Quality systems for genebanks : viability study

Executive summary: This report is part of the activity on best practices of genebank management of the project entitled “Collective Action for the Rehabilitation of Global Public Goods in the CGIAR Genetic resources System: Phase 2” (under the System-wide Genetic Resources Programme) and aims to give a general view about Quality Management Systems (QMS) for genebank management and operations, giving particular attention to the advantages and disadvantages of opting for certification (ISO 9001), accreditation (ISO 17025), Documented Procedures or an hybrid solution between the two or three previous options. It was compiled to advise the genetic resources staff of the CGIAR centers about use of QMS and ISOs and their application for effective genebank management, making use of all known experiences up to date on Quality Management Systems from genebanks in the CGIAR centers, national genebanks and also laboratories with similar activities. This was done through web and literature searches, informal interviews and questionnaires (useful literature review and links are included in the text). A broad feasibility analysis was carried out using PEST (political, economical, social and technical factors) and SWOT (strengths, weaknesses, opportunities and threats) analysis, cost estimations as well as detailed examples presented and grouped into 12 study cases. The results were analyzed from the point of view of quality, costs, effectiveness and risks. Conclusions were drawn at the genebank level as well as for the genebank community as a whole and a decision tree with options to implement a QMS are provided. Main conclusions stressed the need for better QMS, essential for any collaborative efforts between genebanks. The current trends (especially from the users and donors point of view) indicated the need to consider the use of ISO (or other similar QMS) for genebanks, and showed the viability to use ISO 17025 for entire genebank procedures (CIP genebank). The main recommendations for each genebank were: Any CGIAR genebank should have a good a reliable QMS in place, properly documenting all the procedures, as a minimal baseline. If resources allow, the implementation of ISO 17025 is highly recommended but ISO 9001 or an hybrid solution for critical areas are also good options. Regarding the genebank network, it was also recommended that a collective action should be taken and relevant adequate certification/accreditation bodies should be approached to consider a formal quality assurance, using the knowledge from the genebanks that already gained accreditation and adding the specific issues related to each genebank, to minimize costs and implementation time.

Introduction

This report aims to analyze the “viability” (instead of “feasibility” because just about anything is feasible if enough resources and money are devoted to a problem) of using the framework of the International Organization for Standardization (ISO) quality standards (ISO 9001 or ISO 17025) for genebank quality management systems (QMS), with a particular emphasis on their application for genebanks of the CGIAR centers.

There is an increasing pressure to define and use criteria of quality, for commercial as well as research processes and procedures. The concepts underlying have been applied in many areas of modern society to control risk and provide the mechanism for quality improvement. Manufacturing, food production, pharmaceutical industry, environmental controls and information technology are just some of the areas that rely on the application of quality standards and systems to support business. However, the biological / agricultural sciences have been slow to recognize the benefits of these systems and there has been limited QMS application in these fields.

The implementation of an appropriate QMS is particularly relevant for the genebanks of the CGIAR centres. The Centers are constantly striving for the highest standards in order to conserve and maintain (www.srgp.cgiar.org) more than half a million distinct accessions (www.cgiar.org) of

the plant genetic resource global public goods. In addition, the fact that key genebanks in the world have recently taken the lead in the implementation of QMSs and have gained certification (ISO 9001) or accreditation (ISO 17025) of their operations, has prompted the CGIAR to look at the possibility of using ISO quality standards more widely and broadly within its genebank community and has created the need for this preliminary report..

This report is also part of the activity of 'compiling, reviewing and updating the genebank standard operating procedures, a component of the project entitled "Collective Action for the Rehabilitation of Global Public Goods in the CGIAR Genetic Resources System: Phase 2" (GPG2) financed by the World Bank, executed by the SGRP and implemented by Bioversity International. Interdependent activities in the GPG2 include risk mitigation and best practice formulation and dissemination.

This report is addressed to a wide range of audiences, but is aimed primarily at curators or managers of genebanks at various levels and their immediate directors who have the capacity to influence and approve future management processes/structuring within their genebanks.

Options were identified for levels of implementation of a QMS suitable for genebank management. These options ranged from a minimum requirement for a quality system through to formal recognition through accreditation. These options were then analyzed point by point from a value and risk management perspective as well as from an external environment point of view that can influence the choice of options and primary conclusions were obtained after analyzing these influences. Case studies have been reviewed and experience and lessons learnt from these were included in the analysis of the results and to provide secondary conclusions.

