefits to mankind, to research and to development in all areas of basic and applied bio-medical and bio-

technological sciences. However, this improved knowledge is intrinsically associated with the potential for dual application: for beneficial or malicious purpose. The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the dual-use dilemma and confers a responsibility on both those with the knowledge and with the biological resources. The responsibilities of those engaged in the life sciences have an increasing role for in-depth implementation of the Biological and Toxin Weapons Convention (BTWC). Scientific openness and a sense of security are prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out activities in the life sciences. This Code of Conduct on Biosecurity is to help microbial Biological Resource Centres (mBRCs) promote a basic ethical understanding of science compliant with the BTWC and raise awareness to prevent misuse in the life-sciences context.

It is not the aim of this Code to influence the range of bio-resources maintained or life science activities performed at mBRCs. Above all, this Biosecurity Code of Conduct is meant to complement legislative procedures. This Code intends to raise awareness within the mBRCs and outside and to clearly demonstrate that mBRCs are fully compliant with national and international legislation and support the BTWC as an international norm prohibiting biological weapons.

The aim of this Code of Conduct is to prevent microbial mBRCs from directly or indirectly contributing to the development or production of biological weapons or to any other malicious misuse of biological agents and toxins.

Biological Resource Centres commit themselves to this Code of Conduct on Biosecurity considering their specific situation and key role as an essential part of the international infrastructure underpinning biotechnology: providing the world-wide scientific and industrial communities with authentic biological materials required in research, application and teaching as well as related information and services. Being part of the scientific community they conduct activities in the life sciences, offer training courses, expertise and knowledge and they support the bioeconomy.

Many BRCs are entrusted with the collection and controlled supply of potentially hazardous bio-resources. This requires high responsibility, well-established risk analyses and appropriate BRC internal infrastructures, profound knowledge of relevant bio-legislation including export control and respective protective measures. This Code calls for implementation and compliance of awareness, accountability and oversight and targets all those engaged in life sciences activities, laboratory workers, managers, stakeholders and others.

13.5.1 Biorisk management

- Integrate biorisk management throughout the organization, provide adequate resources and identify opportunities for improvement and prevention.

- Assign responsibility to guarantee compliance with legal requirements, communication to staff and relevant third parties, and carry out reliable and appropriate risk assessment.

13.5.2 Raising awareness

- Devote specific attention in the education and further training of all staff to the risks of misuse of biological material, information and life sciences research and the requirements of regulations in this context.
- Maintain attention for and update knowledge on biosecurity by regular training and auditing.
- Raising awareness of related third parties on their responsibilities.

13.5.3 Accountability

- Report any finding or suspicion of misuse of biological material, information and technology directly to competent persons or commissions.
- Protect persons reporting on misuse and ensure that they do not suffer any adverse effects from their actions.

13.5.4 Internal and external communication

- Prevent access for unauthorised persons to internal and external e-mails, post, telephone calls and data storage concerning information about potential dual-use research or potential dual-use materials.
- Regulate the communication of sensitive information.

13.5.5 Research and sharing knowledge

- Screen for possible dual-use aspects during assessment or application procedures and during the execution of research projects.
- Minimize the risk that publication of results on potential dual-use organisms will contribute to misuse of that knowledge.
- Consider biosecurity implications when sharing knowledge.

13.5.6 Accessibility

- Screen staff and visitors where potential dual-use biological materials are stored or used.
- Ensure physical security of and access control to stored potential dual-use material in accordance with its risk classification.

13.5.7 Shipment and transport

- Screen recipients and transporters of potential dual-use biological materials, in consultation with the relevant authorities and parties.
- Perform export control in accordance with applicable regulations.
- Dispatch cultures in appropriate packaging and in accordance with IATA and/or relevant regulations for other means of transport

14 Quality audit and quality review

14.1 Purpose

Periodic audits shall be carried out by management to ensure that the mBRC policies and procedures, as set out in these best practice guidelines and the supplemental domain specific best practice guidelines, are being followed. External, independent audits shall be carried out. A process shall be in place to identify any potential source of non-conformity to mBRC guidance.

14.2 Responsibility

The mBRC manager or a delegate, assisted by mBRC staff if necessary, shall carry out an assessment of the effectiveness of procedures and organise the audit programme.

The Quality Manager shall be responsible for ensuring that reviews are recorded and that any actions are implemented.

14.3 Implementation

Staff of the mBRC shall undertake at least one audit each year according to the schedule described in the Rolling Audit Programme. This programme entails the review of all mBRC activities including documentation, supply, accession, database, training records, equipment and maintenance, enquiries and complaints records and external support services. In addition it shall include a strain deposit trail through to storage and a supply trail from receipt of order to supply. These shall be chosen at random. The Day Work Books, enquiry records and database records shall also be reviewed. The results of the audit and record reviews shall be recorded and any fault rectified.

An external independent qualified person shall carry out a Third-Party Audit of the procedures, preferably each year. This too shall include a biological material deposit trail through to storage and

a supply trail from receipt of order to supply. These shall be chosen at random. The Day Work Books, enquiry records and database records shall also be reviewed. The results of the Third-Party Audit and record reviews shall be recorded and any fault rectified.

A meeting of all audit staff, mBRC staff and line management shall be held annually to review the audit reports, enquiries and complaints received and discuss potential improvement in procedures and monitoring. The results of the review shall be recorded and the Quality Manager is responsible for implementation of actions prescribed.

14.4 Method and procedure for quality checks

All methods and procedures shall be subject to in-use quality checks. For example, the product shall be checked for fitness for purpose, i.e. a sample shall be selected from a preserved batch and appropriate stability checks carried out. Such checks shall be included in the individual documented procedures.

14.5 Communication

The mBRC shall respond to requests for information from its clientele concerning quality and availability of biological material.

The mBRC will implement efficient measures for communicating quality issues with staff that influence quality performance levels.

The mBRC has an obligation of professional secrecy see paragraph 12.10 on confidentiality.

Conclusion

The above text can form the draft document to be presented to ISO if the mBRC community wishes to have a common single international standard for the accreditation of microbial domain BRCs.

References

mBRC shall keep abreast of literature and legislation relevant to the taxonomy, handling and distribution of micro-organisms. This bibliography shall be revised periodically to include key literature.

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Anon (1996b). European Standard EN 829:1996 E: Transport packages for medical and biological

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Dworkin M. et al. (2003), The prokaryotes: An evolving Electronic Resource for Microbiological Community (http://link.springer-ny.com/link/service/books/10125, printed version: 7 volumes).

