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CIP Quality System for Genebank
ISO 17025

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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

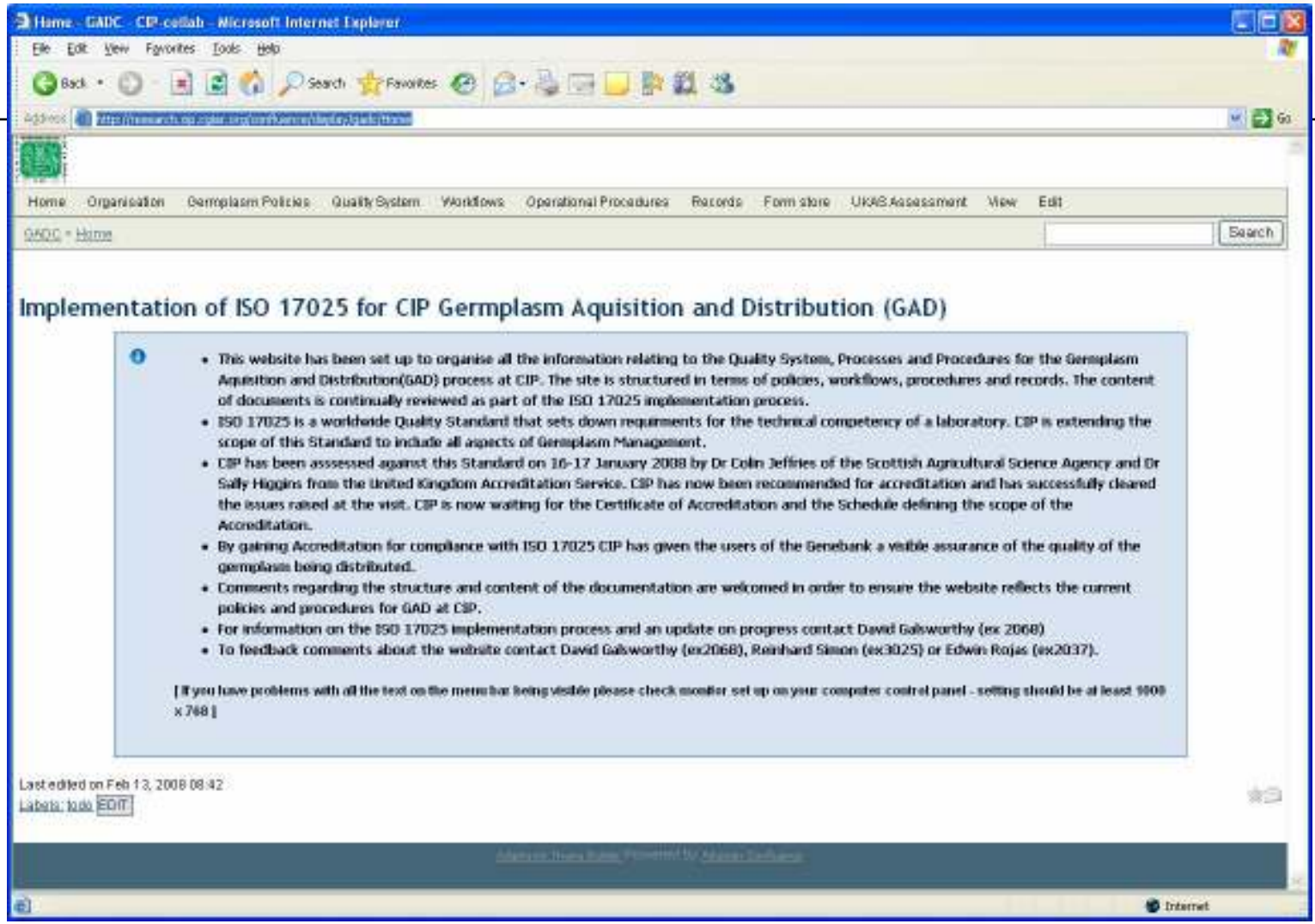
Advantages of using Wiki-Confluence for setup Quality Manual

- 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



The CIP Quality Manual on Wiki (2/11)