Recommendations on how the genebanks can utilize the information in terms of decisions about the level of implementation of a quality system have been given along with suggestions for future development of a coherent quality strategy for the overall CG genebank system and a roadmap for future developments. This report expects to identify and recommend the option(s) whereby "the best value is obtained by balancing the use of resources on one hand and perfection on the other" (http://feasibilityexpert.com).

Annex 1 provides extra information and definitions about QMS in general and the ISO 9001 and ISO 17025 in particular and Annex 2 gives more details about the CIP genebank case study.

Information on genebank QMS implementation

Although all genebanks have some type of quality management system, there is no compiled information on current status. Therefore, information on quality system implementation was requested from as many genebank sources as possible. Within the genebank community there are wide differences in the level of QMS implementation. There is a general agreement amongst the community that there is a need to improve the level of quality in order to help improve performance of their operations. Knowing that there are 1500 genebanks around the world, this is not a surprising fact. The trends for globalization and closer collaboration, along with CG organizational changes will drive the move towards gaining greater confidence in the quality of the genebanks and the need for QMS that support this. Projects like the GPG2 (Global Public Goods – Phase 2) and the Quality Management Systems for AEGIS (A European Genebank Integrated System) are trying to establish joint activities to promote the conservation of plant genetic resources within and between institutes, countries, regions and crops. Therefore, the need for uniformity and transparency on the recommended and currently used procedures has never been greater. Some national and international genebanks are leading these developments: CGN in the Netherlands and IPK in Germany were the first ones to implement a quality system and gain certification to ISO 9001:2000 for their entire genebanks operations. The CIP CGIAR

genebank introduced a QMS and gained accreditation to ISO 17025 for the entire genebank workflow in 2008. The Seed Health Laboratory of CIMMYT that is used as a service laboratory for the CIMMYT genebank also gained accreditation to ISO 17025 in 2007.

Methodology

The compilation of this viability study started with a literature search for ISO quality standards and QMS references and their use in genebanks or related areas (i.e. research laboratories). A draft document was created and shared with QMS experts from various genebank systems. Additional questions were also exchanged with them through email correspondence. Their responses and useful comments were then re-structured and shaped into this document, for final review and their responses have been collated into Table 1. This table was compiled from different sources: existing web sites, publications or direct contacts with scientists involved either on the planning or the establishment of QMS for their departments or institutions. This information aims to giving an idea of the current QMS situation in genebanks or related units.

Technical background of relevant ISO Quality Management Standards

The ISO 9001:2000 is a generic standard of the implementation of a QMS. It can also be complemented by other standards addressing sector specific aspects of quality management. ISO 22000 is an example of a sector specific standard developed for the food industry. Certification to ISO 9001 is offered by certification bodies such as Lloyds, BSI and SGS. These are private companies offering certification in many countries.

ISO 14001 gives the requirements for environmental management systems (for organizations wishing to operate in an environmentally sustainable manner)

ISO 17025 is a quality standard covering the general requirement for the competence of testing and calibration of laboratories. This was applied by CIP for the potato and sweet potato genebank operation. ISO 17025 applies directly to any organizations using standard methods, non-standard methods or laboratory developed methods. It was initially issued by ISO in 1999 and revised in 2005. There are many commonalities with the ISO 9001 standard, but ISO 17025 adds the demonstration of competence. Testing and calibration laboratories that comply with ISO 17025 will also operate in accordance with the requirements of ISO 9001. Accreditation to ISO 17025 is carried out by the national organization responsible for accreditation and the assessment team includes an independent expert peer assessor.

Options for QMS of genebanks

ISO 17025 and ISO 9001 have now been used by genebanks as the basis of their QMS. These quality standards were chosen to be compared here since both their requirements have been shown to meet the operational complexities of the genebank process. The third option chosen was the introduction and implementation of either a manual of genebank operations and procedures or a collection of individual standard operating procedure covering the workings of the genebank. No certification or accreditation would be sought at this stage. The fourth option is a mixture of any of the above including partial accreditation / certification and documentation of procedures.

1. Certification – It is here referred to product certification, referring to the processes intended to determine if a product meets minimum standards, similar to quality assurance, usually related to administrative operational procedures. The ISO 9001 is a generic management standard that can be applied to any business enterprise, public administration, government department or research institute, that has been successfully used in laboratories and genebanks. Certification to ISO 9001 standard does not guarantee the compliance (and therefore the quality) of any end product or service; rather, it certifies that consistent processes are used and the system of an organization is being applied to assure consistency. A pre-requisite for an organization to become certified is to have a documented quality management system that follows the content of ISO 9001. This has been first implemented at the CGN genebank and has now also put in place at the IPK genebank (Table 1).

