



CIP Quality System for Genebank ISO 17025

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IRRI, Philippines

Overview



-
- **About ISO 17025 & Quality Management Systems**
 - **CIP strategy to achieve ISO accreditation**
 - **Main CIP activities from 2007-2008**
 - **Advantages of using Wiki-Confluence for Quality Manual**
 - **The CIP Quality Manual on a Wiki**
 - **Key issues for maintenance of accreditation**
 - **Visiting the On-Line Quality Manual**

About ISO 17025 and Quality Management Systems



- The ISO 17025 is a Quality Management System (QMS) for laboratories (International Standard)
- A QMS is a set of policies, processes and procedures required for planning and execution in the core business area of an organization
- A QMS integrates the various internal processes within the organization
- A QMS is a formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management
- ISO 17025 applies to all organizations performing tests and/or calibrations.
- There are 15 management requirements and 10 technical requirements. These requirements outline what a laboratory must do to become accredited
- The ISO accreditation demonstrates technical competence for a defined scope

CIP strategy to achieve ISO accreditation



- **Contract an ISO expert from UK for one year**
- **The consultant was in charge of:**
 - **Train CIP staff on ISO**
 - **Organize meetings to achieve ISO requirements**
 - **Set up the quality manual and maintain updated the WIKI site**
 - **Propose templates for procedures/protocols and process documentation**
 - **Contact and coordinates activities between CIP and entity of accreditation**

Main CIP activities from January 2007 to February 2008

- **Team was trained in ISO requirements**
- **Review the present workflows to identify if they are up to date and if there any part of process that is missing from them**
- **Identify and collate what documented procedures are available for the process**
- **Create Wiki site to upload documentation**
- **Do internal audits between CIP units**
- **Receive the visit of two supervisors from entity accreditation to validate ISO requirements and document non-conformances**
- **Prepare evidence of clearance of the non-conformances**

Advantages of using Wiki-Confluence for setup Quality Manual

- You can edit your web pages using your favorite browser inside CIPHQ or outside
- Is not necessary advanced knowledge in web page design, in addition RIU can support you.
- Manages and collaborates on all types of documentation and processes in the wiki
- Offers collaborative environment for partners to maintain the web pages updated
- Assign rights for read-only or write, private or public
- This Wiki-Confluence comes with additional features that you can reuse: photo gallery, google maps, etc..
- Export web pages to PDF or MS-Word
- Automatic records any changes (history web page repository), enable rollback
- CGIAR Centers can use a community license, no cost

More details in: <http://www.atlassian.com/software/confluence/>

The CIP Quality Manual on Wiki (1/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home - GADC - CIP-collab - Microsoft Internet Explorer

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Address: <http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home Organisation Germplasm Policies Quality System Workflows Operational Procedures Records Form store UKAS Assessment View Edit

GADC - Home

Implementation of ISO 17025 for CIP Germplasm Acquisition and Distribution (GAD)

- This website has been set up to organise all the information relating to the Quality System, Processes and Procedures for the Germplasm Acquisition and Distribution(GAD) process at CIP. The site is structured in terms of policies, workflows, procedures and records. The content of documents is continually reviewed as part of the ISO 17025 implementation process.
- ISO 17025 is a worldwide Quality Standard that sets down requirements for the technical competency of a laboratory. CIP is extending the scope of this Standard to include all aspects of Germplasm Management.
- CIP has been assessed against this Standard on 16-17 January 2008 by Dr Colin Jeffries of the Scottish Agricultural Science Agency and Dr Sally Higgins from the United Kingdom Accreditation Service. CIP has now been recommended for accreditation and has successfully cleared the issues raised at the visit. CIP is now waiting for the Certificate of Accreditation and the Schedule defining the scope of the Accreditation.
- By gaining Accreditation for compliance with ISO 17025 CIP has given the users of the Genebank a visible assurance of the quality of the germplasm being distributed.
- Comments regarding the structure and content of the documentation are welcomed in order to ensure the website reflects the current policies and procedures for GAD at CIP.
- For information on the ISO 17025 implementation process and an update on progress contact David Galworthy (ex 2068)
- To feedback comments about the website contact David Galworthy (ex2068), Reinhard Simon (ex3025) or Edwin Rojas (ex2037).