EC Council Directive 2000/29/EEC on protective measures against the introduction into the Member States of harmful organisms of plant or plant products. OJ No. L. 169, p.1 of 10.07.2000.

EC Council Regulation 1504/2004 amending and updating Regulation 1334/2000.

EC Council Directive 95/44/EC on establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections.

EC Council Directives 90/219/EEC and 98/81/EC on contained use of genetically modified organisms.

EC regulation 1946/2003 on the transboundary movement of genetically modified organisms (pertains to Cartagena Protocol on Biosafety).

EC Council Directive 2000/54/EEC On the protection of workers from risks related to exposure to biological agents at work. OJ No. L. 262, pp.21-45 of 18.09.2000.

EN 1619:1996 Biotechnology – large-scale process and production – General requirements for management and organisation for strain conservation procedures.

EC Council Regulation No 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology. OJ No L 159 of 30.6.2000 (Amended by: EC Council Regulation 149/2003 of 27 January 2003, OJ L 30 of 05.02.2003, corrigendum OJ L 52 of 27.02.2003).

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ISO 7218:2000, Microbiology of food and animal feeding stuffs. General rules for microbiological examinations.

ISO 9001:2000, Quality Management Systems – Requirements.

ISO 17025:2005, General requirements for the competence of testing and calibration laboratories.

Kirsop, B.E. & Doyle, A. (eds) (1991). Maintenance of Microorganisms and Cultured Cells: A Manual of Laboratory Methods, London: Academic Press.

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Smith, D, Rohde, C (2002). The implication of the biological and toxin weapons convention and other related initiatives for WFCC members. WFCC Newsletter 34: 4-11.

Technical Instructions for the Safe Transport of Dangerous Goods by Air. Doc 9284-AN/905. Council of ICAO, International Civil Aviation Organisation.

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WHO World Health Organization, Geneva, Nonserial Publication, ISBN: 92 4 154650 6. Laboratory Biosafety Manual, Third Edition, English, 2004.

WEBSITES OF INTEREST FOR INFORMATION

This list will require periodic update; mBRCs shall review information available to assist them in compliance with legislation and best practice in the operation of the mBRCs.

Transport and shipping

International Laboratory Accreditation Cooperation (ILAC) http://www.ilac.org/

Micro-Organisms Sustainable use and Access regulation International Code of Conduct www.belspo.be/bccm/mosaicc

CABRI Guidelines http://www.cabri.org/gidelines.html

Canadian Transport www.rural-gc.agr.ca/e4.1_canutec.html

European Commission DGVII – Transport http://europa.en.int/en/comm/dg07/index.htm

Harmonisation of UN documents etc. www.hazmat.dot.gov/rules

International Air Transport Association www.IATA.org/cargo/dg

www.IATA.org/cargo/dg/links.htm

International Civil Aviation Authority http://hazmat.dot.gov/icao.htm

www.volpe.dot.gov/ohm/icao.htm

www.cam.org/~icao/menu3.html

Maritime rules www.eat.co.uk/ncec/complian/bibliog/bysea.html

www.mdnautical.com/imo/cargoes.htm

www.imo.org/pubs/pubcats.htm

www.info.gov.hk/mardep/notices/mdn98149.htm

www.hazmathelp.com/imdg.htm

The European Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR) http://hazmat.dot.gov/RIDADR.htm

www.dsidat.com/products/undisk7.htm

www.volpe.dot.gov/ohm/ridadr.htm

Transport – general

German magazine www.tci-transport.fr

www.hazmathelp.com/dotlink.htm

www.cefic.org

www.storck-verlag.com/english/gela_e.htm

United Nations meetings agenda and minutes
www.unece.org/unece/trans/danger/meetdoc.htm

UN Model Regulations www.unece.org/unece/trans/main/dgdemo/intro.htm

UN Committee of Experts www.tc.gc.ca/tdgoods/consult/unlinks_e.htm

Universal Postal Union http://ibis.ib.upu.org

http://unicc/unece/tra

www.de/facil/upustr.htm

WHO Guidance on Regulations for the Transport on Infectious Substances http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22/en/

Biosafety

Organisation for Economic Co-operation and Development (OECD)
http://www.oecd.org/dataoecd/4/4/34932656.pdf

United Nations Industrial Development Organisation (UNIDO) Bio-safety Information Network and Advisory Service (BINAS) www.who.org/emc/biosafe/index.htm

International Centre for Genetic Engineering and Biotechnology (ICGEB)
www.aphisweb.aphis.usda.gov.biotech

US Animal and Plant Health Inspection Service (APHIS) www.nal.usda.gov/bic/

US Food and Drug Administration (FDA) http://www.fda.gov/

World Health Organization (WHO) Biosafety Programme http://www.who.int/csr/labepidemiology/projects/biosafetymain/en/index.html

U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) rules implementing USA PATRIOT Act and Public Health Security and Bioterrorism Preparedness and Response Act of 2002 http://www.cdc.gov/od/sap/final_rule.htm

Centre for Food Safety and Applied Nutrition (CFSAN) http://vm.cfsan.fda.gov/list.html

Belgian Bio-safety Server www.biosafety.be

The Dutch Genetically Modified Organism Bureau www.rivm.nl/csr/bggo.html

Biotechnology Information Centre (BIC) of the US Department of Agriculture (USDA) www.nal.usda.gov/bic/

UK Advisory Committee on Releases into the Environment (ACRE) www.environment.detr.gov.uk/acre/index.htm

National Chemical Emergency Response UK www.eat.co.uk/ncec/complian/bibliog/bibliog.htm

American Biological Safety Association (ABSA) http://www.absa.org

European Biosafety Association (EBSA) http://www.ebsaweb.eu

International Biosafety Working Group (IBWG) http://www.internationalbiosafety.org/english/index.asp

Advisory Committee on Dangerous Pathogens http://www.doh.gov.uk/bioinfo.htm

Biodiversity

Convention on Biological Diversity: http://www.unep.org/biodiv.html

International Organisations

World Federation for Culture Collections: http://www.wfcc.info/

World Data Centre for Micro-organisms: http://wdcm.nig.ac.jp/

Common Access to Biological Resources and Information: http://www.cabri.org

European Biological Resource Centres Network: http://www.eBRCn.org

ASM – Asian Consortium for the Conservation and Sustainable Use of Micro-organisms http://www.aBRCn;net