2. Accreditation – It is a process in which is certification of competency, authority, or credibility is presented. The accreditation process ensures that their certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically, and employ suitable quality assurance. It is usually related to technical operational procedures. The ISO 17025 is aimed at improving an organization's ability to consistently produce valid results and it has been successfully used for laboratories and also genebanks. ISO 17025 comprises both management and technical requirements. The management requirements are primarily related to the operation and effectiveness of the quality management system. The technical requirements address the competence of staff, validation of methodology and equipment control. Since this standard is about competence, accreditation is used for the formal recognition of that competence. In the same way as ISO 9001, a pre-requisite for an organization gaining accreditation is to have a documented quality management system that follows the requirements of ISO 17025 standard. This quality standard allows organizations to carry out procedures in their own ways, but requires the demonstration of continuous improvement, by regular audit. This was recently implemented for the whole CIP genebank procedures (Table 1).

3. Documentation of Processes - A potential issue with the adoption of ISO quality standards is that they may be difficult to comply with under the specific local constraints faced by the genebank. Therefore, each genebank needs to define and adopt the appropriate minimum standard for its routine procedures taking into account specific risks and local conditions. Regular revisions and necessary updates may be necessary to this minimum specification. As an example, documentation of processes is vital to enable the capture of knowledge accumulated in staff minds over many years.
This in many cases may not have been properly recorded and documented and this lack of proper recording and documentation that allows accessibility to the information is a major issue. The current situation is given in Table 1, and shows many genebanks have only partially documented the workflows and processes of their genebank operations. The completion of the documentation for the whole genebank operations is seen as a minimum requirement in the genebank management. This could eventually lead the genebank towards full implementation of a QMS and more formal verification of performance through certification and accreditation at a time when it is felt that the genebank is ready for moving to this level or if demanded by a external body (e.g. funding body or policy organization).

4. Hybrid solution – The implementation of ISO for particularly critical or high risk activities/procedures of the genebanks is another viable alternative. This would be a compromised situation that would guarantee a more controlled, reliable and therefore liable set of procedures for selected steps of the genebank activities. An example of this approach was carried out at CIMMYT seed health laboratory (see Table 1). It is also mentioned as a possible approach for the regulation and strict control of transgenic related work and development of molecular techniques. This hybrid solution would be a combination of QMS approaches along with documentation of processes depending on the local requirements.

Table 1. Current QMS situation in major genebanks and crop related laboratories

QMS in place	Organization and country	Processes	Certification/ accreditation bodies	Year
Certification				
ISO 9001:2000	CGN (The Netherlands)	Genebank + others	Technische Überwachungs-Verein (TÜV)	2004
ISO 9001:2000	Germobanco Agrícola de la Macaronésia: - CCBAT (Tenerife-Canárias) - CAP (La Palma-Canárias) - BCBA (Terceira-Açores) - ISOPlexis (Madeira)	Genebank	Det Norske Veritas (DNV)	2006
ISO 9001:2000	IPK (Germany)	Genebank + others	DQS GmbH, Deutsche Gesellschaft zur Zertifizierung von Managementsystemen	2007
ISO 9001	INTA (Argentina)	All Genebank units	In process	In process
ISO 9001	PhilRice (Philipines)	R & D		
Accreditation				
ISO 17025:2005	CIMMYT (Mexico)	Seed Health Laboratory *	Mexican accreditation entity (EMA)	2007
ISO 17025:2005	CIP (Peru)	Genebank + pathogen testing	United Kingdom Accreditation service (UKAS)	2008
Certification and accreditation				
ISO 9002 ISO 17025	Rtech labs (USA)	Lab	Det Norske Veritas (DNV) American Association of laboratory Accreditation (A2LA)	1996 2001
ISO 9001 ISO 17025	CSL labs (UK)	Lab	Lloyds Certification Body United Kingdom Accreditation Service (UKAS)	2006 1990
Documented procedures				
Printed Manual + Partial documentation of processes and procedures	CIMMYT (Mexico) IRRI (Philipines) ICRISAT (India) ATFCC (Australia)	Genebank	n/a	n/a
Partial documentation of processes and procedures	CIAT (Colombia) ICARDA (Syria) ICRAF (Kenya) IITA (Nigeria) ILRI (Ethiopia) INIBAP/ Bioversity International (Belgium) WARDA (Benin)	Critical operations in genebank	n/a	n/a
Full documentation of processes and procedures	CNRRI (China)	All Genebank units		
Partial documentation of processes and procedures	CAAS (China) SARDI (Australia) ATCFGRC (Australia) NPGRC SADC (Angola, Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia, Zimbabwe)	All Genebank units	n/a	n/a