[If you have problems with all the text on the menu bar being visible please check monitor set up on your computer control panel - setting should be at least 900 x 768]

Last edited on Feb 13, 2008 08:42

Labels: [wiki](#) [EDIT](#)

Address: Home - GADC - CIP-collab - Microsoft Internet Explorer

Internet

The CIP Quality Manual on Wiki (2/11)

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Address: http://research.cip.cgiar.org/confluence/display/gadc/Home

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GADC

Implementation

Germplasm Acquisition and Distribution (GAD)

Use all the information relating to the Quality System, Processes and Procedures for the Germplasm Acquisition and Distribution (GAD) Membership, terms of reference and meetings Minutes of Meetings

- ISO 17025 is a worldwide Quality Standard. CIP is extending the scope of this Standard to include all aspects of Germplasm Management.
- CIP has been assessed against this Standard on 10-17 January 2008 by Dr Colin Jeffries of the Scottish Agricultural Science Agency and Dr Sally Higgins from the United Kingdom Accreditation Service. CIP has now been recommended for accreditation and has successfully cleared the issues raised at the visit. CIP is now waiting for the Certificate of Accreditation and the Schedule defining the scope of the Accreditation.
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Minutes of Meetings

Internet

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Address http://research.cip.cgiar.org/confluence/display/gadc/Home

Home Organisation **Germplasm Policies** Quality System Workflows Operational Procedures Records Form store UKAS Assessment View Edit

GADC Home

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

Germplasm Acquisition and Distribution

CGIAR Ethical Principles Relating to Genetic Resources

Guidance Documents for Germplasm Management

GADC Policies

Additional Clauses for Phytosanitary Testing Requested on Import Permits

Minimum Health Requirements for Planting Material Movement in Peru

Implementation of the Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

- This website has been set up to organise all the information relating to the Quality System, Processes and Procedures for the Germplasm Acquisition and Distribution(GAD) process at CIP. The site is structured in terms of policies, workflows, procedures and records. The content of documents is continually reviewed as part of the ISO 17025 implementation process.
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Minimum Health Requirements for Planting Material Movement in Peru

Internet

The CIP Quality Manual on Wiki (4/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home Organisation Germplasm Policies **Quality System** Workflows Operational Procedures Records Form store UKAS Assessment View Edit

