

**UNITED KINGDOM NATIONAL CULTURE  
COLLECTION**

**UKNCC**

**QUALITY MANUAL**

**UK NEW STRATEGY FOR MICROBIAL COLLECTIONS**

**1998**



**UNITED KINGDOM NATIONAL CULTURE COLLECTION**

# **UKNCC Quality Manual**

Compiled by David Smith  
CABI BIOSCIENCE UK Centre (Egham)  
Bakeham Lane, Egham, Surrey TW20 9TY

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1. All amendments are listed here following the insertion of the revised pages.
2. Additional pages must be inserted and listed here.
3. All Manual holders must incorporate new or amended documents immediately they receive them.

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## UKNCC Collections Quality Manual

CABI BIOSCIENCE UK Centre (Egham) formerly IMI

Culture collection for Algae and Protozoa (CCAP - Oban)

Culture collection for Algae and Protozoa (CCAP - Windermere)

European Collection of Cell Cultures (ECACC)

National Collection of Industrial and Marine Bacteria (NCIMB)

National Collection of Pathogenic Fungi (NCPF)

National Collection of Plant Pathogenic Bacteria (NCPFB)

National Collection of Type Cultures (NCTC)

National Collection of Wood Rotting Fungi (NCWRF)

National Collection of Yeast Cultures (NCYC)

This manual is issued under the authority of

Quality Manager \_\_\_\_\_

Copy Number.....  
Issued to.....  
Date of issue.....

The UK National Culture Collection incorporates the UK National Collections

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<b>QUALITY POLICY</b>	Issue date November 1998 Issued by D. Smith

## 1.1 UK National Culture Collection (UKNCC) Quality Policy Statement

1.1.1 It is the policy of the UKNCC Collection to endeavour to provide its clients on every occasion with the products and services which they require. The products and services supplied are of marketable quality and will fulfil product claims as defined in the individual member collection catalogues. At all times good techniques and procedures as defined in the individual collection's laboratory procedures manual or standard operating procedures will be in operation and regular audits carried out to ensure that these procedures are followed and are effective.

1.1.2 Primary responsibility lies with the Senior Management of each individual UKNCC Collection, who delegate responsibility for implementation of its policies to named and suitably qualified members of staff. The UKNCC collections either employ a recognised accreditation scheme e.g. ISO 9000 or follow the UKNCC Quality Management System.

1.1.3 The Senior Management of each individual Collection ensure that appropriate resources are available for staff members to discharge their responsibility towards this policy and appoints a Quality Manager, whose duties include:

- i. Establishing, administering and monitoring an efficient up-to-date quality management system.
- ii. Reporting and advising on quality matters.
- iii. Representing the Collection on quality matters when dealing with customers, suppliers and outside bodies.

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

1.1.4 It is the responsibility of all staff to familiarise themselves with the contents of the Quality Manual and comply with the policies and procedures laid down in it, the Laboratory Procedures Manual and associated documentation at all times.

Director of Collection

Signed.....

Date.....



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<b>QUALITY POLICY</b>	Issue date November 1998 Issued by D. Smith

## **1. Quality policy**

### **1.2 Responsible bodies recognising the UKNCC Quality Management System**

#### **OST**

- 1.2.1 The Office of Science and Technology (OST), the commissioning body of the Government Review and subsequent UK Strategy for Microbial Collections 1996-1999

#### **BBSRC**

- 1.2.2 The body appointed by the OST to administer the UK Strategy for Microbial Collections 1996-1999

#### **CCAG**

- 1.2.3 The Culture Collection Advisory Group (CCAG), the steering group appointed to advise the UKNCC on the implementation of the UK Strategy for Microbial Collections 1996-1999

### **UKNCC MEMBER COLLECTION OWNERS**

- 1.2.4 The UK National Culture Collection (UKNCC) owners have approved the principles laid down in the UKNCC Quality Management System and have endorsed appropriate quality management systems in the collections for which they have responsibility.