* Independent from the CIMMYT genebank

Criteria and requirements for QMS in genebanks

Regardless of the option of which QMS model to be chosen or recommended, it must comply with a few requirements. The QMS should have the capacity for improving the quality of operations by:

- Demonstrating control of critical risks
- Improving control of proper functioning of equipment and quality of supplies (like chemicals, reagents, fertilizers and others)
- Improving quality control of processes
- Formalizing training of staff and the demonstration of staff competence
- Supporting best practice implementation
- Compliance with any audit procedures

Consideration of existing capacity and resources will limit the initial scope of the QMS. A strong QMS should have the following characteristics:

- *Compliance with genetic/biological requirements, geographical and political restrictions and regulations*

Genebanks are part of a complex and dynamic system, composed of various steps and processes with the main objective of conserving, studying and disseminating agricultural (plants, animals or other organisms) genetic resources for present and future generations. In addition to biological and environmental restrictions or limitations mostly related to the genetic background of a particular crop and the geographic location of a genebank, there are also national and international political regulations and laws that must be followed, depending on the country hosting the genebank. Most of these regulations are particularly restricted on rights and permissions to collect new germplasm from nature, movement of germplasm within regions or countries and recently the development and dissemination of genetic modified crops.

- *Compliance with institutional structure and methodology of work*

Genebanks can also be structured in different ways, having all the processes in one unit (belonging to the same structure); subdivided into distinct units within the same institution; or even with some of the processes being subcontracted to different institutions. For any of these structures, the processes and units may be co-located or geographically dispersed.

- *Minimize (most) biological and environmental risks*

Genebanks, as any business or research activity, have different levels of risk. Some of the most important or well known includes the risk of distributing:

Materials of the wrong[1] genetic source (see footnote to distinguish between risk A and B),

Pest or diseased/infected materials

Materials inadvertently contaminated by GMO's.

[1] risk A = not sending the requested material (i.e. sending a different accession), due to mislabeling.
risk B = not sending the material with the requested trait (either i) the trait has been lost by genetic erosion, or ii) the trait has been lost by genetic drift, or iii) the trait has been lost by genetic contamination). Controlling risk B is much more tricky and difficult than controlling risk A.

It is widely accepted that at least these and other high risk processes (if not all) must be carried out with extra care and with very clear rules and operating procedures.

- *Adapted to existent capacity and resources in place*

QMSs for genebanks, must be feasible, realistic and practical. There must be a clear cost/benefit analysis carried out. Genebanks have distinct financial structures and resources, so each one of these must be analyzed and weighed when a solution is chosen.

Feasibility analysis

The following analysis is based on various possible precedent conditions. We are considering a broad range of possible hypothetical cases, i.e. genebanks at different levels: some may already have the full set of documented procedures and others may have just documented a few activities. Others may have been ISO certified and be evaluating the possibility (weighing the various pro's and con's) of gaining accreditation.

In order to analyze the different points of view and consequences of choosing one or another of the 4 options selected (certification, accreditation, documented procedures or a hybrid solution) a few tools commonly used for feasibility studies (http://www.io.com/ and http://www.businessballs.com) were selected, namely: the PEST analysis (to evaluate the effects of the most probable external factors) compiled in tables 2, 3, 4 and 5; the SWOT analysis (to evaluate advantages and disadvantages of each option), compiled into tables 6 and 7; a cost assessment estimative (to have a brief idea of the cost implications for each option), compiled into tables 8 and 9 as well as 12 study cases (to evaluate real cases and their main motivations, process followed, benefits/disadvantages or keys for success as well as their current trends), shown in individual text boxes.

a) ***PEST analysis*** *– the PEST market analysis tool is a useful tool to understand the market growth or decline as well as the position, potential and direction of a business or organization. It is an acronym for Political, Economic, Social and Technological factors. It generally helps to identify SWOT factors, and therefore it is carried out before the SWOT analysis. Genebanks provide Global Public Goods as part of their mandate and therefore be strongly influenced by society and environmental rules. Although this kind of business analysis is generally developed to evaluate business opportunities some features can also be useful adapted to the evaluation of genebank management opportunities.*