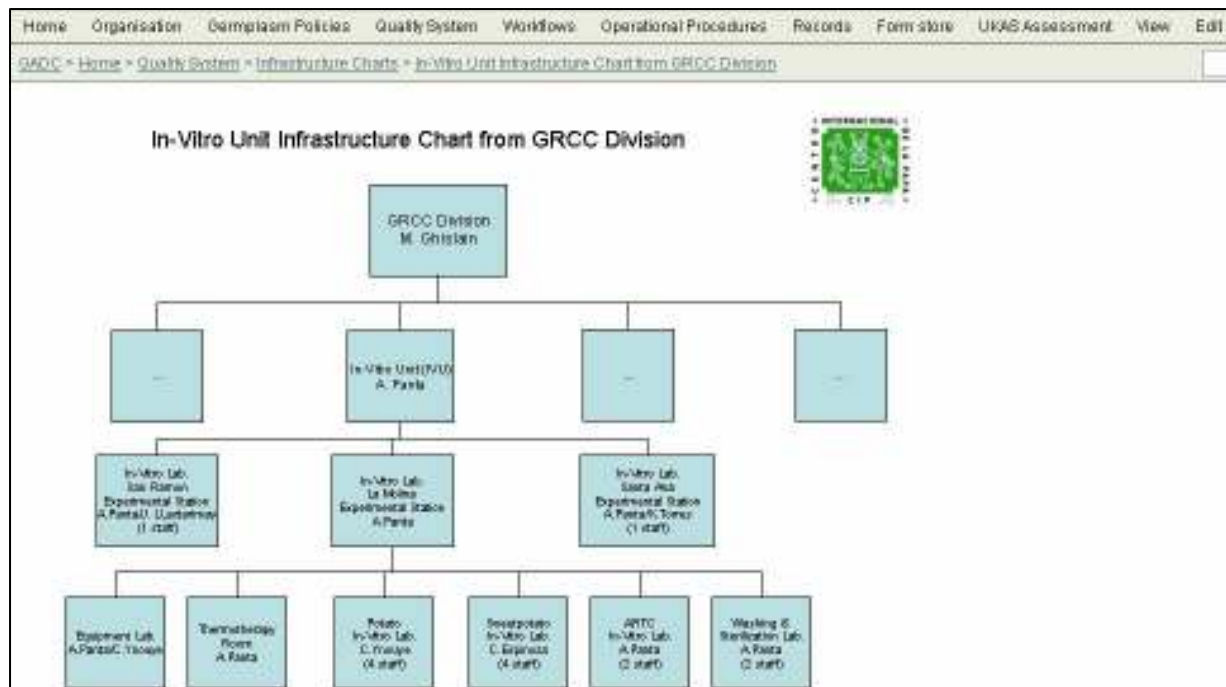
GADC > Home

Implementation of ISO 17025

- This website has information on the acquisition and implementation of documents related to ISO 17025.
- ISO 17025 is a standard that sets down requirements for the technical competency of a laboratory. CIP is extending its ISO 17025 implementation process.

Quality System

- Scope
- Quality Policy Statement
- Quality System Structure
- Infrastructure Charts**
 - Germplasm and Distribution Unit Infrastructure Chart
 - In-Vitro Unit Infrastructure Chart from GRCC Division
 - ICM-Virology Infrastructure Chart**
- Accreditation and Approval Bodies
- Management Requirements
- Technical requirements
- Document List
- Balanced Scorecard



The CIP Quality Manual on Wiki (5/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home	Organisation	Germplasm Policies	Quality System	Workflows	Operational Procedures	Records	Form store	UKAS Assessment	View	Edit
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GADC > Home > Workflows > The Workflow System

The Workflow System

- General Overview Workflow
- Acquisition
- Quarantine
- Health Testing
- Conservation
- Pathogen Elimination
- Distribution

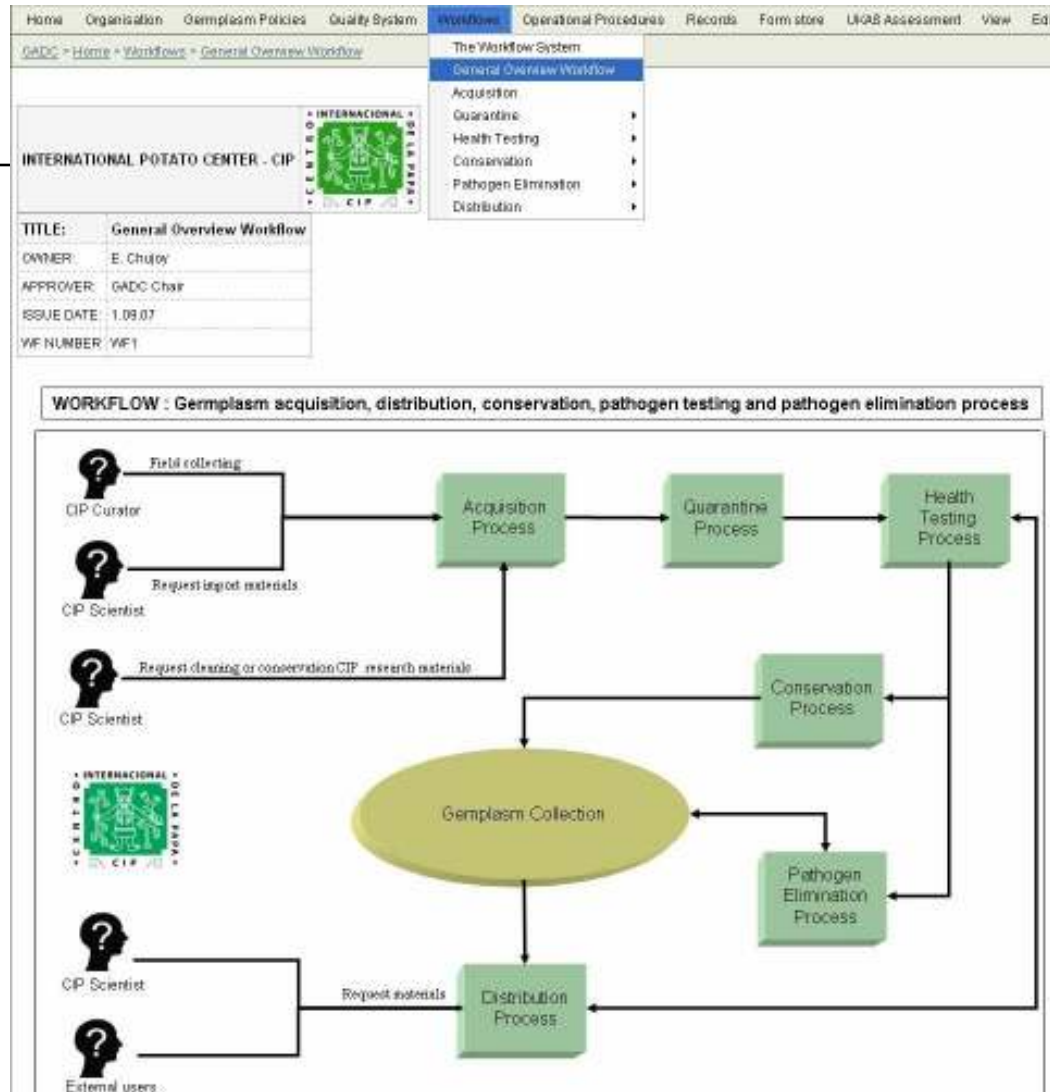
All the processes associated with Germplasm Acquisition and Distribution material. The Workflows have been linked to the database system that follow up of all genetic resources data on acquisition, conservation, pathogen elimination, and distribution.