ECCO, European Culture Collection Organisation: http://www.eccosite.org

Food and Agriculture Organization (FAO): http://www.fao.org/

World Animal Health Organization (OIE): http://www.oie.int/eng/en_index.htm

International Plant Protection Convention (IPPC): https://www.ippc.int/IPP/En/default.jsp

International Police Organization (INTERPOL): http://www.interpol.int/

The Australia Group: http://www.australiagroup.net/

Biological Weapons Convention (BWC): http://disarmament.un.org/wmd/bwc./

MIRCEN Scholarships: http://portal.unesco.org/sc_nat/

UNESCO People, Biodiversity and Ecology http://www.unesco.org/mab/index.shtml

WIPO - World Intellectual Property Organization : http://www.wipo.int

ISO - International Organization for Standardization: http://www.iso.ch/iso/en

Patents

Budapest Treaty on the International recognition of the Deposit of Micro-organisms:

http://www.wipo.int/treaties/en/registration/budapest/

Taxonomy and Nomenclature ICSP

International Committee on Systematics of Prokaryotes (ICSP): http://www.the-icsp.org/

Bacterial Nomenclature up-to-date: http://www.dsmz.de/bactnom/bactname.htm

Species 2000 Indexing Project: http://www.sp2000.org

List of bacterial names with standing in nomenclature: http://www.bacterio.cict.fr/

Viruses' names: http://www.ncbi.nlm.nih.gov/ICTVdb/; http://www.micro.msb.le.ac.uk/3035/virusgroups.html

Fungal names: http://www.ukncc.co.uk

Bacterial Code of Nomenclature: http://www.the-icsp.org/Code history.htm

Index Fungorum: http://www.indexfungorum.org

Annexes

Annexe 1. Tables

Table 1. Maintenance and Calibration Requirements for Equipment Commonly Used in mBRCs

Item	Maintenance required	Verification of function
Autoclaves	Cleaning, pressure vessel, system of surveillance, maintenance contract as required; run with indicators	As recommended by manufacturer
Incubators	Cleaning, system of surveillance, maintenance contract as required	Manufacturers' standard on service
Liquid nitrogen storage vessels	Cleaning, leakage, pressure	Once yearly Manufacturers' Test
Centrifuges	Cleaning, system of surveillance, maintenance contract as required	Regular cleaning Manufacturers' service
Cryo-storage tanks	Removal of condensation and ice	
LN_2 store oxygen level alarm	System of surveillance, maintenance contract as required	Manufacturers' standard on service
LN_2 level alarms	Look for malfunction	None
Programmed Cooler	System of surveillance, maintenance contract as required	None
Cryomicroscope	Clean after use, Temperature calibration	Calibration equipment provided for test at each time of use
Spin and shelf freeze-drier	System of surveillance, maintenance contract as required	Calibration of the vacuum gauge
Microscopes	Clean after use, System of surveillance, maintenance contract as required	
Laminar Flow Cabinet	Clean after use, airflow	Annual functionality test
Class II Microbiological Safety Cabinet	Clean after use System of surveillance, maintenance contract as required	Manufacturers' standard on service
-20°C Freezer	Temperature check	None
-80°C Freezer	Temperature check and registration System of surveillance, maintenance contract as required Security advices	
Media Preparation equipment	Clean after use	
Balance	System of surveillance, maintenance contract as required Clean after use	Manufacturers' standard on service
pH Meter	Clean after use	Test against Manufacturers' standard

1. LN_2 = Liquid Nitrogen

Table 2. Minimum Data Sets (MDS) and Recommended Data Sets (RDS) for Microbial Accessions to mBRCs

Filamentous fungi	**Filamentous fungi**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Misapplied names
Other collection numbers	Isolated from
Name	Mutant
Organism type	Literature
Restrictions	Sexual state
Status	Race
History of deposit	
Conditions for growth	
Form of supply	
Geographic origin	
Yeasts	**Yeasts**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Isolated from
Other collection numbers	Mutant
Name	Sexual state
Organism type	Literature
Restrictions on distribution	Misapplied names
Status	Race
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	
Microalgae	**Microalgae**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Literature
Other collection number	Conditions for storage
Name and taxonomy	Isolate history
History of deposit	
Isolate history	
Form of supply	
Geographic origin	
Conditions for growth	
Bacteria	**Bacteria**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Serovar
Other collection numbers	Other names
Name	Isolated from
Infrasubspecific names	Mutant
Organism type	Genotype
Restrictions on distribution	Literature
Status	
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	

Table 2. Minimum (MDS) Data Sets and Recommended (RDS) for Microbial Accessions to mBRCs (*cont.*)

Cyanobacteria	**Cyanobacteria**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Other names
Other collection numbers	Isolated from
Name and taxonomy	Mutant
Infrasubspecific names	Genotype
Organism type	Literature
Restrictions on distribution	
Status	
History of deposit	
Conditions for growth	
Form of supply	
Geographic origin	
Archaea	**Archaea**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Other names
Other collection numbers	Isolated from
Name	Mutant
Infrasubspecific names	Genotype
Organism type	Literature
Restrictions on distribution	
Status	
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	
Plasmids	**Plasmids**
Minimum Data Set (MDS)	**Full Data Set (FDS); RDS is not applicable**
Collection Accession number	Constructed from
Name	Incompatibility group
Other culture collection numbers	Transfer ability
Type	Helper
Class	Copy number
Literature	Molecular weight
History of deposit	Cloned gene
Restricted distribution	Transposable element
Host for distribution	Promoter
Medium	Ribosome binding site
Selectable phenotype	Start codon
Replicon	Terminator
Host range	Further information (Remarks on propagation and/or on properties and/or on history, other name(s), etc)
	Restriction sites
	Sequence detail
	Price code
	Properties and application

Table 2. Minimum (MDS) Data Sets and Recommended (RDS) for Microbial Accessions to mBRCs (*cont.*)