Table 2. *Understanding the Political external environment (the P in the PEST analysis) in which the choice between the four options can be made, considering supporting factors or obstacles to its adoption.*

Options	Political influences	Supporting option adoption	Obstacles to option adoption
Certification	*Future legislation on access* *Government policies on germplasm* *Funding opportunities* *Donor requirements* *Distribution policies*	*Moderate* *Moderate* *Strong* *Strong* *Strong*	*Little* *Little* *Little* *Little* *Little*
Accreditation	*Future legislation on access* *Government policies on germplasm* *Funding opportunities*	*Strong* *Strong* *Strong*	*None* *None* *None*

	Donor requirements *Distribution policies*	*Strong* *Strong*	*None* *None*
Documented Procedures	*Future legislation on access* *Government policies on germplasm* *Funding opportunities* *Donor requirements* *Distribution policies*	*Little* *Little* *Little* *Little* *Little*	*Moderate* *Moderate* *Strong* *Strong* *Strong*
Hybrid	*Future legislation on access* *Government policies on germplasm* *Funding opportunities* *Donor requirements* *Distribution policies*	*Moderate* *Moderate* *Moderate* *Moderate* *Moderate*	*Little* *Little* *Little* *Little* *Little*

Both certification and accreditation (Table 2) seem to have a similar potential to benefit from external funding opportunities (i.e. a genebank with a good QMS as better chances to attract funds from increasingly exigent donors), satisfying current and future trends of donor requirements as well as distribution trends that are becoming more and more stringent and demanding in terms of quality standards. On the other hand, these same 5 political aspects (detailed in the second column) can also become moderate or strong obstacles limiting the adoption of the Documented Procedures minimal approach (detailed in the last column). Regarding policies and legislation trends, there may be a strong force towards adopting at least certification and possibly accreditation. Tighter legislation rules and government regulations could pose obstacles to the adoption of Documented Procedures in some more strict environments. The hybrid solution has the advantage of flexibility, dependent on the proportion of activities adopting an ISO compliant QMS. It would have an intermediate potential to benefit quality assurance (certification) or control (accreditation) in genebanks. Table 2 shows that there are strong external political influences and trends towards the adaptation of the certification or accreditation systems or hybrid solutions, in detriment of maintaining only the documented procedures.

Table 3. *Understanding the Economical external environment (the E in the PEST analysis) in which the choice between the four options can be made, considering supporting factors or obstacles to its adoption.*

Options	***Economic influences***	**Supporting option adoption**	**Obstacles to option adoption**
Certification	*Demand and distribution trends* *Users drivers*	*Strong* *Strong*	*None* *None*
Accreditation	*Demand and distribution trends* *Users drivers*	*Strong* *Strong*	*None* *None*
Documented Procedures	*Demand and distribution trends* *Users drivers*	*Little* *Little*	*Strong* *Strong*
Hybrid	*Demand and distribution trends* *Users drivers*	*Moderate* *Moderate*	*Little* *Little*

Table 3 shows the economical external influences that can either benefit or limit the adoption of each of the four QMS options.
The implementation of QMS could have a significant negative economic effect (internal economic factor, related to the genebank, does not considered above in the external economic effects table) during implementation due to the consultancy and accreditation / certification fees (more details are shown in Table 8 and 9). However, if properly implemented the improvements in the system could lead to saving from increased productivity and efficiency of the operations. ISO could then also have a positive economic overall effect since it would improve the demand and distribution potential of any genebank products and services, due to the increased trust and reliability demonstrated to the end users. Genebanks either certified or accredited would also

benefit when competing for work against genebanks without a strong QMS system in place. However, it is very difficult to quantify long term economic advantages and on-going maintenance costs of certification / accreditation due to the additional complexity and cost of implementation when compared to use of documented system or a hybrid system since the systems already in place are still very young.