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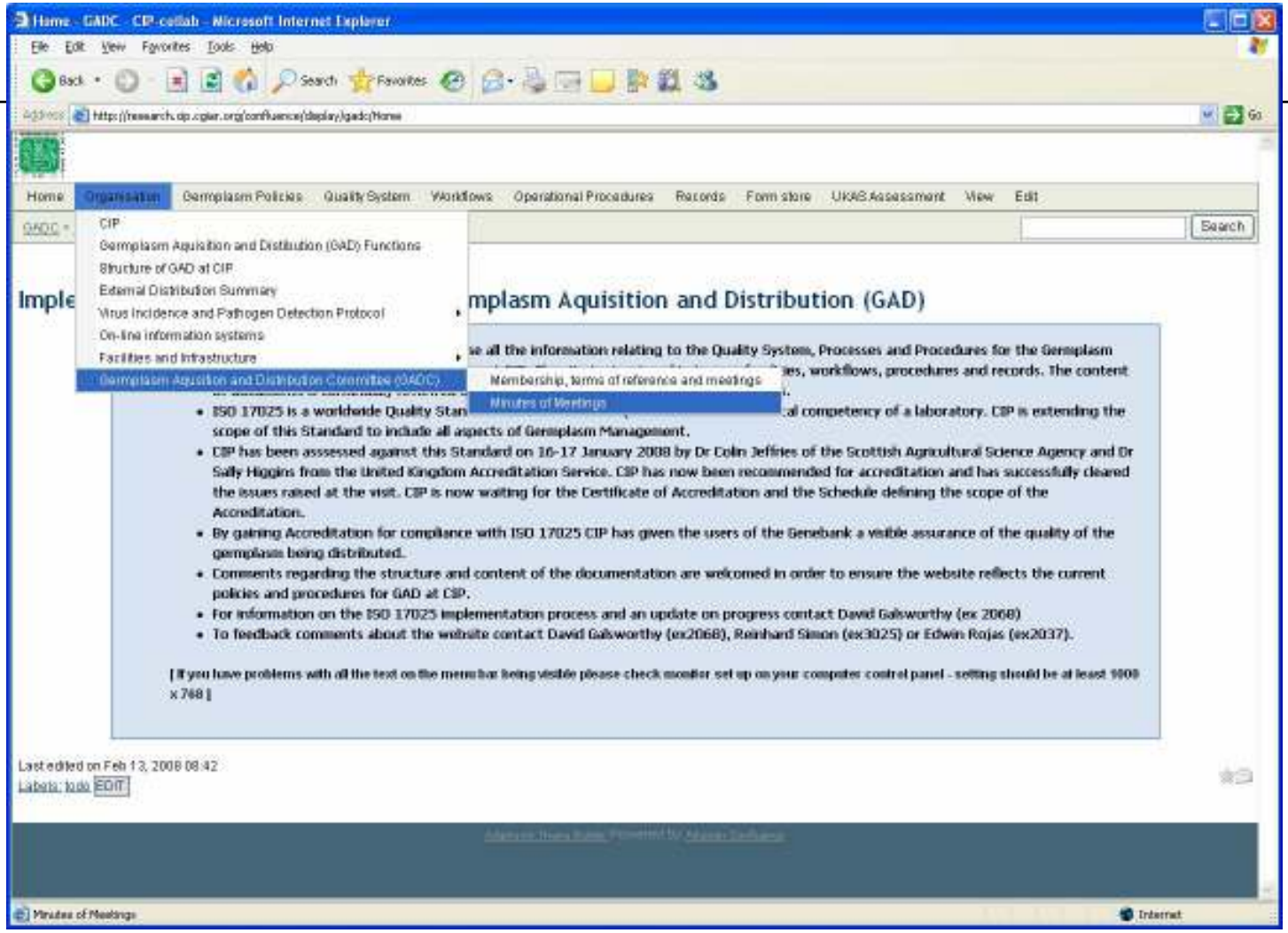

The CIP Quality Manual on Wiki (3/11)

