

OECD GLOBAL FORUM ON KNOWLEDGE ECONOMY:  
BIOTECHNOLOGY

**GUIDANCE FOR THE OPERATION OF  
BIOLOGICAL RESEARCH CENTRES (BRCs)**

PART 1:  
GENERAL REQUIREMENTS FOR ALL BRCs



ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

## ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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## **GUIDANCE FOR THE OPERATION OF BIOLOGICAL RESOURCE CENTRES (BRCs)**

### **PART 1: GENERAL REQUIREMENTS FOR THE OPERATION OF BIOLOGICAL RESOURCE CENTRES**

#### **Committees responsible**

The OECD Task Force on Biological Resource Centres and partners in the EU project (QLRT-2000-00221) European Biological Resource Centres Network prepared this guidance in consultation with:

- Common Access to Biological Resources and Information (CABRI) Technical Committee.
- World Federation for Culture Collections (WFCC).

Compliance with this guidance is mandatory for all BRCs that are part of the global Biological Resource Centres Network.

#### **Foreword**

This guidance provides the basis for best practice in the management of Biological Resource Centres and all laboratories maintaining replicable biological materials. It draws together the key principles and best practice of quality management systems and operational guidelines prescribed by individual national public service collections and national, regional and world culture collection organisations. The initial input was provided from the Common Access to Biological Resources and Information (CABRI) Guidelines and the UK National Culture Collection (UKNCC) Quality Management System. It has been adapted to meet the needs of the user community.

This document provides specific guidance on the operation of Biological Resource Centres (BRCs) as defined by the OECD (2001) “*Biological Resource Centres: Underpinning the Future of Life Science and Biotechnology*” for both assessors and producers preparing for certification as a BRC. The guidance provided herein is intended to be used to supplement agreed authoritative international operating standards for the competence of laboratories. In case of dispute, appointed independent BRC certification bodies will adjudicate on unresolved matters. The appropriate international operating standards to be referred to will be decided at a later date.

Guidance for the operation of BRCs is presented at two levels. Compliance with all relevant guidance is mandatory for BRCs that are part of the Global Biological Resource Centre Network. General criteria for the operation of all Biological Resource Centres are described in this document: *Guidance for the Operation of Biological Resource Centres (BRCs): Part I: General Requirements for all BRCs*.

- Part 2. Guidance for the operation of Biological Resource Centres: Micro-organism domain.
- Part 3. Guidance for the operation of Biological Resource Centres: Animal cell domain.
- Part 4. Guidance for the operation of Biological Resource Centres: Human cell domain.
- Part 5. Guidance for the operation of Biological Resource Centres: Plant cell domain.

# Part 1. General requirements for all Biological Resource Centres

## 1. Introduction

**1.1.** 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 should be maintained without change to ensure reproducibility and sustainability.

**1.2.** 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 certification must hold data that is directly linked to biological materials held in a certified Biological Resource Centre (BRC).

**1.3.** It is the policy of BRCs to provide their users on every occasion with the products and services they require. These products and services should 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.

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

## 2. Scope

**2.1.** This guidance gives general instructions for the acquisition, maintenance and provision of biological materials and on the management of Biological Resource Centres as defined by the OECD (see definition below, section 3.2).

**2.2.** The purpose of this guidance is to help ensure that biological materials are of the highest standard and authentic. The preservation techniques used should 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.

**2.3.** The guidance is divided into parts. Part 1 *General Requirements for all BRCs*, which are normative for all candidate BRCs. Subsequent parts provide domain specific criteria *e.g.* Part 2. *Guidance for Micro-organism Domain Biological Resource Centres* which are normative and implemented according to the type of biological material provided by the BRC.

### **3. Definitions**

#### **3.1. Biological materials**

The term ‘Biological material’ as used in this document covers all materials listed in the Organisation for Economic Co-operation and Development (OECD) definition of BRCs given below.

#### **3.2. 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.”

#### **3.3. 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 guidance (parts 2-5 listed in the foreword above) for BRCs.

### **4. Organisational requirements**

The candidate BRC must meet the OECD definition and be compliant with appropriate national law, regulations and policies. The application for certification must describe and document the nature of the biological resources being held and for which certification is being sought. It must define the biological domain and therefore the domain specific criteria that apply *e.g.* micro-organisms, animal, plant or human materials.

#### **4.1. Long-term sustainability**

**4.1.1.** The BRC must provide evidence of a strategy for its long-term sustainability. Adequate and reliable sources of funding vary from government support, income from services and private support.