- <http://sol/workflow/main.aspx> The "Germplasm Acquisition, Distribution and Distribution" can be placed here or communicated to CIP-ADU@cgiar.org for metafiles on the use of the germplasm. A search tool "The Genetic Resources Search" is available in the system.
- <http://sol/appdb/research/Div2GRCC/CIPCLU/main.aspx> "The Cleaning Unit System (CIPCLU)" contains information on specific clones in the process of pathogen elimination or invitro transfer
- <http://sol/appdb/research/Div4ICM/CIPVIR/main.aspx> Reports of PSTVd testing can be obtained in the Virology Lab Info Management System (CIPVIR)
- <http://sol/appdb/research/Div2GRCC/SEARCH/search.aspx> "The Genetic Resources Search" is a tool that allows the search of passport, morphological, evaluation, and conservation data. Its has been linked to the CIPGADC whereby specific data on acquisition and distribution can be searched
- <http://sol/appdb/research/RIU/REPORTSD/> Reports of distribution of genetic resources can be obtained in the form of PivotTables in Excel.

Staff make requests for all GAD activities electronically now the the system is fully integrated and functional. The web page of the system now includes all relevant information for CIP staff to deal with plant movement issues.

The CIP Quality Manual on Wiki (6/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>



The CIP Quality Manual on Wiki (7/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home Organisation Gemplasm Policies Quality System **Workflows** Operational Procedures Records Form store

Q&A - Home > Workflows > Conservation > In vitro Conservation

INTERNACIONAL POTATO CENTER - CIP

TITLE: In Vitro Conservation Workflow
OWNER: A. Parba
APPROVER: D. Taw
ISSUE DATE: 1.09.07
WF NUMBER: WF14

- The Workflow System
- General Overview Workflow
- Acquisition
- Quarantine
- Health Testing
- Conservation**
 - Wild Potatoes
 - Native Potatoes
 - Sweetpotato
 - ARTCs
 - In vitro Conservation**
 - Identity Verification
- Pathogen Elimination
- Distribution

In vitro Conservation and Regeneration: Sub-collections

Duration	Potato	Sweetpotato
2-5 years	8-12 months	
1-2 months	1-2 months	
6 months	1 year	
2-3 months	3-3 months	
	3 months	
	3 months	

The CIP Quality Manual on Wiki (8/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

Home Organisation Gemplasm Policies Quality System **Workflows** Operational Procedures Records Form store UKAS Assessment View Edit