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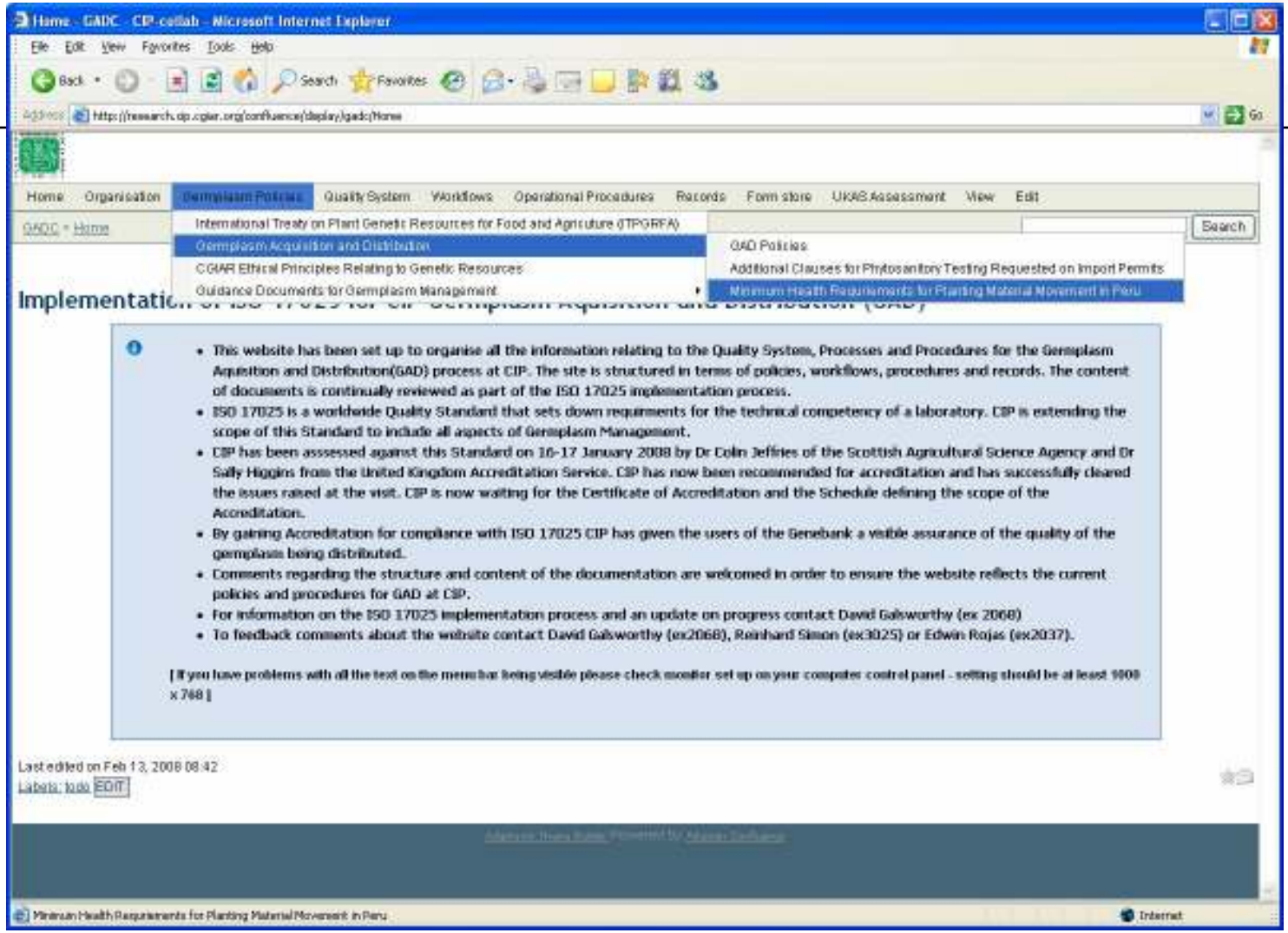

The CIP Quality Manual on Wiki (4/11)

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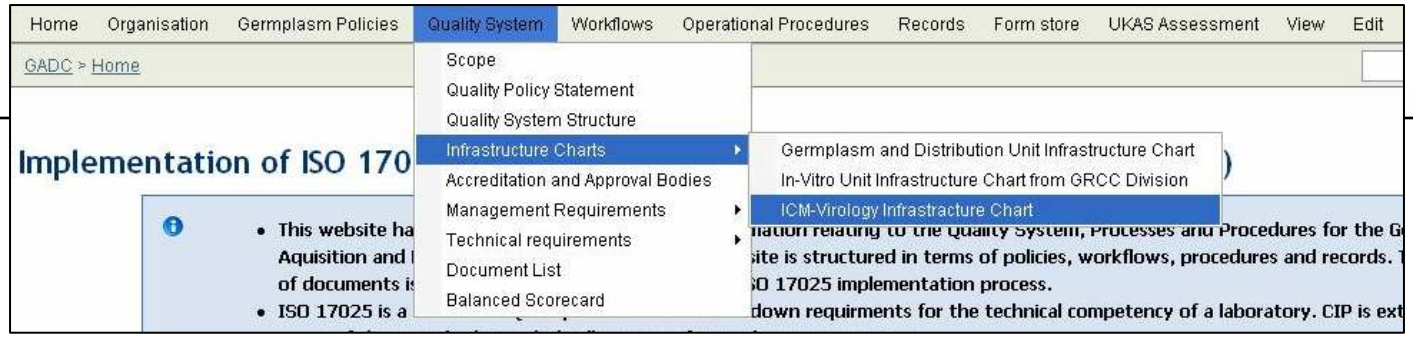