Protozoa	**Protozoa**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Biochemical or molecular characteristics
Other collection numbers	Other name
Name	Substrate or host
Organism type	Year of isolation
Stage	Literature
History of deposit	
Status	
Restriction on distribution	
Conditions for growth	
Form of supply	
Geographic origin	
Phages	**Phages**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Cell surface receptor
Element name	
Element type	
Other culture collection numbers	
Restricted distribution	
Literature	
History of deposit	
Host for propagation	
Host used for propagation	
Lysogenicity	
Virus used for	
Viruses	**Viruses FDS = MDS**
Minimum Data Set (MDS) = Full Data Set (FDS)	
Accession number	
Virus name	
Virus name abbreviation	
Former name	
Genus	
Pathotype, serotype, strain	
Original host	
Geographic origin	
Isolate history	
Reference isolate	
Quarantine regulations	
Remarks	
cDNA and gDNA Libraries	**cDNA and gDNA Libraries, MDS = RDS**
Minimum Data Set (MDS)	
Library Name	
Organism	
Type (cDNA or gDNA)	
Vector	
Insert Size	
Library Coverage	

Table 3. Quality control procedures recommended for micro-organisms upon receipt

Micro-organism	Viability	Purity	Identity	Stability
Plasmids	Confirm presence by growing the host/plasmid combination on appropriate selective medium.	Check the texture, the size and the opacity of the colonies grown on selective medium. Check also for homogeneity of the colonies and for absence of contaminants.	Check plasmid length by determination of the molecular weight of the covalently closed circle (ccc) DNA or by analysis of the restriction site pattern.	Confirm presence by growing the host/plasmid combination on appropriate selective medium. Confirm presence by PCR for cryptic plasmid.
Yeasts and Filamentous fungi	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic) and physiological features, where appropriate use biochemical features and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
Bacteria	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.
Cyanobacteria	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium or specific contaminant medium.	Identify to genus level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.

Table 3. Quality control procedures recommended for micro-organisms upon receipt

(*cont.*)

Archaea	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.
Viruses	Test infectivity to indicator hosts and propagation hosts.	Use electron microscopic observations.	Combine host reaction, electron microscopic observations and reaction with specific antisera. Where appropriate, use molecular tools.	
Phages	Test infectivity to indicator propagation host.	Test plaque morphology, use electron microscopic observations, test host spectrum.	Test plaque morphology, use electron microscopic observations, test host spectrum.	Test phage titre (pfu/mL)
Microalgae	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macro- and microscopic) features and where appropriate use physiological and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
Protozoa	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium or specific contaminant medium.	Identify up to species level using morphological (macroscopic and microscopic), and/or where appropriate use biochemical features and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
DNA libraries			For DNA libraries, analysis of the restriction site patterns. For individual clones of ordered DNA libraries, identity done by sequencing.	

Table 4. Recommended preservation methods and distribution forms

	Preservation	Distribution forms	Useful information
Plasmids	Two of the following methods : Cryopreservation of the H/P below -70°C. Cryopreservation of the H/P in LN_2. Freeze-drying of the H/P. Preservation of the plasmid DNA (preferably precipitated under ethanol) can also be applied as a preservation method.	Actively growing H/P on agar slant Actively growing H/P in liquid medium Cryopreserved H/P in dry ice Freeze-dried H/P Pure DNA	Plasmids containing genes that may tend to destabilise the physical and/or functional integrity (either by insertion, deletion or point mutation) shall preferably be deposited, maintained, tested and delivered as pure DNA.
Yeasts and Filamentous fungi	Two of the following methods : Cryopreservation below –140°C is preferred Cryopreservation below –80°C is accepted Freeze-drying or L-drying of the strain Sporulating-strains shall be maintained by at least two of the four different preservation methods listed, one of which shall be cryopreservation or freeze drying Non-sporulating strains will be maintained under oil or water or freeze drying and cryopreservation.	Actively growing strain on agar slant Freeze-dried or L-dried material in vials sealed under vacuum or inert gas Cryopreserved material in dry ice. Suspensions in liquid Liquid suspension deposited on filter paper	-
Bacteria	Two of the following methods : <u>Cryopreservation</u> below -140°C is preferred in a freezer below -80°C is accepted <u>Drying:</u> L-drying Shelf-freeze-drying Vacuum drying Spin-freeze drying	Actively growing strain on agar slant Freeze-dried or L-dried material in sealed vials Cryopreserved material in dry ice	-

Table 4. Recommended preservation methods and distribution forms (*cont.*)

Cyanobacteria	Two of the following methods : L-drying Cryopreservation in or above liquid nitrogen, in ultra low temperature (below -140°C) or on agar slant Freeze drying Serial transfer (if long term preservation is not possible)	Actively growing strain on agar slant Actively growing strain on liquid medium Cryo-preserved material in dried ice Freeze-dried material in sealed vials	-
Archaea	Two of the following methods : Cryopreservation below -140°C is preferred below -80°C is accepted L-drying Freeze-drying	Actively growing strain Freeze-dried or L-dried material in sealed vials Cryopreserved material in dry ice	-
Viruses	Two of the following methods : Virus maintenance in situ LN2 Freeze-drying	Freeze-dried material in sealed vials Cryopreserved material in dry ice	-
Phages	Two of the following methods: LN2 L-drying on filter paper in glass ampoule Storage of aliquots at -4°C	LN2-aliquots at ambient temperature or in dry ice Freeze-dried material is sealed ampoule Liquid aliquot (refrigerator)	-
Microalgae	Two of the following methods : Sterile liquid medium Sterile semi-solid medium (agar, alginate beads) Cryopreservation below –140°C	Actively growing in liquid/semi-solid medium Cryopreserved material in dry ice	-
Protozoa	Cryopreservation in or above liquid nitrogen below –140°C	Actively growing strain on liquid medium, or in animal biological liquid. Cryopreserved material in dry ice	-
DNA libraries	Two of the following methods: Cryopreservation of the H/P below -70°C Cryopreservation of the H/P in LN2 Freeze-drying or L-drying Preservation of the DNA precipitated under ethanol	Pure DNA Actively growing H/P Cryopreserved H/P in dry ice Freeze-dried H/P	-

H/P = host/plasmid combination; LN_2 = liquid nitrogen

Table 5. Summary of key elements of national and international regulatory controls related to micro-organism domain mBRCs