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<b>QUALITY MANAGEMENT SYSTEM</b>	Issue date November 1998 Issued by D. Smith

## 2. Quality Management System

### 2.1 Aims and Form of Quality Management System

- 2.1.1 The UKNCC Quality Management System draws together procedures of all its member collections to provide consistently reliable and reproducible products and services. Where recognised Quality Management Systems are in place, e.g. ISO 9000 and NAMAS Accreditation, these are followed by the individual collections. The UKNCC Quality Policy statement is an agreement between the collections to provide a unified quality service to its customers.
- 2.1.2 The Quality Manual together with the Laboratory Procedures Manual provide working documents to define the ways and means by which the UKNCC policy, outlined in the quality policy statement is achieved. They identify the organisation of the Collection and its structure and give procedures for quality audit and reviews. These documents and procedures maybe replaced by those of other accepted Quality Management Systems (see para. 2.1.1).

### 2.2 Quality Manual

- 2.2.1 The Quality Manager is responsible for the amendment of the Quality Manual to comply with the management structure and operation of the UKNCC member collection while its authorisation is the responsibility of the Senior Management.
- 2.2.2 The Quality Manual is distributed as required but a system must be in place to ensure all recipients receive updates as necessary.

### 2.3 Quality Management

- 2.3.1 The Quality Manager's responsibilities and authority are detailed in section 1.1.2. Where possible a deputy quality manager should be appointed to deputise in their absence. The Quality Manager has direct access to the Senior Management of the Collection on matters concerning quality.

### 2.4 Documentation

- 2.4.1 The Quality Manager is responsible for the control and maintenance of all documents relating to the quality of the Collection work. He/she is accountable to the Senior Management of Collection or other intermediary line management. Holders of copies of manuals (2.2.2) are responsible for their safekeeping and maintenance as specified by the Quality Manager.

To implement the UKNCC quality policy, three levels of documentation are employed, namely the Quality Manual, the Laboratory Procedures Manual OR Standard Operating procedures (SOPs) and laboratory records. The Quality Manual deals primarily with policy administration and management aspects. The Laboratory Procedures Manual is concerned with procedures and technical functions. A series of laboratory records are maintained by the collection, including laboratory books, these are specified in the individual UKNCC member collection Laboratory Procedures Manual.

The Quality Manager agrees and authorises Collection Laboratory Procedures that are made available through the Laboratory Procedures Manual.

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<b>QUALITY MANAGEMENT SYSTEM</b>	Issue date November 1998 Issued by D. Smith

2.4.2 Copies of procedures are made available to enquirers, course participants and staff through the Quality Manager who ensures all documentation is correctly updated. Alterations to any operating documents are not allowed unless agreed to or by the specific instructions of the Quality Manager. Amendment sheets are 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 or Tipp-Ex are not allowed. The alterations must be signed and dated.

The Quality Manager is responsible for issuing all amendments to the Quality Manual. Amendments are recorded in the Amendment section of this Manual.

- 2.4.3 All laboratory staff adhere to the laid down policies and procedures. Departures from documented procedures are not allowed unless senior management has first been consulted. Written permission and justification must then be included in the relevant records.
- 2.4.4 Where staff fail to follow laboratory procedures an assessment of the effect on work in hand is made and recorded. If failure has been brought about by a misunderstanding or misdirection the error is investigated, rectified and retraining implemented if necessary.

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<b>ORGANISATION AND MANAGEMENT</b>	Issue date November 1998 Issued by D. Smith

### 3. Organisation and Management

#### 3.1 Management

The Collection and level of parental organisation partner to the UKNCC is defined in the UKNCC Memorandum of Understanding (MOU) on Co-operation between Member Collections of the United Kingdom National Culture Collection (UKNCC). The organisational structure relevant to each collection is defined in the individual Collection's Laboratory Procedures Manual and covers:

- Organisation
- Company, parental or host organisation
- UKNCC Collection
- Commercial Structure
- Scope
- Organisational Charts
- Management - Senior Staff

#### 3.2 General Management

In the absence of senior staff their duties are undertaken by their designated deputies.

All staff are issued with a job description which details the limitations and extent of their responsibilities.

All procedures are carried out as laid down in the Laboratory Procedures Manual.

