Gaining and maintaining the world's first ISO Accreditation for a genebank

David Galsworthy[1], **Reinhard Simon**[2,3], Genoveva Rossel[2], Carlos Chuquillanqui[2], Segundo Fuentes[2], Edwin Rojas[2], Giovanna Muller[2], Ana Panta[2], Ivan Manrique[2], Zea Brenda[2], Rosario Falcon[2], David Tay[2], Enrique Chujoy[2] and Ian Barker[2]

[1]The Food and Environment Research Agency, Sand Hutton, York, YO41 1LZ, United Kingdom
[2]International Potato Center (CIP), PO box 1558, Lima, Peru
[3]Corresponding author: r.simon@cgiar.org

CIP is committed to provide quality germplasm to its clients around the world. In 2006 the decision was made to formalize current practices under an international standard as an additional safety net for consistent quality. Implementing an ISO standard means effectively applying the principles of scientific peer review to product delivery and is thus very compatible within the social culture of a research institute. CIP is the first genebank in the world that opted to implement the ISO 17025 standard for testing laboratories which includes technical review of procedures and protocols on top of management review. The implementation of the formal framework further streamlined processes and protocols. As a side effect documentation management took advantage of modern online tools to auditing document changes and facilitating remote access by external auditors reducing the need for international travels. The implementation process up to the initial accreditation took a year; this is relatively fast and due to the availability of formal pre-existing documentation of main processes as well as the support by advanced laboratory information systems capable of providing complete audit trails on accession transactions. Last but not least the high staff motivation was crucial for the implementation. After another year the new system proved its viability since several former key staff left but thanks to the existing documentation and procedures new staff could quickly be incorporated. The ISO accreditation thus proved its worth and its internal scope is being extended.

Keywords: genebank, management, quality, accreditation, bar code, laboratory information management systems.

Introduction

One of the primary functions of a genebank is the distribution of plant materials; these materials are products and the results of technical processes. As for any product it is important to ensure that the product is 'fit for use': this includes in the case of plants vigor and health. In 2008the International Potato Center adopted a formal 'quality management system' based on ISO 17025 for the distribution of its in-vitro genebank materials.

The *International Standards Organization* (ISO, www.iso.org) is a non-governmental organization and has among its members individual countries and collaborates with other organizations like the United Nations. The quality standards produced by ISO includes the general standard for the implementation of a quality management systems – ISO 9001 and the standard that covers the requirements for the competence of laboratories - ISO 17025. Both these are potentially of interest to research organizations and some some governments have already started to insist that organisations in the field of plant production and distribution comply with these standards. For Examples of this include the the Dutch genebank that has implemented ISO 9000 certification for all its operations (T. van Hintum, pers. comm.) and the CIMMYT genebank has implemented ISO 17025 for itsits seed health testing unit (T. Payne, pers. comm.) at the request of the respective governments. It is important to note that ISO 9000 refers to the overall management of the quality system and ISO 17025 expands this to cover the technical implementation of the processes in terms of the competence to carry these out and comply with current technical best practices. ISO 9000 is assessed through *certification*, whereas ISO 17025 is assessed through *accreditation*.

The principles of an ISO compliant *quality management system* are related to good scientific practice: the whole process should be (a) transparent and fully document the process of how e.g. the final product is derived from the raw materials, (b) include internal controls to check on adherence to procedures, protocols and standards, and (c) include regular external review by experts in the field. ISO quality management aims to provide for continuous self-improvement through critical review.

Materials and methods

The principal processes (in-vitro laboratory; virology laboratory) included for the ISO accreditation process had counted with extensive process and protocol level documentation before the project start. In addition, an information technology infrastructure allowing real-time data logging was available using advance bar-code based tracking applications for laboratory information management.

A crucial element was the support of upper management that allowed the hiring of a consultant (DG) dedicated to project. The project depended largely also on the activation of in-house expertise through motivation and concurrent improvements in infrastructure and process management.

Results

ISO 17025 was accredited by UKAS (United Kingdom Accreditation Service) according to the planned schedule in February, 2008, for "the acquisition, maintenance and distribution of in-vitro plant material following pathogen screening techniques using symptom detection on grown on plants and on host range plants after inoculation with sap; the detection of pathogens using DAS-ELISA and NASH diagnostic techniques. This is for both potatoes and sweetpotatoes…". This gives a visible additional assurance of quality to all users of CIP genebank materials. The overall time-line of the project was about one year from the hiring of the consultant to accreditation. This was extremely fast and built on the prior established workflows and associated documentation.

During the one year period of the implementation several amendments were made including : (a) the use of internet based wiki-pages using Confluence (www.atlassian.org) for managing all documents with version control in a central repository; (b) the standardization of all documents and addition of missing ones; (c) the training of internal auditors; (d) the appointment of an ISO manager to coordinate audits; (d) completion of a validation of the processes to clearly demonstrate their effectiveness (e) the concurrent further improvement of protocols, procedures, and supporting IT infrastructure to further minimise risks.

Wiki technology is used to maintain a complete trail of changes to all documents related to management of processes under ISO quality management. This traditionally requires a lot of additional effort for updating documents. Using a web based system also allowed to easily centralize documentation while maintaining access for 'process and protocol owners' and simultaneously obviate the majority of the administrative red-tape. It also allowed transparent access for the external UK based evaluators early on in the process and thus saved on international travel and assessment costs. . The centralization of documentation served also as an opportunity to standardize documents according to the ISO requirements and helped identify gaps. One important addition was the establishment of a formal internal audit system. The intensive internal review both by the quality management system specialist and the technical teams involved served further to improve on processes, protocols and information technology to enhance specifically transparency and ease of use by users and auditors. This included for example real-time photo documentation of virus infection on indicator plants with wireless enabled digital cameras.

The ISO quality management system has proved to be sustainable for more than a year, without need for the input from external consultants as documented by the successful continuation of the accreditation. The improved documentation and procedures has helped to manage the departure of several key staff during 2008 by ensuring that there is a very well organised knowledge base that smoothed the transfer of responsibilities for technical procedures to the new staff.

Discussion

The successful implementation of the project to acquire ISO 17025 accreditation was largely due to (a) senior management support, (b) existing advanced and well documented procedures and protocols along with efficient and effective information systems, (c) early and continued involvement of all staff to contribute and improve documentation; (d) validation of processes helping to improve the efficiency of germplasm pathogens; (e) sustainability through staff commitment and community building.

The accreditation gives credit to the innovative genebank and senior management since CIP was the first genebank world wide to do so and gives the genebank the the highest level of recognition possible (Jorge, 2008).

CIPs improved in-house capability in formal quality management systems is now being used to extend the scope of ISO accreditation in a step-wise manner to other areas of genebank management and beyond.

CIPs move to adopt ISO 17025 served as a use case in a recent study from CG genebank community under the GPG2 (Global public goods – phase 2) project funded by the World Bank to assess the applicability of formal quality management systems for genebanks (Jorge, 2008). Jorge and Galsworthy summarize that recent developments relevant to the genebank community suggest that quality management should be based on the ISO approach and preferably use ISO 17025. Thus, the introduction of ISO 17025 at CIPs genebank already proved its value beyond and underlines its potential as a model genebank.

References

Jorge, MA and Galsworthy, D (2008): Quality systems for genebanks: viability study.