Action	Requirement	Law, Regulation, Convention	Further information
Collecting in the field	Prior Informed consent from a recognised authority	Convention on Biological Diversity	http://www.biodiv.org
	Mutually agreed terms on use	Convention on Biological Diversity	http://www.biodiv.org
	Consent from the land owner	Property law	
Import	Non-indigenous plant pathogens require licenses from country authority	Quarantine regulations	
	Human, animal and plant pathogens can often only be imported to specified laboratories	Health and Safety	
Handling: Manipulation; Growth	Containment dependent on hazard	Control of Biological Agents - Health and Safety EC Directive 2000/54/EEC on Biological Agents	http://www.brad.ac.uk/acad/sbtwc/btwc/nat_imp/leg_reg/uk/ec_com_2000_54.pdf#search='EC%20Directive%202000/54/EEC%20on%20Biological%20Agents
Genetic manipulation	Containment of manipulated organisms	Council Directive 98/81/EC from October 26th amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/protocol.asp http://www.biosafety.be/GB/Dir.Eur.GB/Cont.Use/90.219/TC.html http://www.biosafety.be/GB/Dir.Eur.GB/Cont.Use/98_81/98_81_TC.html
Deposit as part of a patent process	Long-term storage and compliance with the Budapest Treaty	Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures	http://www.wipo.int/treaties/en/registration/budapest/

Table 5. Summary of key elements of national and international regulatory controls posting to micro-organism domain mBRCs(*cont.*)

Storage	Appropriate containment	Health and Safety Licence to hold pathogens Security	
Export to another country	Some plant and animal pathogens require export licences	Quarantine regulations	
	Dangerous organisms with potential for dual use	Export Licences for dangerous organisms, Biological and Toxin Weapons Convention (BTWC)	http://binas.unido.org/binas/regs.php http://www.opbw.org/convention/documents/btwctext.pdf http://www.dfat.gov.au/isecurity/pd/pd_4_96/pd9.html
Distribution	Packaging and transport considerations	IATA Dangerous Goods Regulations (DGR), Universal Postal Union (UPU) United Nations Committee of Experts on the Transport of dangerous goods	http://www.iata.org/cargo/dg/dgr.htm http://www.upu.int/ http://www.unece.org/trans/danger/danger.htm
	Sovereign rights over the strains	Convention on Biological Diversity	http://www.biodiv.org
	Access and benefit sharing	Bonn Guidelines	http://www.biodiv.org
	Intellectual Property Right	Patent Cooperation Treaty (PCT) The Budapest Treaty (BT)	http://www.wipo.int/treaties/en/registration/pct http://www.wipo.int/treaties/en/registration/budapest
	Customer licensed to receive organism	National regulations	
	Dangerous organisms	EU Council Regulation No 1334/2000 of the 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology	http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000R1334_do_001.pdf#search='EU%20Council%20Regulation%20No%201334%2F2000'

Annexe 2 OECD BEST PRACTICE GUIDELINES ON BIOSECURITY FOR BRCS

Introduction

Biological resources underpin all biological sciences research. They provide the source material for scientific investigation, leading to many of the discoveries on which biotechnology is founded. Providing for high quality maintenance and rapid low-cost exchange of biological resources and quality information on them is a key issue for efficient advancement of the biological sciences. Quality assurance and protocols followed by Biological Resource Centres (BRCs) meet this need.

BRCs espouse openness of information and the ability to exchange material quickly; they therefore need to provide certain safeguards that such material and information will not be misused for nefarious purposes. The prospect of bioterrorism generates the need to secure facilities that work with, store or transfer dangerous biological material to ensure that such materials are not susceptible to misuse for malevolent ends. Thus, to contribute most effectively to scientific and economic development, BRCs should not only promote scientific openness but also a sense of security. The two goals are equally important and should be balanced and should be mutually reinforcing.

To deliver such a balanced and mutually reinforcing effect the aim of biosecurity best practice guidelines for BRCs is to reduce the probability that dangerous biological material could be obtained by unauthorised persons and deployed to cause harm, without unduly hindering research or being financially burdensome. Such best practice guidelines should be clearly articulated and grounded in an understanding of the biological material and the operations of BRCs.

1. General Provisions

The biosecurity best practice guidelines stated herein provide a basis for establishing best practices to secure the maintenance and provision of biological materials held by BRCs. They are designed to be implemented in conjunction with the general operational guidelines for all BRCs and the applicable specific domain best practices for BRCs.

BRCs should implement these biosecurity best practice guidelines in a manner that does not conflict with obligations under national, local and/or international laws and regulations.

2. Scope

These biosecurity best practice guidelines are designed to apply to BRCs. They propose a framework for risk assessment of materials held within a BRC as well as a framework that sets out best practices for management of such risk.

The frameworks for risk assessment and risk management contained herein provide tangible tools for biosecurity. These are necessary but not sufficient to ensure biosecurity, however. Just as important will be a demonstrable culture of responsibility and awareness of security throughout a BRC. The assignment of an individual within a BRC who has, as part of his/ her responsibilities, the general oversight of procedures within a BRC to ensure biosecurity is essential to achieve best practice and will contribute towards the said culture of security. The management and staff of a BRC should also share a sense of responsibility for biosecurity and a BRC should be able to demonstrate that this is the case.

3. Definitions

The definitions in *General Best Practice Guidelines for all BRCs* apply with the additions below.

"Biosecurity": Institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by BRCs**.**

"Risk assessment": The process of identifying sources of potential harm associated with the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by BRCs, assessing the likelihood that such harm will occur and the consequences if that harm occurs

"Risk management": The process of weighing policy alternatives, considering risk assessment and other factors relevant for biosecurity, and selecting appropriate prevention and control actions**.**

"Security breach": A security breach is any violation of the biosecurity best practice guidelines where these are intended to be in place as best practices.

"Risk communication": The interactive exchange of information and opinions among personnel of the BRC and, where appropriate, other parties, concerning risk-related factors and risk perceptions.

4. Assessing biosecurity risks of biological material

BRCs should ensure that a detailed inventory of the different biological materials they hold is available.

BRCs should conduct a risk assessment of the biological materials in their inventories for the purpose of assigning such materials to biosecurity risk levels, which may be assigned as high, moderate, low or negligible (see Table 1). The level of biosecurity risk of biological material should be determined according to the best available information on its potential for malicious misuse (including economic consequences) as well as its virulence**.** Risk assessment should address the potential of biological materials, should they be obtained and misused by unauthorised persons, to cause harm to the health of humans, crops, livestock or infrastructure.

The provision of biosecurity should be regarded as a benefit to society at large. The burden of risk analysis should thus be shared collectively by BRCs and the broader science policy community. BRCs should engage in and together develop expert networks that can contribute to the provision of risk analysis.

BRCs should share their experience with other BRCs as regards the results of qualitative risk assessment and the reasons for assigning the biosecurity risk level of a particular biological material, and make all such documentation available to competent national authorities.