##### 3.2.1 Laboratory Environment

It is the responsibility of the organisation to provide an environment that is conducive to manufacture of products free from contamination and to accurate measurement and recording. It is the responsibility of the member of staff allocated to the task to check that the accommodation is clean and well lit and that usual aseptic techniques are followed. Only authorised staff may use specified equipment (see Laboratory Procedures Manual), the appropriate protective clothing should be worn and safety procedures followed.

##### 3.2.2 Accession of strains to the collection

Organisms for deposit meet the acquisition criteria of the Collection, fall into the groups agreed in the UKNCC MOU and have documentation providing isolation data, in particular the country of origin and identity or characterisation information. The collection will check against the dangerous pathogens list in *UKNCC controls on the distribution of dangerous organisms* before accepting a strain. The depositor must provide proof that prior informed consent to collect and deposit the strain in a collection had been obtained or reasonable efforts had been taken to do so. Conditions of deposit must be determined and agreed e.g. laid down in a materials transfer agreement to meet the Convention on Biological Diversity.

Organisms are received directly into a laboratory where a laid down procedure is followed to ascertain whether the organisms can be handled safely i.e. the appropriate containment level is in place (see Laboratory Procedures Manual). A unique accession number is allocated to the strain, which is never reassigned if the organism is later discarded.

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<b>ORGANISATION AND MANAGEMENT</b>	Issue date November 1998 Issued by D. Smith

The viability, purity, identity, growth requirements, and methods of maintenance and/or preservation of the strain are determined and the information recorded (as laid down in Laboratory Procedures Manual). These records are retained along with information on preservation and growth.

#### *Viability*

The culture is grown on the medium or host most suited, recorded on the accession record and in the Collection database. A check is made to ensure that the original growth characteristics have not altered.

#### *Purity*

Critical examination is carried out to ensure that the culture is not unintentionally mixed, by using the methods most suited for the organism and as laid down in the Laboratory Procedures Manual.

#### *Stability*

Pre- and post-preservation comparisons are made. Morphology, pathogenicity, assay properties, and biochemical properties are checked where appropriate. All observations are recorded and retained for future reference.

#### *Identity*

Where possible the identities of cultures are confirmed before or at deposit by a specialist. Strains are checked again by these experts before (if there are additional transfers of the organism before it is preserved) and after preservation and during maintenance procedures to ensure quality is maintained.

### **3.2.3 Preservation**

A selection of preservation methods for organisms being accessed into the Collection is made based on recommendations made by the depositor and/or on previous experience. The organism is preserved by at least two methods normally one is a long-term method either freeze-drying or cryopreservation below -140°C.

The technique for contract preservation is selected and agreed with the customer. A copy of the relevant Laboratory Procedure can be provided to the client, if requested, or a specific protocol designed by them agreed.

### **3.2.4 Stock Control of the Preserved Organisms**

Stocks of preserved organisms are replenished at different intervals dependent upon the preservation method used. Details of the inventory control, lead times and re-stocking practices are documented in the individual collection's Laboratory Procedures Manual.

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### 3.2.5 Supply

#### ***Order placement***

The Collection accepts fax and mail orders with an official customer order number and in the case of most non-pathogenic strains will also accept telephone and e-mail orders. The collection will check against the dangerous pathogens list in *UKNCC controls on the distribution of dangerous organisms* and observe the control measures in place. An order can only be accepted when the required accompanying documentation is provided.

#### ***Customer undertaking***

The customer must agree to operate within the spirit of the Convention of Biological Diversity and to follow any restricted distribution that may be required by control regulations.

#### ***Supply***

Turnover of freeze-dried material is, where practicable, within three working days if pertinent and necessary licenses and/or documentation are provided. Otherwise despatch is normally within three working days of receipt of the required documentation.

If a culture cannot be supplied as a freeze-dried sample within the three-day period the customer is contacted with an estimated supply date. If there is delay anticipated in supply the customer is contacted by telephone, fax or e-mail to ensure new deadlines are satisfactory. If the situation changes during recovery of the strain(s) the customer is informed.