**4.1.2.** The BRC must have commitment from its owner or host organisation that should enable it to maintain its role in the acquisition, maintenance and provision of biological materials. If its future is threatened, the BRC must have a plan to ensure that its key holdings remain available.

#### **4.2. Responsibilities of management**

**4.2.1.** Primary responsibility lies with the BRC manager who 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 must be available to all staff of the BRC and should particularly be made available to new staff, students and visitors.

**4.2.2.** The Senior Management of each individual BRC must ensure that appropriate resources are available for staff members to discharge its responsibility towards this policy. The BRC must 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 BRC on quality matters when dealing with users, suppliers and outside bodies.

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

### **4.3. Staff - qualifications and training**

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

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

**4.3.3.** Authorisation to use specialist equipment should be documented in training records. For example new staff should 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.

**4.3.4.** 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.

**4.3.5.** It is the responsibility of all staff to familiarise themselves with documented protocols and comply with the policies and procedures laid down in the BRC Standard Operating Procedures and associated documentation at all times. It is the management's responsibility to ensure that staff have access to Quality Manuals and that they are understood and kept informed of any amendments.

### **4.4. Hygiene**

**4.4.1.** All staff must follow the procedures laid down under the appropriate level of containment for the organisms being handled to avoid contaminating samples and risk of infection (details are provided in the Domain Specific Guidance for BRCs).

## 5. Premises

An environment must be provided that is conducive to handling authenticated materials appropriate to the organism domain and to 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 must be worn and safety procedures followed.

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

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

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

### 5.1. Biological Resource Centre operations

**5.1.1.** Appropriate areas are required for the specific operation of a BRC as appropriate to the domain of the biological materials. The activities that must 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.
- Supply, delivery/sales (kept separate from incoming accessions).
- Decontamination and cleaning of equipment and processing of wastes.
- Duplicate collection in a remote building or alternative site (as a measure to mitigate against risk of disaster).

**5.1.2.** 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.

**5.1.3.** Other areas associated with the BRC must be structurally sound, unobstructed, clean and free from laboratory materials.

### 5.2. Construction and operation

Construction must meet appropriate national regulations and policies e.g. to the containment level appropriate for the risk (hazard) group of the organisms worked with. If major building, renovation, repair or dirty work is necessary in BRC laboratories, activities must be suspended until the work is completed.

### **5.3. Access**

The minimal requirement is to restrict access to the BRC to authorised staff or those accompanied by them. BRCs housing dangerous biological materials must pay particular attention to security and where appropriate be fitted with security devices.

### **5.4. Maintenance and inspection**

Cleaning and decontamination procedures should be documented. Buildings must be cleaned on a regular basis. Cleaning of organism containment areas and specialist equipment should be performed by authorised and trained staff using appropriate personal protection equipment following documented procedures.

### **5.5. Outside support services and supplies**

Any support services used by the BRC must be of adequate quality to sustain confidence in its activities. Supplies should be sought from reputable companies with, where possible, proven quality of products. Preference should be given to services and supplies covered by certification schemes. Where no independent assurance of quality of support services is available, the BRC must be responsible for confirming the quality of vital supplies. Copies of purchase orders should be held on file and records of suppliers, standing orders etc. should 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 must be laid down in a predefined schedule. Instructions for these activities should be laid down in the manufacturer's handbooks/manuals or in the BRC procedure. Service records should be maintained and copies of key documents should be held in the BRC Equipment Maintenance and Calibration Log books in the care of the Quality Manager.

## **7. Documentation management**

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

### **7.1. Compliance with internal documentation**

All staff must adhere to the prescribed policies and procedures. Any departures from documented procedures must be agreed by senior management prior to deviation. Written permission and justification must 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 must be investigated, rectified and retraining implemented if necessary.

## 8. Informatics

**8.1.** The BRC must make data available describing the biological material and its origin to the Global Biological Resource Centre Network (GBRCN). The BRC must store data and produce electronic catalogues based on authenticated and validated information. Data should also be retained for traceability in compliance with relevant national laws, regulations and policies. Depositors are responsible for assuring the quality of data associated with the biological material. The BRC may require evidence to assure the validity of the data.

**8.2.** The authentication of data may differ from centre to centre, but a BRC should:

- Provide traceability of data through a history of modifications (dates and signatures of inputs, validations modifications and deletions).
- Ensure regular data back-up (daily if data input is large > 50 records) off-site storage of data is desirable.
- Give signature for data entry, validation, modification or deletion.
- Secure the access to the database using 'log-ins' and passwords.