Table 4. *Understanding the Social external environment (the S in the PEST analysis) in which the choice between the four options can be made, considering supporting factors or obstacles to its adoption.*

Options	***Social influences***	**Supporting option adoption**	**Obstacles to option adoption**
Certification	*User attitudes and options*	*Strong*	*Strong*
	Staff attitudes	*Strong/Little*	*Little/Strong*
	Brand, company technology image	*Strong*	*None*
	User demand patterns	*Strong*	*Little*
	Trends and role models (scientists)	*Strong*	*Little*
	Advertising and publicity	*Strong*	*Little*
Accreditation	*User attitudes and options*	*Strong*	*Strong*
	Staff attitudes	*Strong/Little*	*Little/Strong*
	Brand, company technology image	*Strong*	*None*
	User demand patterns	*Strong*	*None*
	Trends and role models (scientists)	*Strong*	*None*
	Advertising and publicity	*Strong*	*None*
Documented Procedures	*User attitudes and options*	*Little*	*Moderate*
	Staff attitudes	*Strong/Little*	*Little/Strong*
	Brand, company technology image	*Little*	*Strong*
	User demand patterns	*Little*	*Strong*
	Trends and role models (scientists)	*Little*	*Strong*
	Advertising and publicity	*Little*	*Strong*
Hybrid	*User attitudes and options*	*Moderate*	*Moderate*
	Staff attitudes	*Strong*	*Moderate*
	Brand, company technology image	*Moderate*	*Moderate*
	User demand patterns	*Moderate*	*Moderate*
	Trends and role models (scientists)	*Moderate*	*Moderate*
	Advertising and publicity	*Moderate*	*Moderate*

Social aspects can exert a strong force on whether to adopt or not certain options, particularly when regulatory bodies can positively influence the image of key features of genebanks (Table 4). User attitudes, demands and options acting in parallel with important role models, trends, image and publicity can, in some situations, greatly influence top management decisions to adopt certification or accreditation. The most social opposing force can often be the resistance of staff at all levels to what can possibly be laborious and time consuming changes (more details about these pros and cons are discussed in Tables 6 and 7), although sometimes genebank staff determination and conviction to adopt one of the ISO system can really make a difference towards its adoption (this is why staff attitudes was considered to have a dual strong/little possibility to either support or limit the certification, accreditation or Documented Procedures). The utilization of tools to minimize the bureaucracy of the system and promote ease of use can be used effectively to reduce staff resistance to any ISO procedure as well as giving the opportunity for staff involvement at all stages of the system and procedure development.

Often, the most comfortable option for the genebank staff is the adoption of documented procedures that are not very stringent, but this is also often not the best option in terms of image, publicity or users demands for quality assurance. Although certification does not necessarily

guarantee[2] improved quality, the perception and image of certification is equivalent to accreditation and both are very positive for the general public

Table 5. *Understanding the Technological external environment (the T in the PEST analysis) in which the choice between the four options can be made, considering supporting factors or obstacles to its adoption.*

Options	*Technological influences*	Supporting option adoption	Obstacles to option adoption
Certification	*User requesting mechanisms/technology*	*Strong*	*Little*
	Innovation potential	*Moderate*	*Moderate*
	Technology access, licensing, patents	*Moderate*	*Little*
	Genebank capacity	*Moderate*	*Moderate*
	Replacement technology/solutions	*Moderate*	*Moderate*
	Research funding	*Strong*	*Little*
	Technology availability and development	*Moderate*	*Moderate*
Accreditation	*User requesting mechanisms/technology*	*Strong*	*Little*
	Innovation potential	*Strong*	*Little*
	Technology access, licensing, patents	*Strong*	*Little*
	Genebank capacity	*Strong*	*Strong*
	Replacement technology/solutions	*Strong*	*Little*
	Research funding	*Strong*	*Little*
	Technology availability and development	*Strong*	*Little*
Documented Procedures	*User requesting mechanisms/technology*	*Little*	*Strong*
	Innovation potential	*Little*	*Moderate*
	Technology access, licensing, patents	*Little*	*Strong*
	Genebank capacity	*Little*	*Moderate*
	Replacement technology/solutions	*Little*	*Moderate*
	Research funding	*Little*	*Strong*
	Technology availability and development	*Little*	*Strong*
Hybrid	*User requesting mechanisms/technology*	*Strong*	*Little*
	Innovation potential	*Moderate/Strong*	*Little*
	Technology access, licensing, patents	*Moderate/Strong*	*Little*
	Genebank capacity	*Moderate/Strong*	*Little*
	Replacement technology/solutions	*Moderate/Strong*	*Little*
	Research funding	*Strong*	*Little*
	Technology availability and development	*Moderate/Strong*	*Little*

From the technological view (Table 5), accreditation is definitely the best option, providing room for quality assurance, improvement of capacity and competition as well as innovation potential, possibly attracting more funds from research projects if they procedures are well described and with good quality. The next best option is the hybrid, if accreditation is used for the critical procedures of the genebank, the ones that may have more technological requirements. These same technological improvements may be the factors that can create some obstacles for the adoption of certification, since this option is often regarded as not necessarily innovative, competitive with new technologies or solution/capacity driven. The technological features somehow linked to social aspects like the users request or research funding are the ones that may regard certification as good as accreditation, as well as the hybrid solution, when comparing options. These same social aspects of the technology can be the main obstacles for the adoption of documented procedures, as well as competition factors like development of new technologies and patents development in a genebank.