#### ***Information provided with the organism supplied***

- Conditions for growth and media formula (when requested)
- Safety data sheet
- Instructions for opening ampoules or vials (when appropriate)

#### ***Packaging***

To meet the postal, IATA and quarantine regulations.  
Labelled 'to be opened in the laboratory' with appropriate customs declaration, biological hazard label and import permit where appropriate.

#### ***Invoicing***

Invoices are normally despatched with the strains unless otherwise instructed or where proforma invoices have been paid in advance.

#### ***Refunds***

All strains are checked for viability, purity and identity after preservation. Freeze-dried material may be sent directly from stock so long as it is within the storage period considered to be the normal shelf life for the microorganism. Despite rigorous quality control and standard procedures being followed it may be possible that the strain may fail to grow, may be contaminated or may not have the property stipulated in the order or that is reasonably expected of the organism on receipt. If the customer is not

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deemed at fault it is normal policy to provide the customer with a replacement culture where this is possible. If not a refund is given. Cultures from cryopreservation or other methods of storage are grown and viability, purity and identity are checked before despatch, if refunds are considered appropriate they are given.

***Concerns, comments and complaints regarding cultures supplied***

The Collection records all customer queries and where possible acknowledges by return of post or on the same day by fax, telephone or e-mail and investigates complaints as soon as received.

**3.2.6 Confidentiality**

All work carried out for a client is to be treated as strictly confidential to that client. This applies to all requests for strains, safe and patent deposits, preservation protocol design, preservation contracts and to the fact that the product or service was requested.

The names of past or present clients are only revealed where organisms are purchased from the open collection, they are never revealed in relation to other work or services, except with the clear permission of the client.

*Transmission of results*

When telephone, Fax or email reports are requested the identity of the caller or receiver must be first established by telephoning the client at their previously notified company address.

**3.3 Staff - Qualifications and Training**

- 3.3.1 It is the UKNCC Collection's policy to use only staff who are employed by, or under contract to, the Collection. Staff are engaged at all levels from school leavers to post doctoral but they are not allocated to any piece of work until their training appropriate to the job is completed.
- 3.3.2 Staff are trained in skills specific to the job and receive in-post training which is reviewed annually. Information on staff qualifications and training are held in training records and/or personal files.
- 3.3.3 Authorisation to use equipment etc. is documented with training records. New staff are not allowed to use autoclaves, freeze-drying equipment, cryopreservation facilities nor safety cabinets etc. until they have been trained in their use and then only under supervision until they are competent.
- 3.3.4 Training records are retained for all staff.

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<b>QUALITY AUDIT AND REVIEW</b>	Issue date November 1998 Issued by D. Smith

## **4. Quality Audit and Quality Review**

### **4.1 Purpose**

- 4.1.1 Periodic audits are carried out by management to ensure that the Collection policies and procedures, as set out in this manual, are being followed. All activities are audited at least once each year. Additionally one independent audit is carried out each year.

An annual review of the Quality Management System and laboratory procedures is carried out.

### **4.2 Responsibility**

- 4.2.1 The Quality Manager assisted by Collection staff, as necessary, carries out the assessment of the effectiveness of the laboratory procedures. An independent member of staff carries out an independent audit.
- 4.2.2 It is the responsibility of the Quality Manager to verify that all corrective actions required by audits have been completed, within the agreed time scale.
- 4.2.3 Through agreement with the Curator of Collection an independent member of staff of another UKNCC member collection carries out an annual audit of the Quality Management System and laboratory procedures.
- 4.2.4 The Quality Manager is responsible for ensuring that reviews are recorded and that any actions implemented.

### **4.3 Implementation**

The arrangements for the quality audit and Quality Management System review are detailed in Laboratory Procedures Manual.

### **4.4 Planning and documentation**

- 4.4.1 All audit records, reviews and implementation records are held by the Quality Manager.

### **4.5 Quality Control System**

In addition to audits and reviews, method and procedure quality checks, detailed in the Laboratory Procedures Manual, are carried out.



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<b>EQUIPMENT</b>	Issue date November 1998 Issued by D. Smith

## **5 Equipment**

### **5.1 Calibration, Testing and Maintenance of Equipment**

An inventory of all equipment is held and maintained. All major items of equipment are on maintenance contract and records are retained.