**8.3.** The BRC must use a standard terminology and format for data exchange and a standard protocol for data transmission.

**8.4.** To keep consistency between BRCs for searching and retrieving of information from catalogues and databases:

- Each record should contain a minimum data set (see domain specific criteria).
- Spell checking for every field is a basic requirement.
- Vocabulary should be checked against standard reference lists.
- Language of data provided to the GBRCN: International English.

**8.5.** It is necessary to adopt a standardised approach to certain scientific symbols. To avoid any errors due to incorrect reading of a character set, standard ASCII alternatives to symbols should be used. Examples include:

- Greek letters cannot be used, they should 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 cm<sup>3</sup> and CO2 replaces CO<sub>2</sub>).

### 8.6. Internet publication and data protection

**8.6.1.** National data protection regulations shall be adhered to. Where BRC data are made available online or on disk only selected fields containing non-confidential information should be presented. Files are stored in secure cabinets.

**8.6.2.** The BRC shall respect a defined update frequency for data publication on the Internet through the GBRCN.

## **8.7. Retention**

**8.7.1.** User records must remain available for a minimum of five years and must be archived. BRC database records must be retained as long as a strain remains viable. On the loss of a strain the database record should 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.

## **9. Preparation of media and reagents**

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

**9.2.** Supplies of materials for use must be of high standard and must not be contaminated.

## **10. Accession of deposits to the BRC**

### **10.1. Receipt and handling of biological materials**

**10.1.1.** The BRC must document and implement procedures for the receipt and storage appropriate to the type of biological materials handled.

**10.1.2.** A risk assessment should be carried out on the biological material to be held to determine, as far as possible, the potential of harm to personnel, the public and the environment. The risk assessment must be reviewed and updated regularly.

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

### **10.2. Accession**

**10.2.1.** The BRC must 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 should balance capability, capacity with scientific and user's needs.

**10.2.2.** BRCs must only accept deposits of biological material that meet its acquisition criteria and fall into the groups of its specialist expertise.

**10.2.3.** The biological material received must 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).
- d. Geographical origin of isolation (the minimum requirement is the country of origin or the furnisher of the source, substrate or host).
- e. Depositor's strain number or other collection number(s), if deposited elsewhere.
- f. Cell preservation or storage conditions where known.
- g. Hazard information *e.g.* in the form of a safety data sheet.

**10.2.4.** The BRC must assign a unique collection number to the biological material and must, where necessary, complete the information under 10.2.3 f and g.

### **10.3. Quality checks on the biological material**

**10.3.1.** The BRC must 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 must be recorded. These records should be retained and can be used as a base line when in-storage maintenance checks are performed or for validation after preservation restocking.

**10.3.2.** Where possible the identity of the biological material should be confirmed after receipt by a specialist (employed or contracted by the BRC or its parental organisation). The biological material should be checked again by these experts before (if there are additional transfers of the biological material before it is preserved) and after preservation. This step should include an additional identity check performed by the depositor.

**10.3.3.** A "maintenance plan" (*i.e.* a scheme for periodic control of the preserved material) should 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 should be appropriate to the biological material and be laid down in the domain specific criteria.

**10.3.4.** See domain specific recommendations for specific details of quality controls.

## **11. Preservation and maintenance**

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

### **11.1. Methodology**

**11.1.1.** The biological material must be preserved by at least two methods (where two distinct methods are not applicable to the biological material, cryopreserved stocks should be maintained in separate locations) and as master cell banks and as stocks for distribution. The details of the preservation techniques are laid down in the domain specific criteria.

**11.1.2.** The labels must include at least the batch date or number and the BRC accession number. Where possible an indication of expiry date should be provided to the user of the biological material. Biological materials with specific hazards must be clearly differentiated.

## **11.2. Stock control of the preserved biological materials**

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

**11.2.2.** The BRC must produce the master stock from the original biological material. This master stock must be used to generate the distribution stock. The BRC must use the distribution stock to supply biological materials.

**11.2.3.** The BRC should adapt the size of these master and distribution stocks to the anticipated distribution rate.

## **11.3. Storage of preserved biological materials**

**11.3.1.** The biological material must be stored under environmental parameters that assure the stability of its properties (see domain specific obligations).

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

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

## **11.4. Validation of methods and procedures**

**11.4.1.** The BRC must document all methods and procedures used in validation (see domain specific criteria).

**11.4.2.** The results of method and procedure validation must be recorded.

## **12. Supply**

### **12.1. Order placement**

**12.1.1.** BRCs must only supply biological materials for which they have been given the rights to distribute. They should only supply to users who have the appropriate facilities and meet the specific requirements for receipt as required by relevant national and international regulations and policies.