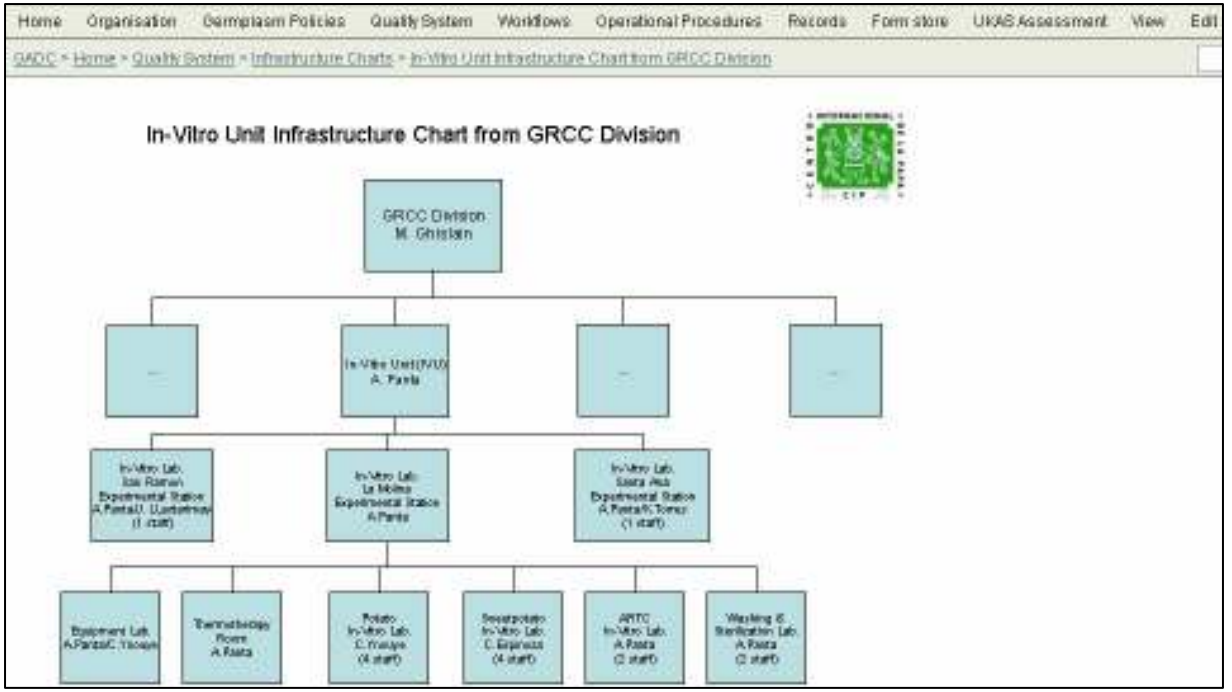

The CIP Quality Manual on Wiki (5/11)