[2] Certification can only guarantee that the processes are done as initially described, but does not assure that the methodology is the best/most suitable one. Accreditation does the same, but in addition also does the validation of the methodology, i.e. assuring the processes used are the most efficient and effective.

b) ***SWOT analysis*** *– It is an extremely useful tool for understanding and decision-making for all sorts of situations in business and organizations. It is an acronym for Strengths, Weaknesses, Opportunities and Threats.*

Table 6. *Strengths and weaknesses of each of the four possible options to adopt*

Options	***Strengths***	***Weaknesses***
Certification	*- External commitment that forces the recording of all the processes and methods used in genebank activities* *- Regular certification of process consistency* *- Assures consistency* *- Improves users assurance of reliability and satisfaction* *- Demonstrates international recognition*	*- Inherent cost of certification fees* *- Initial implementation can demand high level of resources and commitment* *- If implemented in a highly bureaucratic restrictive manner then staff resistance could be a problem* *– Perceived inflexibility to deal with exceptional circumstances due to the rigidity of documented procedures* *- It does not necessarily verify and improve the technical competence of the organization*
Accreditation	*- External commitment that forces the recording as well as regular improvement of all the processes and methods used in genebank activities* *- Most highly regarded quality standard for an organization* *- Assures consistency plus technical competence of the processes* *- Regular revision, update and improvement of methodologies* *- Improves quality and performance and therefore users satisfaction* *- Demonstrates international recognition* *- Validation of key processes demonstrates fitness for purpose*	*- Inherent cost of accreditation fees* *- Initial implementation can demand high level of resources and commitment* *- If implemented in a highly bureaucratic restrictive manner then staff resistance could be a problem* *– Perceived inflexibility to deal with exceptional circumstances due to the rigidity of documented procedures*
Documented procedures	*- Minimal commitment is needed to document all genebank processes*	*- No external force driving the progress towards timely implementation* *- Limited or no monitoring of changes in processes to ensure documentation is updated to reflect the changes* *- Limited enforcement of necessary recording of actions carried out during the processes* *- Irregular checks for compliance* *- Irregular updates and improvement*
Hybrid	*- Partial commitment of an intermediate solution (in terms of costs, time, resources, commitment and advantages and disadvantages)* *- Based on priority definition to minimize major risks* *- Improves performance and quality of risky processes*	*- Unbalanced/distinct quality criteria for parallel activities/processes* *- External costs/effort of accreditation/certification could be the same as or even more than an overall implementation (due to the increase of number of assessment visit required from each assessment body)* *- Requires a judgment of priorities*

		and risks to determine which activities are covered by which solution

Table 7. *Opportunities and threats of each of the four possible options to adopt*

Options	***Opportunities***	***Threats***
Certification	*- Detailed documentation for staff training and capacity building* *- Matching the research quality with the current commercial trends for quality* *- Health and safety regulations do not form part of the standard but it is an opportunity to minimize risks of accidents*	*- Work may need to be adjusted (partially repeated) in the near future to upgrade into an accreditation* *- Resistance to the decision of implementation may arise, especially in genebanks with good documented procedures already established (anti-change reactions)* *- Implementation taking more time and resources than expected* *- Lack of sustainability to fully implement it or to keep it in the future (funds, resources)*
Accreditation	*- Detailed documentation for staff training and capacity building* *- Matching the research quality with the current commercial trends for quality* *- Health and safety regulations do not form part of the standard but it is an opportunity to minimize risks of accidents*	*- Resistance to the decision of implementation may arise, especially in genebanks with good documented procedures or certification already established (anti-change reactions)* *- Implementation taking more time and resources than expected* *- Lack of sustainability to fully implement it or to keep it in the future (funds, resources)*
Documented procedures	*- Base for future expansion into ISO if required* *- Detailed documentation for staff training and capacity building* *- Flexibility to adopt and test new documented procedures for some activities* *- Establishing possible inexistent or incomplete health and safety regulations*	*- The inexistence of an external obligation for completeness may jeopardize its full accomplishment* *- Adopted procedures may not be the best* *- Lack of regular peer review* *- Work may need to be adjusted (partially repeated) in the near future to implement ISO* *- It may become obsolete with possible near future trends of market and donor opportunities, requiring further upgrade into ISO*
Hybrid	*- Custom (Genebank) made according to own priorities* *- Expandable according to custom (Genebank) needs* *- Test case for further expansion into the whole genebank* *- Especially relevant to deal with emerging and increasingly risky areas of genebank management, like molecular and transgenic research or health and environmental issues related with the exchange of plant materials*	*- Failures within the linked processes with lower standard levels may compromise some of the results within the certified/accredited processes of the genebanks.* *- Work may need to be partially repeated in the near future to expand the ISO into more processes of the genebank, possibly involving some of the same technical personal of the genebank, that may have preferred to go through the ISO process all at once.*