5.1.1 All equipment in the Collection is used and maintained in accordance with the instructions laid down in the manufacturer's handbooks/manuals.

5.1.2 Operating and maintenance instructions are normally displayed or held close to the equipment.

### **5.2 Authorisation for use**

5.2.1 All operators are fully trained in the use of equipment and records maintained in their personal training record.

### **5.3 Monitoring**

Any equipment suffering damage or that gives suspect results or malfunctions or is otherwise shown to be defective or unfit for use is immediately removed from service. The item is promptly labelled or marked and is not returned to service until it has been repaired, re-commissioned and revalidated as appropriate.

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<b>MEASUREMENT, TRACEABILITY AND CALIBRATION</b>	Issue date November 1998 Issued by D. Smith

## **6. Measurement, traceability and calibration**

### **6.1 Policy**

- 6.1.1 All measuring instruments and equipment are calibrated as necessary in order to provide traceability and reproducibility. The Quality Manager or his/her designate is responsible for establishing and implementation of the calibration programme (see Laboratory Procedures Manual).

Measurement devices forming an integral part of equipment or are fixtures are calibrated *in situ*. Measuring devices can also be calibrated by qualified service and calibration engineers off-site.

### **6.2 Calibration**

Instruments or equipment requiring calibration that are part of the Collection activities are identified in the relevant Laboratory Procedure. Responsibility for ensuring the necessary calibrations are carried out lies with the Quality Manager or his/her designate and records are retained.

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<b>METHODS AND PROCEDURES</b>	Issue date November 1998 Issued by D. Smith

## **7. Methods and Procedures**

### **7.1 Policy and scope**

- 7.1.1 All procedures used in the Collection are documented, see Laboratory Procedures Manual.

### **7.2 Availability**

Copies of the Laboratory Procedures Manual are held by the Quality Manager and other relevant Collection staff.

### **7.3 Documentation of Methods and Procedures**

- 7.3.1 The individual originating any new methods or procedures for use in the Collection is required to produce a draft copy, which must be approved, signed and issued by the Quality Manager. These methods must not be included in the Laboratory Procedures Manual until they have been validated and then approved by senior management.
- 7.3.2 Amendments to these methods must be approved by the Quality Manager and noted in the amendment section of the Laboratory Procedures Manual.
- 7.3.3 Any piece of work to be undertaken by the Collection that does not utilise already documented and validated procedures requires a clear statement of the work to be undertaken which is agreed by the client. A written proposal must be prepared, agreed with the client and where appropriate must be subjected to technical validation before the contract is accepted.

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<b>LABORATORY ACCOMMODATION AND ENVIRONMENT</b>	Issue date November 1998 Issued by D. Smith

## **8. Laboratory accommodation and environment**

### **8.1 Accommodation and Conditions**

8.1.1 The accommodation and environment is required to meet the following conditions:

- i. The Collection laboratories are clean and well lit
- ii No source of excessive or unusual microbial contamination is introduced
- iii Adequate bench and storage space is furnished consistent with the type and volume of work.
- iv. The relevant containment facility is available to protect the work and worker from potential release of aerosols containing microorganisms or hazardous chemicals (see health and safety manual for full details).

If major building, renovation, repair or dirty work is necessary in the laboratories of the Collection activities are terminated until the work is completed.

### **8.2 Access**

Access to the Collection store areas is restricted to authorised staff or those accompanied by them.

### **8.3 Housekeeping**

The buildings are cleaned on a regular basis; details of cleaning contract, cleaning schedules are retained and recorded in the Laboratory Procedures Manual.

Procedures for the cleaning of laboratory benching and equipment are detailed in the Laboratory Procedures Manual.

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<b>RECEIPT AND HANDLING OF ORGANISMS FOR DEPOSIT</b>	Issue date November 1998 Issued by D. Smith

## **9. Receipt and Handling of Organisms for Deposit**

All parcels containing microorganisms are opened in a laboratory. Those parcels that may contain unknown or hazardous organisms are opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of organisms. Safe procedures are laid down.