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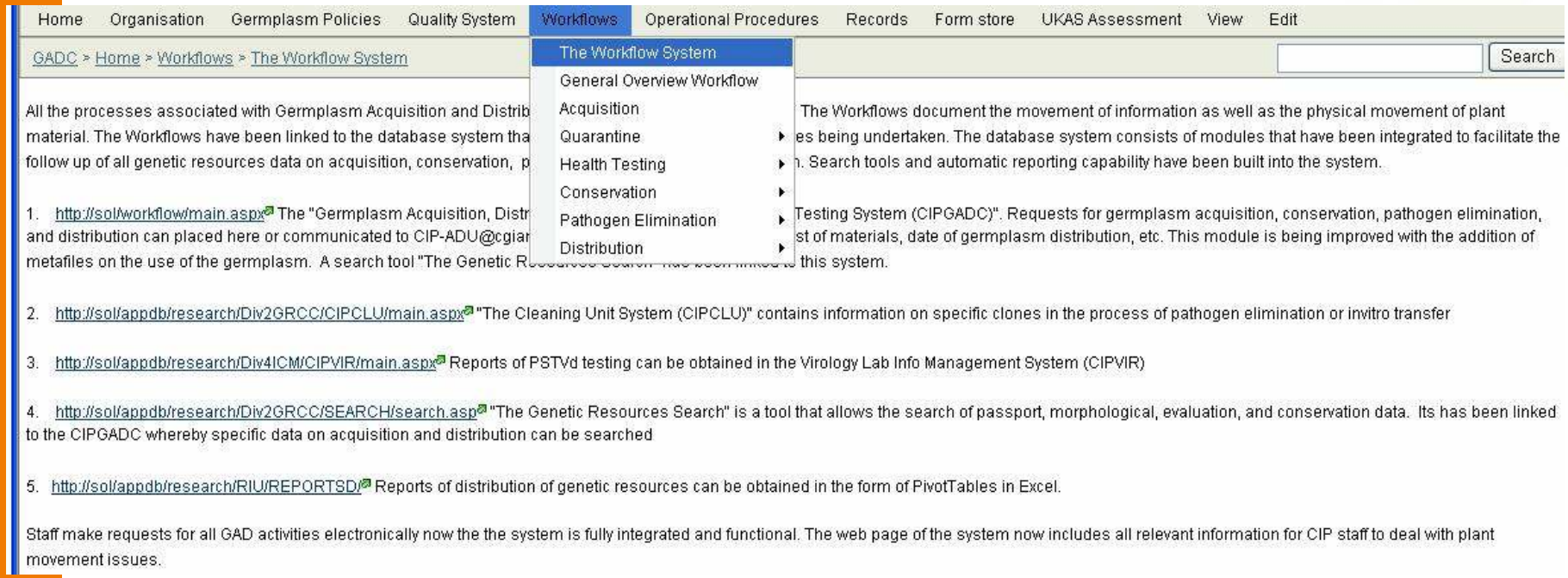

The CIP Quality Manual on Wiki (6/11)

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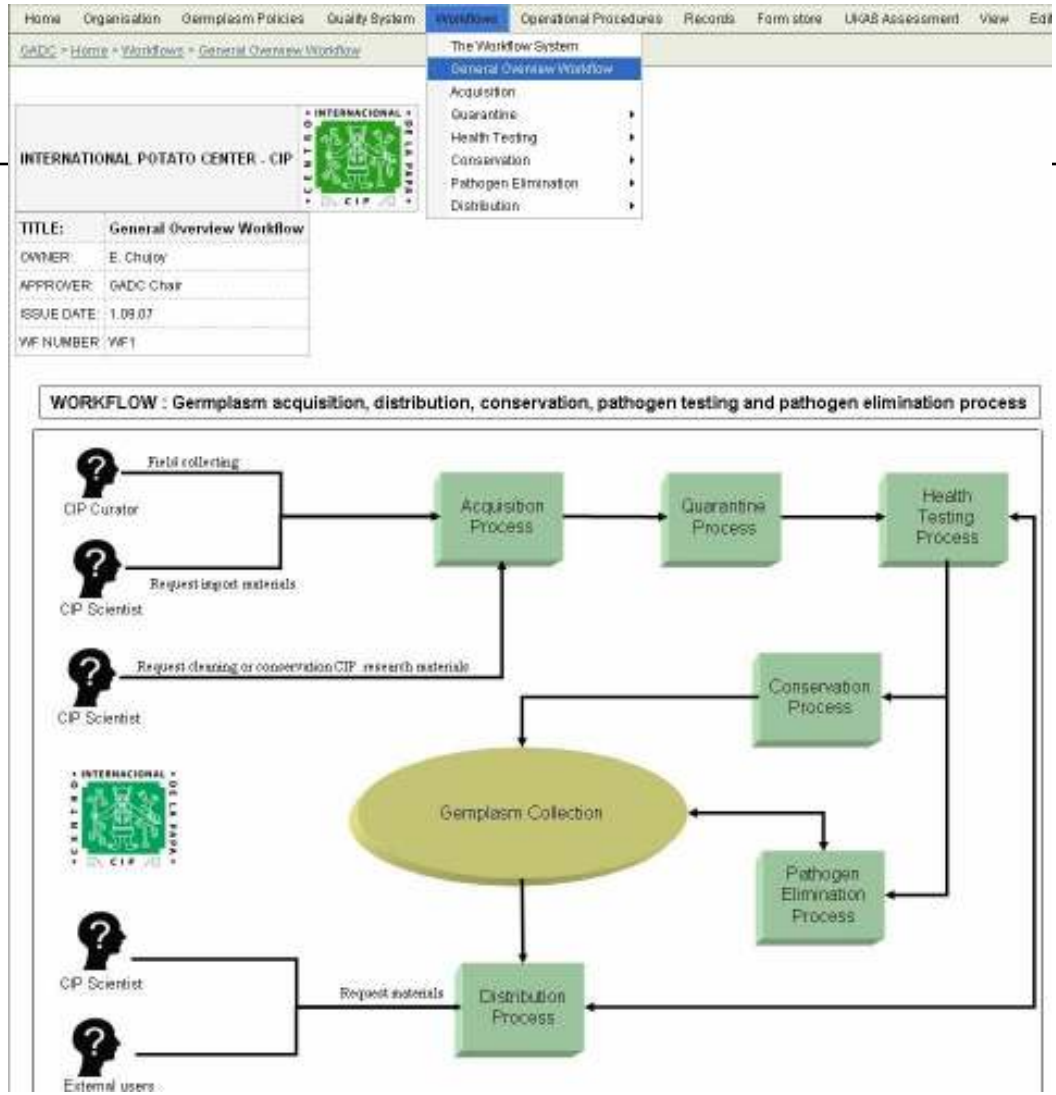