DeDC - > Workflows - Health Testing - Potato Diagnostic Workflows

INTERNACIONAL POTATO CENTER - CIP

TITLE: DAS-ELISA Diagnostic Workflow

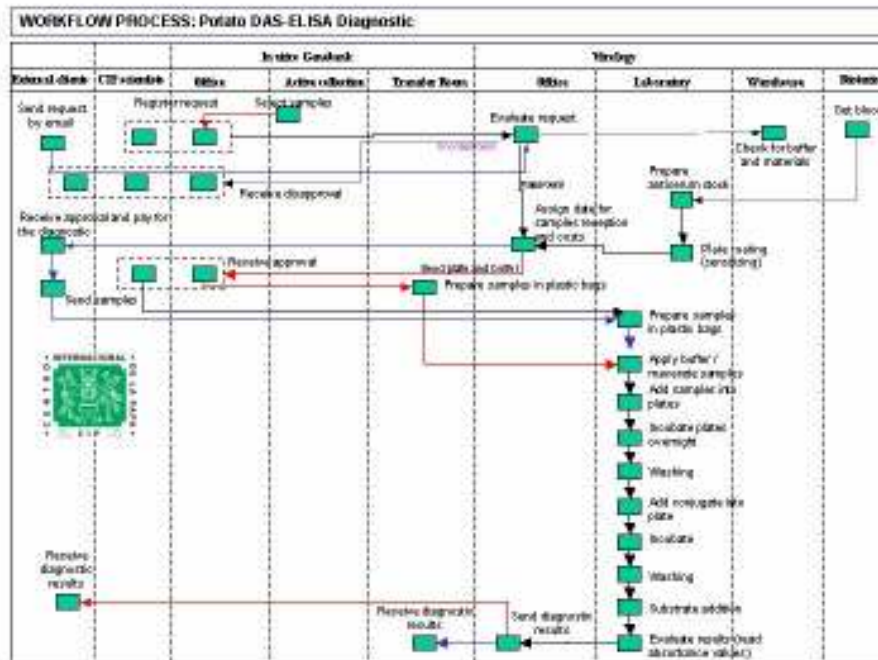
OWNER: G. Muller

APPROVER: L. Barker

ISSUE DATE: 1.09.07

WF NUMBER: WF6

- The Workflow System
- General Overview Workflow
- Acquisition
- Quarantine
- Health Testing
 - Potato Diagnostic Workflows
 - Sweet Potato Diagnostic Workflows
 - DAS-ELISA Diagnostics
 - Host Range Diagnostics
 - Potato Pathogen Testing Workflow
 - Nash Diagnostics
- Conservation
- Pathogen Elimination
- Distribution



The CIP Quality Manual on Wiki (9/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

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gadc > Home > Operational Procedures > Health Testing Procedures > Health St

INTERNACIONAL POTATO CENTER - CIP

Quality Procedures
Acquisition Procedures
Quarantine Procedures
Health Testing Procedures
Conservation Procedures
Pathogen Elimination Procedures
Distribution Procedures

Plant Health Categories Selection Procedure
Health Status Decision Making Process
Health Status Testing and Virus Elimination in Potato
Health Status Testing and Virus Elimination in Sweetpotato
Potato Diagnostic Procedures
Sweet Potato Diagnostic Procedures
Detection of Bacterial Infection
Produccion y Mantenimiento de Plantas Indicadoras
Production and Maintenance of Indicator Plants

TITLE: Health status testing and virus elimination in potato
OWNER: C. Yisoaga / A.Parras
APPROVER: D.Tay
ISSUE DATE: 7.02.08
OPERATIONAL PROCEDURE NUMBER: OP 17

INTRODUCTION

Virus elimination will be carried out in all materials maintained or generated at CIP prior to its distribution. A virus elimination technique has been developed on the basis of thermotherapy and meristem culture with an efficiency close to 100%. Pathogen tested clones can be of Health Status (HS): HS1: clones negative to pathogens of quarantine importance and pathogens detected by NASH and ELISA tests; these clones can be distributed only within Peru. HS2: accessions negative to all pathogens reported up to date (detected by NASH, ELISA and Host Range test), they can be distributed internationally.

SCOPE

This procedure covers the health testing and virus elimination of potato gemplasm maintained in the genebank or generated at CIP prior to its distribution.

SAFETY

No specific requirements above the normal laboratory safety procedures.

See the following link for details of media preparation: [Preparation of Cultivation Media](#)

MATERIALS

Equipment	
Autoclave	Medium dispenser
PHmeter	Analytical balance
Laminar flow chamber	Shakers
Refrigerator	Cultivation growth chamber
Oven	Microwave oven
Stereoscope	
Other materials	
Glass test tube	Cotton
Petri dishes	Alcohol
Forceps	Burner
Blades	Sterilizer
Saraná wrap or Parafilm	Jiffy

The CIP Quality Manual on Wiki (10/11)