Samples are divided into:

- i. No risk of infection (hazard group 1) and low risk of infection (hazard group 2). These can be handled safely in containment level 2 facilities.
- ii. Known pathogenic organisms of groups 3 and 4. These are handled at containment level 3 or 4, despatched to a facility that can handle them or they are destroyed (see Laboratory Procedures Manual).
- iii. Unknown organisms. These must be screened for possible pathogens.

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<b>RECORDS</b>	Issue date November 1998 Issued by D. Smith

## 10. Record System

Methods and procedures are recorded in the Laboratory Procedures Manual.

Data on organisms deposited into the Collection for unrestricted distribution are recorded as hard copy or on the Collection Database. Data on safe and patent deposits are not entered into the databases with public access. Information is also recorded in hard copy.

Information on the preservation and that generated after receipt of the deposits is also recorded in hard copy, this information is also stored on the Collection database for strains deposited in the open collection but not for safe and patent deposits.

Information associated with preservation contracts is stored in customer files.

Details of the daily practices in the laboratory are maintained in an individual worker's laboratory book.

The type and detail of procedure records are specified in the Laboratory Procedures Manual.

### 10.1 Strain information recorded

#### Deposits

The normal minimum data recorded for each deposit is:

- a) Name (where one can be applied)
- b) Depositors name and address
- c) Substrate or host from which the organism was isolated
- d) Geographical location of isolation
- e) Depositors strain number or other collection number(s)
- f) Assigned strain number

See Laboratory Procedures Manual for details of information stored and data validation.

#### Supply

- a) Name, address and contact numbers of the requester
- b) Organisms requested
- c) Collection order number
- d) Date of receipt of order and supply

### 10.2 Protection

The UKNCC Collection database is accessed from outside the collection via the UKNCC central server. Where this data is made available online or on disk only selected fields containing non-confidential information are presented.

Files are stored in secure cabinets.

### 10.3 Retention

Customer records are archived after 5 years.

UKNCC Collection database records are retained so long as an organism remains viable. On the loss of a strain the database record is printed and stored on file before the entry is removed from the database.

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<b>HANDLING COMPLAINTS AND ANOMALIES</b>	Issue date November 1998 Issued by D. Smith

## **11. Handling complaints and anomalies**

The Collection acknowledges all customer queries by return of post or on the same day by fax, telephone or e-mail and investigates complaints as soon as received.

### **11.1 Policy and procedures**

All complaints are logged.

#### *Supply of strains*

Replacement cultures are normally provided free of charge if the client is not deemed at fault. If an organism fails to grow it is recovered from another source if available and re-preserved before despatch to the customer.

#### *Contract Preservation*

On receipt of a query all raw data, reports etc. retained by the collection are audited to determine the source of the problem. Re-preservation is offered which is at the Collection's expense if the problem is deemed to have occurred through the collection's actions and at the clients expense if otherwise.

### **11.2 Records**

All enquiries/complaints are logged in the enquiries logbook and written records of responses/solutions etc. are stored.

### **11.3 Audits**

As stated in 11.1 areas highlighted by queries are immediately audited. Depending on results preserved stocks are replenished.

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<b>OUTSIDE SUPPORT SERVICES AND SUPPLIES</b>	Issue date November 1998 Issued by D. Smith

## **12. Outside Support Services and Supplies**

The Collection recommends other national or international collections to supply strains not held where it is possible (see Laboratory Procedures Manual for details). Where deposits are outside the remit of the Collection suitable collections are recommended, patent deposits are referred to other International Depositary Authorities.

### **12.1 Policy**

It is the policy of the Collection to procure support services and supplies that are of adequate quality to sustain confidence in its activities. Supplies are sought from reputable companies with, where possible, proven quality of products.

Preference is given to services and supplies covered by certification schemes.

Where no independent assurance of quality of support services is available the collection where possible confirms the quality of vital supplies.

### **12.2 Records**

Copies of purchase orders are held on file and the Technical/Administration Services Manager maintains records of suppliers, standing orders etc.



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<b>SITE SECURITY</b>	Issue date November 1998 Issued by D. Smith

### **13. Site Security**

Arrangements for site security are laid down in the Laboratory Procedures Manual.