The CIP Quality Manual on Wiki (7/11)

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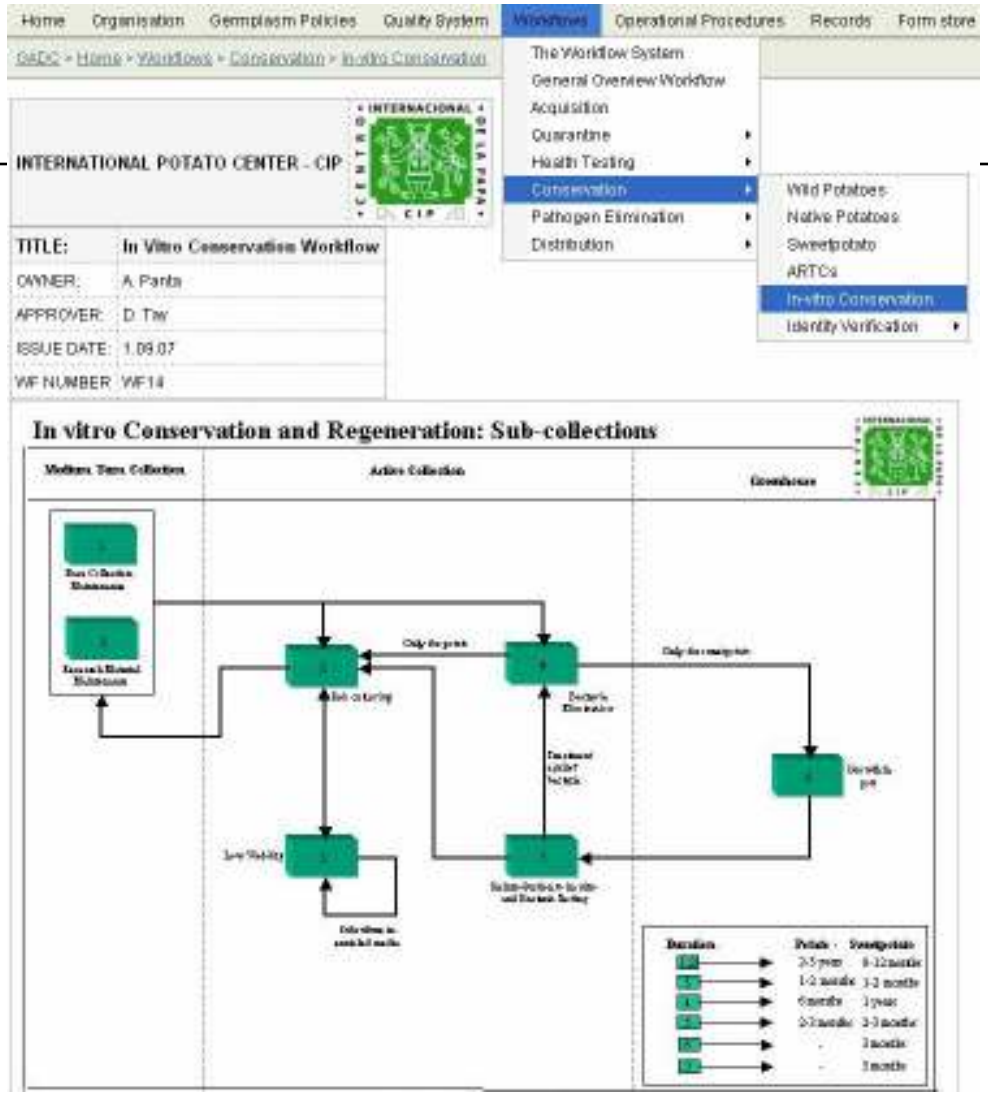