BRCs should determine a biological material's biosecurity risk level as a function of its potential for malicious misuse and its virulence. Establishing the biosecurity risk level of a particular material is instrumental to applying the Biosecurity Risk Management Practices in Section 6 below.

BRCs should assess potential for malicious misuse based on the following key factors:

Availability: the number of facilities that stock the biological material and their geographical distribution.

Amplification: the ease with which the biological material can be replicated, for example whether it can be grown in culture and its growth rate.

Skills and knowledge: the ubiquity or rarity of the skills and knowledge necessary to amplify and/or genetically modify the biological material.

Dispersal: the ease and effectiveness with which the biological material can be dispersed, such as by air, water, food or by other means into the environment. This might include (but not be limited to) a biological material's aerosolisation and inhalation characteristics.

Environmental viability: the hardiness of the biological material across a range of temperatures, humidity levels, light exposures.

Countermeasures: the existence of and ease of access to prophylaxis, post-exposure treatments and detection and decontamination measures.

Economic consequence: the extent to which the biological material may be used to bring about harmful economic consequences for humans, crops, livestock or infrastructure.

BRCs should assess virulence based on the following key factors:

Infective dose: the smallest quantity of the biological material necessary to cause infection.

Pathogenicity: the disease-causing ability of the biological material.

Lethality: the ability of the biological material to cause death to the host.

Transmissibility: the ease with which the biological material can spread either by vector to host, or host to host.

In addition to the key risk factors set out above, other factors could materially affect the assessment of a biological material's potential for malicious misuse as well as its virulence. Where such factors are known it is the responsibility of the BRC to ensure that due account is taken of them in determining the overall biosecurity risk level of a biological material.

It is important to remember that in some cases, one risk factor may be so significant that it may determine the overall risk rating for a particular biological material. Thus, BRCs should carry out risk assessment in such a manner that risk factors are weighed.

In conducting risk assessment, if there is doubt as to whether a particular factor of a biological material should be characterised as high, moderate, low or negligible, BRCs should consider assigning that factor to the higher of the two possible levels. This need not imply that the overall biosecurity risk level for biological material is deemed higher.

BRCs, with the broader scientific community, should take steps, as a priority, to develop common methodologies for risk assessment and should seek to develop quantitative and qualitative tools and assessments that assist in completing appropriate and comparable risk assessment. For example, they may conduct statistical analysis for the purpose of establishing average biosecurity risk levels for the same type of biological materials, and to signal conflicting biosecurity risk levels, in different BRCs. Reporting will also allow the establishment of a data base that BRCs may use as a reference. Such an approach will permit the harmonisation of data generation, and thus lead to an increasingly harmonized framework of risk assessment and risk management amongst BRCs. In developing common tools and methodologies, BRCs, with the broader scientific community, should be sure to draw on appropriate existing – including international – tools and methodologies. For example some list-based approaches currently used to assign risk may be deemed as useful inputs to risk assessment for the purpose of biosecurity.

5. New acquisitions/re-assessment of inventory

BRCs should make biosecurity risk assessment, as described in Section 4, part of the acquisition process of new biological material.

When being transferred between BRCs, a summary of a biological material's risk assessment should be made available to the recipient BRC. A new risk assessment should only be conducted if, after reviewing the summary, there appears to be new circumstances or information that affects the original assessment; in such case, the procedure for risk assessment set-out in Section 4 should be followed.

BRCs should re-assess the biosecurity risk level of materials for which there is new information about their virulence or potential for malicious misuse.

6. Biosecurity risk management practices

BRCs should implement the biosecurity management practices contained in sections 6.1-6.9 below in a graded manner to reflect the level of biosecurity risk of biological materials.

Risk management applies to biological material at all times, including the receipt, storage, use, transfer and disposal of materials.

BRCs should establish a timetable for internal audits to check for the level of compliance with the risk management practices. These evaluations should conform to the rolling audit and review programme as described in the document *General Best Practice Guidelines for all BRCs* Section 13.3.

BRCs should designate a biosecurity officer, at operational level within the BRC, whose responsibility it is to ensure internal compliance with the biosecurity best practice guidelines contained in this document.

6.1. Physical security of BRCs

BRCs should conduct all activities with biological material in an area that corresponds to the appropriate biosecurity risk level resulting from the application of the biosecurity risk assessment described in Section 4. A potential scheme of physical security levels is given in Table 1 below.

Table 1. Potential scheme of physical security applicable to biosecurity risk levels associated with the BRCs

Biosecurity risk level	Physical security
Negligible or Low	General security area
Moderate	Restricted area
High	High security area

BRCs should design (or adapt the design of existing construction of) their physical facility to reflect the requirements of sections 6.1.1-6.1.3 below. BRCs should supplement the general security area (6.1.1) by additional layers of physical security within the facility, if they possess biological material that presents a high or moderate biosecurity risk level. Biological material presenting a moderate biosecurity risk should be stored and worked with primarily in a restricted area (6.1.2), whereas biological material presenting a high biosecurity risk should be stored and worked with in a high security area (6.1.3).

6.1.1 General security area

BRCs should implement physical security measures that provide a general security barrier against theft and persons gaining unauthorised access to facilities and the material therein. The area enclosed by the general security barrier typically marks the physical boundary of the BRC. The general security barrier should be equipped with access controls, typically available to all staff at the facility. Access controls can be in the form of manual keys, electronic key-cards, presentation of staff ID badge to security guard etc. The general security area may or may not be equipped with a 24-hour intrusion detection system.

6.1.2 Restricted area

The restricted area is characterised by an additional layer of security and access controls through which only those staff authorised to have access to the materials held within may pass. Access to a restricted area requires an additional access item that is only available to individuals who are authorised to access the materials held within. The access item may be a manual key, key-card, electronic access code or a specific ID badge signalling that the individual has a different level of access than staff with access to the general security area only. Restricted areas should be enclosed on all sides within the general security area, *i.e.* the restricted area should not share a boundary with a public area. The restricted area should be equipped with a 24-hour intrusion detection system.

6.1.3 High security area

The high security area should be nested within a restricted area and should not under any circumstances share a physical boundary with the general security area. The high security area is characterised by an additional layer of security and access controls through which only those staff authorised to have access to the materials held within may pass. Access to the high security area requires an additional access item that is only available to individuals who are authorised to access the materials held within. The access item, key, key-card, electronic access code, specific ID badge should signal that the individual has a different level of access than staff with access to only the general or general and restricted areas. The high security area should be equipped with a 24-hour intrusion detection system.