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

PROCEDURE

2.1 Material

- 2.1.1 Starting material can come from *in vitro* plantlets from CIP genebank, *in vitro* plantlets from outside CIP or from roots, tubers or cuttings.
- 2.1.2 *in vitro* plantlets from outside CIP must pass an incubation period of 7 days under quarantine conditions before its multiplication for the initial health status testing.
- 2.1.3 Roots, tubers or cuttings must be planted in pots under quarantine conditions. Initial health status testing (NASH for PSTVd and PVT and ELISA for PVS, PVY, PVX, APLV, PLRV, APMoV) must be carried out under ADU responsibility. If the material resulted infected with the viroid PSTVd, incinerate the material.
- 2.1.4 Introduce *in vivo* material into *in vitro* according to the protocol for introduction to *in vitro* culture. Select a vigorous and bacteria-negative clone. This mother plant is grown from one explant containing one bud.
- 2.1.5 If the material came from *in vitro* plantlets from CIP genebank, culture one apical shoot tip for 5 weeks in a 16x125mm test tube with MSA media. This plantlet is considered the mother plant.

2.2 Initial Health Status testing

- 2.2.1 Multiply the mother plantlet into four test tubes:
 - a) Place 1 explant containing the apical shoot of the mother plant in a 16x125mm test tube with MSA media. This tube will be conserved as the stock H50.
 - b) Place 2-4 explants containing 1 bud in a 16x125mm test tube with MSA media. These tubes will be used for Test A (NASH test).
 - c) Place 2-4 explants containing 1 bud in a 16x125mm test tube with MSA media. These tubes will be used for Test A (ELISA test).
 - d) Place 1 explant containing 1 bud in a 16x125mm test tube with MSA media. This tube will be used for Test B (ELISA and Host range test).

Test A

- 2.2.2 The two tubes containing each 2-4 stems with leaves from 3-4 week old *in vitro* plantlets grown in MSA medium, with a height of at least 1/2 of the test tube, are sent to CIP Health Quarantine Unit (HQU) for ELISA (PVS, PVY, PVX, APLV, PLRV, APMoV, PVV, PW and AVB-c) and NASH (PSTVd and PVT) tests. Testing of virus is made following the protocols published by Jayasinghe and Salazar (1993). If the material resulted infected with the viroid PSTVd, incinerate the material.
- 2.2.3 Accessions that resulted positive to test A are submitted to the virus elimination protocol.
- 2.2.4 Accessions that resulted negative to test A are submitted to Test B.

Test B

- 2.2.5 1 month-old *in vitro* plantlet is transferred to jiffy and grown under greenhouse conditions for 2 months (see host range test protocol).
- 2.2.6 Remove 2-3 leaflets from the apical, medium and basal part of the plant, with a total weight of 1 g approx. Place the leaflets in a 4"x6"x6" plastic bag. The first 3 samplings are done under the supervision of HQU.
- 2.2.7 Add 0.01 M phosphate buffer (pH 8) in a proportion of 1:3 with the sample and macerate. Phosphate Buffer is provided by HQU.
- 2.2.8 The indexing is made using the following species: *Nicotiana tabacum* "White Burley", *N. glauca*, *N. debneyi*, *N. benthamiana*, *N. bignoniifolia*, *N. clevelandii*, *Chenopodium quinoa*, *C. murale*, *Datura stramonium* or *D. metel*, *Gomphrena globosa* and *Lycopersicon esculentum* "nutgers". The first 3 inoculations are done under the supervision of HQU.
- 2.2.9 If the clone resulted negative to test A and B, multiply the stock and submit it to the bacteria detection test using nutritive media (NB) [5.0 g/l peptone, 1.0 g/l beef extract, 2.0 g/l yeast extract, 10.0 g/l glucose, and 5.0 g/l sodium chloride at pH 7.0] and nutrient agar (ND) supplemented with 1% D-glucose. Incubate the cultures at 32-34°C and 21°C respectively for 21 days. If the clone resulted negative, the accession is declared HS2 and is included in the *in vitro* Genebank.
- 2.2.10 Clone resulting positive to the bacteria detection test (cloudy medium) are submitted to the bacteria elimination process.
- 2.2.11 Accessions that resulted positive to test B are submitted to the virus elimination protocol.