The CIP Quality Manual on Wiki (8/11)

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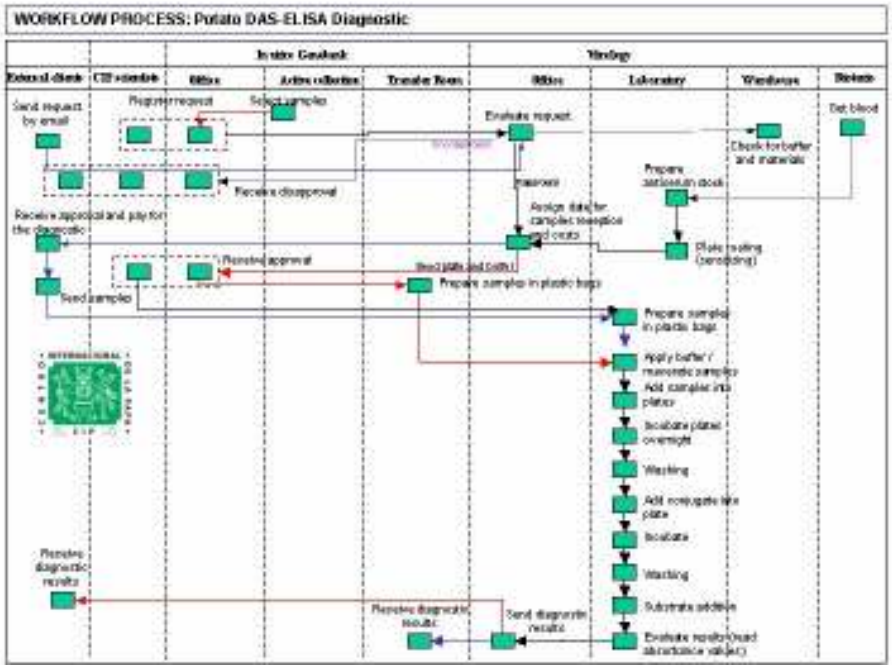

The CIP Quality Manual on Wiki (9/11)

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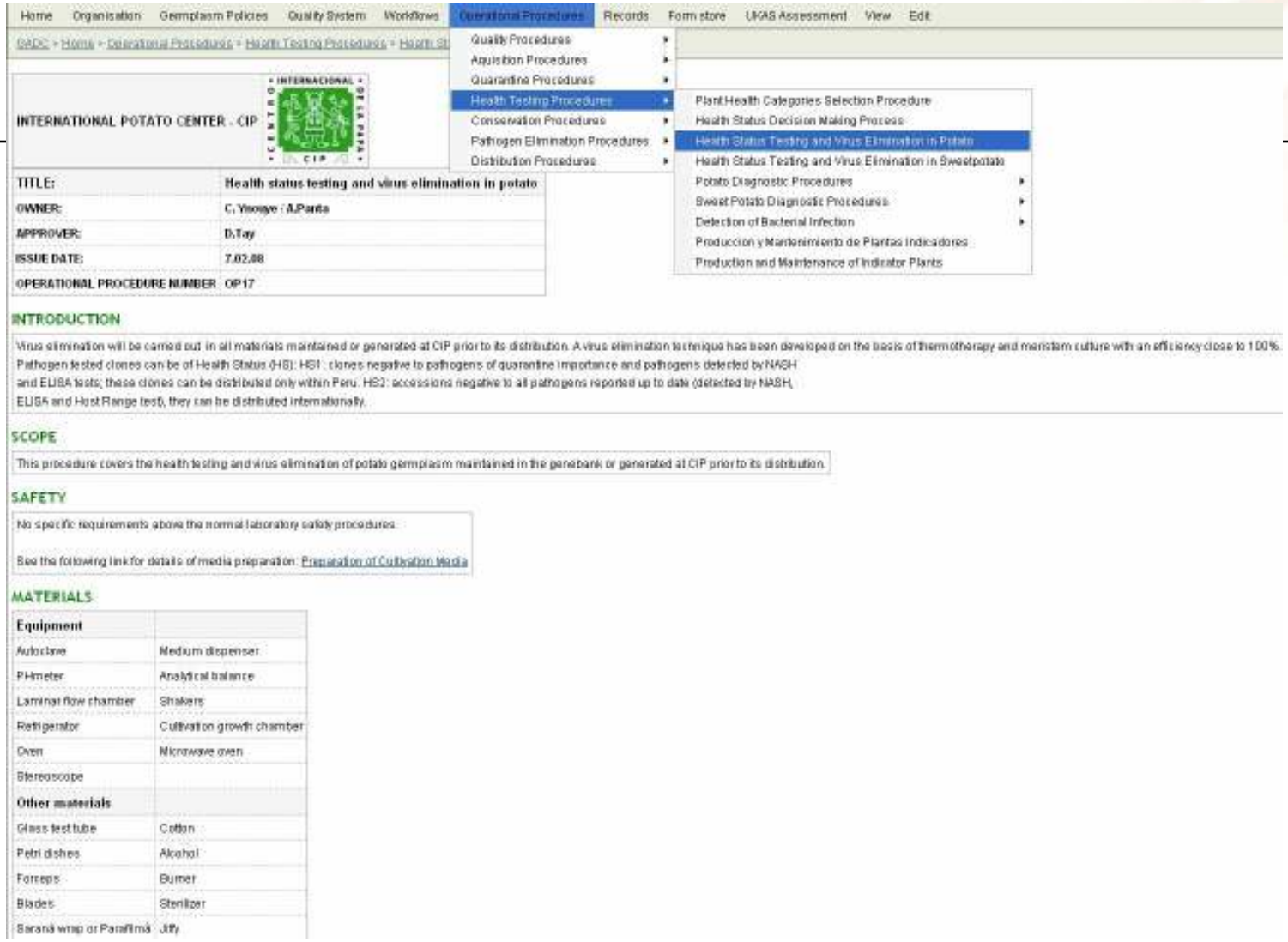