The construction of restricted and high security areas should be such that any apertures (windows, ventilation shafts) that are sufficiently large for a person to gain entry through are secured to prevent this. Emergency exit doors should be releasable only from the inside, unless prevailing safety codes provide otherwise.

BRCs should maintain equipment/facility maintenance logs of the security areas, including names and affiliation of maintenance personnel.

6.2. Security management of personnel

The BRC manager should ensure that attentive management practices in the supervision of staff are the norm.

BRCs should institute security screening, in line with national privacy law, and set in place best practice guidelines describing how decisions on appointments (or granting existing staff a higher access level) should be taken according to the nature of the facts that emerge about the individual. Background checks of staff whose duties require them to have access to material that presents a high or moderate biosecurity risk should be conducted prior to the granting of access to such biological materials.

All staff should be issued with an identification token, preferably equipped with a photograph of its issued holder, and providing information as to their level of access. Identification tokens should be worn at all times except in circumstances where doing so would present a health and safety risk (when wearing a biohazard suit for example). Identification tokens should be surrendered upon termination of employment at the BRC. BRCs should keep records of current and former employees, while paying due respect to their privacy.

6.3. Security management of visitors

BRCs should establish a system of security controls for visitors.

A BRC's system of security controls should include a list of the types of visitors that it allows to enter its facility and classifies whether the visitor should be escorted or unescorted.

Unescorted visitors should be subject to the same security management procedures as BRC personnel (see section 6.2). Alternatively the facility may choose to accept the security clearance conferred on the visitor by a government agency, or other appropriate body, provided that security clearance is current.

In general, escorted visitors should not have access to restricted or high security areas.

BRCs should maintain visitor logs, ensure that visitors do not enter the facility with prohibited items, and issue visitors with a colour coded badge (or equivalent means) according to the level of biosecurity risk to which they have access. Badges should either automatically expire when the visitor leaves, or be taken from the visitor on exiting. Appropriate visitor-to-escort ratios should be established for different security areas (for tours within the general security area 10:1 or higher may be appropriate, whereas escorting maintenance staff within the high security area may require a 1:1 ratio).

Permission to visit the facility should be granted by the manager of the BRC or a designee. Decisions on visits to restricted and high security areas should be taken in consultation with the biosecurity officer (where such an individual is distinct from the manager of the BRC). Only those personnel that have the appropriate level of access should escort visitors within restricted and high security areas.

6.4. Incident response plan

BRCs should devise and adopt an incident response plan, which sets forth a protocol to be followed by BRC staff for recording, reporting and investigating security breaches. Guided by applicable laws, BRCs should determine how to report investigations of security breaches.

BRCs should ensure that every staff member (including non-technical staff) is fully notified of the incident response plan and trained in the actions they should take in the event of a security breach.

The incident response plan should indicate the reporting requirements in case of a security breach. BRCs should alert the responsible national authorities if a security breach involves biological material with a high or moderate biosecurity risk level, and be prepared to communicate information on associated risks to the local community if so requested by competent national authorities.

For security breaches involving biological material with a high or moderate biosecurity risk level, the incident response plan should identify the internal staff and external national authorities to whom the security breach is to be reported, in what order, and any other actions they need to take. These actions should include immediately instigating appropriate biosafety measures to reduce any health and safety risks to laboratory staff and the local community arising from the breach, and in

as far as it is safe to do so, avoid disturbing the scene of the breach and any evidence until authorities arrive.

The incident response plan should identify individuals responsible for retrieving and compiling information that may assist investigating authorities, including where relevant, a list of people who have legitimate access to the material, the biosecurity risk level assigned to the biological material or data compromised (*e.g.* infective dose, pathogenicity, lethality, transmissibility, environmental viability, availability of therapeutic agents) and the inventory of requests received for the material.

6.5. Staff training and developing a biosecurity-conscious culture

BRCs should devise and implement a biosecurity training course to instruct relevant staff (both technical and non-technical staff) in the biosecurity procedures of the facility. The training course should explain to staff the key elements of the Risk Management Practices and ensure that staff are aware of their responsibilities and the procedures that should be followed during the course of their work. The course should give staff specific instruction on what constitutes a breach of security procedures and if appropriate, provide information about disciplinary sanctions that will be applied if a staff member deviates from the BRC's biosecurity policy.

In particular, the course should instruct on the Incident Response Plan, ensuring that all staff are fully aware of the actions they should take if they detect a security breach, or witness activity that they deem suspicious on security grounds.

The biosecurity training course should comprise one element of the general orientation course that new staff typically undergo.

Appropriate risk communication and the creation of a biosecurity-conscious culture in the community are important elements in establishing biosecurity. In addition to undertaking sufficient biosecurity measures, a BRC should conduct its activities in a transparent manner and strive to build trust in its relations with the local community

6.6. Material control and accountability

BRCs should establish a system of material control and accountability, which includes conducting and maintaining inventories of biological materials in their collections and identifies individuals who have access to or custody of biological materials at any point in time.

The system should provide accurate knowledge of what biological materials exist in a BRC, where those materials are, and who has access to them or custody of them at any given time. Material control and accountability applies to all biological materials held by BRCs, including those with only negligible or low biosecurity risk associated with them. Individual vials need not be counted except in the case of high biosecurity risk level materials.

6.7. Supply of material

BRCs may grant requests from facilities that seek to acquire, use and maintain biological material that presents a negligible or low risk, subject to national legislation.

Biological material that presents a moderate or high biosecurity risk should only be transferred to facilities that ensure biosafety and biosecurity measures appropriate to handle such material are in place.

BRCs should document all acquisition requests in particular for high and moderate biosecurity risk level materials, including requests refused and the reason for refusal. BRCs should be able to

provide competent national authorities with a record of all acquisition requests for such materials whether the request was accepted or declined, if requested by such national authorities.

In order to bring to light in a timely manner that biological materials have been lost or diverted during transport, BRCs should condition dispatch of biological material with a high or moderate biosecurity risk level upon agreement of the receiving party to provide notice of successful receipt in their as agreed timeframe.

6.8. Transport security

BRCs should institute procedures that secure material during packaging and transport to reduce the risk of theft.

Internal and external transfers of biological material that present a negligible or low biosecurity risk do not require any additional security measures other than those required by national or regional/international regulations.