2.3 Virus elimination: chemotherapy, meristem isolation and culture

- 2.3.1 Multiply the stock H50 plantlet into four 25x150mm test tubes with MSA media, placing 4 explants on each test tube.
- 2.3.2 3-4 week old *in vitro* plantlets are submitted to chemotherapy at 32-34°C during one month.
- 2.3.3 Six meristems of 0.1-0.3 mm long, comprising the meristematic dome plus one or two leaf primordia, are excised using a dissecting knife handle with a blade No.11 and cultivated in 13x100mm test tubes with potato meristem medium (Reinke 1).
- 2.3.4 Meristems are sub-cultivated at 3, 6, and 9 days after meristem excision, then every 7, 10 or 15 days, till obtaining a rooted plantlet with at least 3 nodes.

2.4 Final Diagnostic

- 2.4.1 After plantlets are obtained from meristem culture, select the clone with better growth development and multiply into 4 tubes.
- 2.4.2 Repeat the health status testing (2.2) to detect any remaining virus infection.
- 2.4.3 If the clone resulted negative to test A and B, multiply the stock and submit it to the bacteria detection test using nutritive media (NB) [5.0 g/l peptone, 1.0 g/l beef extract, 2.0 g/l yeast extract, 10.0 g/l glucose, and 5.0 g/l sodium chloride at pH 7.0] and nutrient agar (ND) supplemented with 1% D-glucose. Incubate the cultures at 32-34°C and 21°C respectively for 21 days. If the clone resulted negative, the accession is declared HS2 and is included in the *in vitro* Genebank. Identity verification must be conducted to these materials before their distribution.
- 2.4.4 Clone resulting positive to the bacteria detection test (cloudy medium) are submitted to the bacteria elimination process.
- 2.4.5 If the clone resulted positive to test A or B, select another clone and repeat the health status testing (2.2).
- 2.4.6 If the 6 clones resulted positive to test A or B, the accessions must enter the clearing process again (chemotherapy and meristem culture).

The CIP Quality Manual on Wiki (11/11)

Home Organisation Compliance Policies Quality System Workflows Operational Procedures **Records** Form store UKWS Assessment View Edit

QADC > Home > Records > Audit Records > Records of Audit Findings 07

- Audit Record
 - Audit Programme
 - Records of Audit Findings 07
 - Records of Audit Findings 08
 - Audit Summary Tracker sheet
- Training Records and CVs
- Equipment and Environment Records

Records of Audit Findings 07

Audit number	Area covered by the Audit	Date of audit	Number N/Cs	Number of O/Ss	Date for clearance of N/Cs	Date of clearance of N/Cs	Audit records
001.07	Sampling and preparation of sample extracts for DAS-EUSA Plating out sample extracts for DAS-EUSA Detection of virus by DAS-EUSA	18-20 June 2007	6	8	1 September 2007	all clear - 15.12.07	001.07 Audit Findings
002.07	Preparation of tubers / sweet potato cuttings for national distribution	18 June 2007	2	0	1 September 2007	all clear - 1.12.07	002.07 Audit Findings
003.07	Preparation of distributions 2007-75 and 2007-32	2-3 July 2007	9	0	1 September 2007	all clear - 10.1.08	003.07 Audit Findings
004.07	Inoculation and handling of host range plants as part of the overall diagnosis process	31 August 2007 [on-going]	9	1	1 October 2007	all clear - 17.12.07	004.07 Audit Findings
005.07	Conservation processes / management of the long-term collections Propagation process In-vitro plants	10-11 September	14	2	1 November 2007	all clear - 10.1.08	005.07 audit findings
006.007	Sampling of plants for diagnostic Testing	12 September	2	1	1 November 2007	all clear - 15.12.07	006.007 audit findings
007.007	Complasm Request and Document	13 September	2	7	1 November 2007	N/C 1 ongoing clear 10.1.08	007.07 audit findings
008.007	DAS-EUSA detection of potato viruses	17 September	5	1	1 December 2007	all clear 10.1.08	008.07 Audit Findings
009.007	Quality System Documentation	19 September	2	4	1 November 2007	all clear - 8.11.07	009.07 Audit Findings
		Total	50	29			

Key issues for maintenance of accreditation

- **Formalising the role of the Quality Manager**
- **Formalising the role of the Technical Management**
- **Communication with accreditation entity (UKAS)**
- **Documentation updated and reviewed on the Wiki**
- **Management review meeting need to be organized**
- **Maintain audit programmes**

Thanks!

<http://research.cip.cgiar.org/confluence/display/gadc/Home>

user: guest2008 password: guest2008