Home | Organisation | Germplasm Policies | Quality System | Workflows | Operational Procedures | Records | Form store | UKAS Assessment | View | Edit

GADC > Home > Operational Procedures > Health Testing Procedures > Health St

- Quality Procedures
- Aquisition 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

INTERNATIONAL POTATO CENTER - CIP

TITLE:	Health status testing and virus elimination in potato
OWNER:	C. Yuvaye / A.Panta
APPROVER:	D.Tay
ISSUE DATE:	7.02.08
OPERATIONAL PROCEDURE NUMBER	OP17

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 germplasm 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
Saranã wrap or Parafilmã	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 infested 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 HS0.

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, PYV, PVV and AVB-o) and NASH (PSTVd and PVT) tests. Testing of virus is made following the protocols published by Jayasinghe and Salazar (1993). If the material resulted infested 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"x8" 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: *Nicotina tabacum* "White Burley", *N. glutinosa*, *N. debneyii*, *N. benthamiana*, *N. bigelovii x N. cleverlandi*, *Chenopodium quinoa*, *C. murale*, *Datura stramonium* or *D. metel Gomphrena globosa* and *Lycopersicum esculentum* "rutgers". 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: thermotherapy, meristem isolation and culture

2.3.1 Multiply the stock HS0 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 thermotherapy 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 (Annex 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 cleaning process again (thermotherapy and meristem culture).

The CIP Quality Manual on Wiki (11/11)

Records of Audit Findings 07

Audit number	Area covered by the Audit	Date of audit	Number N/Cs	Number of O/Bs	Date for clearance of N/Cs	Date of clearance of N/Cs	Audit records
001.07	Sampling and preparation of sample extracts for DAS-ELISA	18-20 June 2007	6	8	1 September 2007	all clear - 19.12.07	001.07 Audit findings
	Plating out sample extracts for DAS-ELISA						
	Detection of virus by DAS-ELISA						
002.07	Preparation of tubers / sweet potato cuttings for national distribution	19 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	6	1 September 2007	all clear - 10.1.08	003.07 Audit findings
004.07	Innoculation 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 collectionsPropagation process In-vitro plants	10-11 September	14	2	1 November 2007	all clear - 10.1.08	005.007 audit findings
006.007	Sampling of plants for diagnostic Testing	12 September	2	1	1 November 2007	all clear - 19.12.07	006.007 audit findings
007.007	Germplasm Request and Document	13 September	2	7	1 November 2007	NC 1 ongoing clear 10.1.08	007.07 audit findings
008.007	DAS-ELISA 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