6.8.1 Internal transport

Biological material that poses a high biosecurity risk should neither be left unattended nor temporarily stored outside the high security area.

BRCs should employ a strict chain of custody approach to the internal transfer of biological material that presents a moderate or high biosecurity risk and movement from one high security or restricted area, via a restricted or general security area, to another high security or restricted area.

This procedure should aim to be as minimally burdensome as possible while allowing subsequent analysis of the transactions and transfers made within the scope of the preceding paragraph.

6.8.2 External transport

BRCs should follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances to ensure safe and secure packaging and transportation of biological material.

Biological material exempt from the WHO guidelines (non-infectious micro-organisms allocated to Risk Group1) may be sent by (air) mail or other means of transport according to the Universal Postal Union (UPU) requirements.

BRCs should follow the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) and other applicable regulations, including those for road transport, to ensure that all requirements for packaging and shipping dangerous goods on ground and air are met.

BRCs should ensure that staff responsible for the distribution of biological material have the necessary knowledge and training to comply with applicable national and regional/international laws and regulations. Staff responsible for the distribution of dangerous goods (including infectious substances) via air should have the shipper's training certificate as required by IATA.

6.9. Security of information

BRCs should undertake an information risk assessment, to determine what information presents a biosecurity risk and take steps to protect information that could reasonably be used to facilitate the theft of high or moderate biosecurity risk material (*e.g.* access codes).

6.9.1 Information that relates to access to materials

Information that could reasonably be used to facilitate the loss or theft of biological materials with a high or moderate biosecurity risk level should be protected by proportionate measures to ensure the security of this information. The information should be secured against unauthorised access by appropriate physical and/or electronic means (depending on the format in which the information is stored and the resources available to the BRC).

Access to information pertaining to biological materials associated with high or moderate biosecurity risk levels should be granted on a need-to-know basis, and granted only to those individuals with security clearance to access material at the same biosecurity level as the information sought. For example, individuals with clearance to access moderate biosecurity level material should be able to access (if necessary) information up to that security level, but not above.

6.9.2 Information that relates to the collection

BRCs should develop a policy to guide them in deciding what kinds of information relating to the collection should purposefully be withheld from entering the public domain.

The BRC staff should be aware that their repository of knowledge could present a security risk. BRCs may choose to address this issue through encouraging staff to adopt a code of conduct specific to biosecurity.

NOTES

These notes are to be read jointly with their corresponding sections found in the biosecurity best practice guidelines.

Scope

BRCs distinguish between biosecurity and biosafety measures. Biosafety entails the use of containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. Biosecurity is intended to deter or detect the loss or theft of dangerous biological materials for illicit or malicious purposes. These biosecurity best practice guidelines focus on preventing unauthorised access to dangerous biological materials in BRCs. They are not intended to address biosecurity in other types of facilities, nor do they address specific measures related to crisis management in the event of a security breach.

Biosecurity risk management practices for BRCs

The biosecurity officer need not be a separate, full-time position; its functions may belong to the responsibilities of the BRC manager or another employee of the BRC.

6.1. Physical security of BRCs

The purpose of physical security measures is to minimize opportunities for unauthorized entry into BRCs, and to prevent the unauthorized removal of materials from their facility. Physical security measures can be manual, such as locks on internal and external doors, freezers and storage cabinets, or electronic, such as electronic access and biometric access controls, or they can be based on manpower (private security guards). Intrusion detection sensors and cameras, although not physical barriers, can provide an instant alert in the case of a security breach. In exceptional circumstances biometric controls may be deemed appropriate.

6.3. Security management of visitors

BRCs possessing high or moderate biosecurity risk material should develop a policy addressing prohibited items for both staff and visitors and inform staff about what particular items are prohibited.

Although escorted visitors generally should not have access to restricted or high security areas, some circumstances (such as essential maintenance work) may require it.

6.4. Incident response plan

The severity of a security breach should be evaluated in accordance with risks that arise as a consequence of it. For example, a missing link in the documented chain of custody should be considered a less severe security breach than unauthorized entry into the facility or misappropriation of biological material.

6.5. Staff training and developing a biosecurity-conscious culture

BRCs should seek to raise awareness of the need to secure biological materials against their unauthorised acquisition and misuse by holding seminars, information campaigns and other activities as they consider appropriate to the nature of the facility and the tasks performed by their staff. An important component of developing a biosecurity-conscious culture is the development of a code of conduct by staff.

6.7. Supply of material

It is incumbent on the requesting facility, not the BRC, to prove to the BRCs satisfaction that it has put in place biosafety and biosecurity measures appropriate to handle high and moderate biosecurity risk level materials.

6.8.2 External security

The WHO Guidelines may be found at the following web link:
http://whqlibdoc.who.int/hq/1997/WHO_EMC_97.3.pdf.

The International Postal Union requirements may be found at the following web link:
http://ibis.ib.upu.org.

The IATA regulations can be found at the following web link: http://www.IATA.org/cargo/dg.

An example of transport regulations is the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR regulations). The ADR regulations can be found at the following web link: http://www.unece.org/trans/danger/publi/adr/ADRagree_e.pdf.

6.9.1 Information that relates to access to materials

This includes information pertaining to the facility (physical plans detailing the layout of the facility and the location of the master control of electrical and communication services that are essential for keeping security barriers in place), personal information on employees that could be used for blackmail, sensitive documentation such as a review that points to weaknesses in a facility's security programme, and information that could potentially assist in gaining unauthorised access to biological materials and inventories.

The key question in conducting the information risk assessment is whether possessing the information would permit the holder to severely compromise the health of humans, crops, livestock or infrastructure.

6.9.2 Information that relates to the collection

Information that relates to the collection includes detailed information on organisms, such as that relating to environmental hardiness, aerosolisation, cultivation method, sequence data *etc.* Such information, in particular that relating to organisms that present a high or moderate biosecurity risk, can present a security risk itself.

In deciding what information relates to the collection, BRCs may be guided by the Journal Editors' Statement on Scientific Publication, see: *Security Journal Editors and Authors Group, Proceedings of the National Academy of Sciences* (PNAS), February 18, 2003, Vol. 110, No. 4, pp. 1464.

A source for various laboratory biosecurity codes of conduct can be found at the following web link: http://www.biosecuritycodes.org/.

Significance of this deliverable

This deliverable could be the first step of a norm for the management of BRCs. It has the advantage to have been written by scientists in charge of collections and so it fits quite well with the routine work of a collection.