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

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

## **12.2. Availability of the biological material ordered**

**12.2.1.** If a biological material cannot be delivered within the specified delivery time, the BRC must contact the user with an estimated supply date. The BRC should recommend where possible other national or international BRCs to supply biological materials not held.

## **12.3. Information provided with the biological material supplied**

**12.3.1.** The BRC must 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. Examples of MTA content can be found as an annex to the Bonn Guidelines (<http://www.biodiv.org>) and as an output of the MOSAICC project (<http://www.belspo.be/bccm/mosaicc>) - both voluntary codes of practice.
- Fax-back sheet to acknowledge receipt of materials may be desirable.

## **12.4. Packaging**

**12.4.1.** The BRC must pack and send its biological material according to current postal, IATA and ADR regulations. It must also meet the additional requirements imposed by quarantine and/or biosecurity regulations.

## **12.5. Invoicing for supply charges if made**

**12.5.1.** Invoices should normally be despatched with the material unless otherwise instructed or where *proforma* invoices have been paid in advance.

## **12.6. Traceability of biological materials supplied**

**12.6.1.** The BRC must 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 should be maintained. The records must be maintained to meet national law, regulations and policies.

## **12.7. Handling complaints and anomalies**

**12.7.1.** The BRC must record all user queries or complaints and where possible acknowledge by return of post or on the same day by fax, telephone or e-mail.

**12.7.2.** The BRC should investigate the complaints as soon as received and implement the necessary corrective actions. All complaints should be included in regular trend analysis.

**12.7.3.** Records of responses/solutions should be stored.

## **12.8. Refunds**

**12.8.1.** 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 should be given.

## **12.9. Confidentiality**

**12.9.1.** All work carried out for a client is treated as strictly confidential to that client unless national requirements apply. This applies 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 BRC activities in a way that the customer is not identified.

**12.9.2.** The names of past or present clients are only revealed with the clear permission of the client.

## **13. Quality audit and quality review**

### **13.1. Purpose**

**13.1.1.** Periodic audits must be carried out by management to ensure that the BRC policies and procedures, as set out in this guidance and the supplemental domain specific guidance, are being followed. External, independent audits must be carried out. A process must be in place to identify any potential source of non-conformity to BRC guidance.

### **13.2. Responsibility**

**13.2.1.** The BRC manager or a delegate, assisted by BRC staff if necessary, must carry out an assessment of the effectiveness of procedures and organise the audit programme (see section 12.3).

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

### **13.3. Implementation**

**13.3.1.** Staff of the BRC must undertake at least one full audit each year, which should include a strain deposit trail through to storage and a supply trail from receipt of order to supply. These should be chosen at random. The Day Work Books, Enquiry records and database records should also be reviewed. The results of the audit and record reviews must be recorded and any fault rectified.

**13.3.2.** An external independent qualified person must carry out an audit of the procedures, preferably each year. This too should include a biological material deposit trail through to storage and a supply trail from receipt of order to supply. These should be chosen at random. The Day Work Books, Enquiry records and database records should also be reviewed.

**13.3.3.** The external audit should also include a review of documented procedures ensuring that the procedures referred to are in place and are carried out as prescribed. The results of the audit and record reviews must be recorded and any fault rectified.

**13.3.4.** A meeting of all audit staff, BRC staff and line management must 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 must be recorded and the Quality Manager is responsible for implementation of actions prescribed.

### **13.4. Method and procedure quality checks**

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

### **13.5. Rolling audit programme for internal audit**

**13.5.1.** The management must carry out a rolling audit and review programme supported by BRC staff. This entails the review of all BRC activities including documentation, supply, accession, database, training records, equipment and maintenance, enquiries and complaints records and external support services. This must be supported by an independent audit, a quality management system review meeting, a Quality Manual review and a review of the Documented Procedures all carried out to the schedule described in the Rolling Audit Programme.

## **14. Bibliography and useful information sources**

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

ISO 17025:1999 General requirements for the competence of testing and calibration laboratories.

ISO Guide 34: 2000(E) General requirements for the competence of reference material producers.

## **15. Useful web sites**

[www.cabri.org](http://www.cabri.org)  
[www.belspo.be/bccm/mosaicc](http://www.belspo.be/bccm/mosaicc)  
[www.ukncc.co.uk](http://www.ukncc.co.uk)  
[www.wfcc.info](http://www.wfcc.info)  
[www.biodiv.org](http://www.biodiv.org)