	- Detailed documentation for staff training and capacity building *- Matching the research quality of risky procedures with the current commercial trends for quality* *- Establishing and reinforcing health and safety regulations and some opportunities for updates and improvements*	

c) ***Cost assessments*** *(Implementation and operational expenditures) - Due to the complexity of the costs, that greatly depend from each individual situation and characteristics of the genebank, it was not possible to have many concrete figures for this comparison, but some hypothetical examples are given.*

Table 8. *Estimative of costs of implementation (details of processes also given for the ISO requirements) for each option*

System implementation stages for ISO 9001 or ISO 17025 (that must be in place before the assessment visit):	**Needs**	**Details and examples**
Overall system design Quality procedure production Documentation of procedures and workflows* Introduce recording system to allow re-creation of all activities at a later stage Internal audit training Internal audit plan and implementation Production of training records Establish environmental controls as necessary Validate methodology of processes** Produce equipment records and evidence of equipment control Produce evidence of compliance	The external input required depends on the level of implementation and expertise already in place	For example, in CIP, it required a 1 year consultant (with expertise in quality systems design and implementation) effort for one person + support from other CIP staff. CIP estimate a cost of $40,000usd plus 12 months consultancy salary to achieve accreditation. For the establishment of a quality management system IPK consulting services for ca. 15 days. For the maintenance of the QM system, a QM Manager is employed for half time. IRRI estimated to have spend about $8,000usd so far in training and awareness expenses
Certification/Accreditation/	**Pre-assessment** *Assessor effort costs for each assessor (daily basis)**** *Travel + subsistence (per assessor)* **Assessment** *Assessor effort costs for each assessor (daily basis)****	*1 day x 1 person (up to 1200usd/day/person)* *2 days x 2 people (up to 1200usd/day/person)*

	Travel + subsistence (per assessor)	
Documented procedures	Documentation of procedures and workflows	The costs required to produce these depends on how much documentation exists in each case and also availability of staff to produce the documentation
Hybrid	**Pre-assessment** *Assessor effort costs for each assessor (daily basis)**** *Travel + subsistence (per assessor)* **Assessment** *Assessor effort costs for each assessor (daily basis)**** *Travel + subsistence (per assessor)*	*1 day x 1 person (up to 1200usd/day/person)* *2 days x 2 people (up to 1200usd/day/person)* CIMMYT costs for overall assessment cost $70,000usd

*Ideally this should be already in place in any genebank system
** Only for ISO 17025
****Representative from the certification/accreditation body + another assessor a (technical expert in the field, in the case of accreditation)*

Table 9. *Estimative of ongoing as well as internal costs (giving details of required steps and hypothetical examples) for each option*

Options	*General requirements*	*Detailed requirements*	*Hypothetical examples*
Ongoing costs			
*Certification/Accreditation****	*Annual fees* *Assessment visits*	*Annual fees* *Assessor effort costs for each assessor (daily basis)**** *Travel + subsistence (per assessor)*	*About 400usd/year* *2 days x 2 people (up to 1200usd/day/person)* *Depends on location* CIP estimates $25,000usd for revalidation costs
Documentation procedures	*none*	*none*	*none*
Hybrid	*Annual fees* *Assessment visits*	*Annual fees* *Assessor effort costs for each assessor (daily basis)**** *Travel + subsistence (per assessor)*	*About 400usd/year* *2 days x 2 people (up to 1200usd/day/person)* *Depends on location* CIMMYT costs for maintenance $25,000usd/year
Internal costs			
Certification/Accreditation	*Internal audits (own staff)*	*Initial audit training* *Audits* *Review process (document review)*	*2 days (1200usd/day/per trainer)* *10 days over 12 month period*

			2 days over 12 month period
Documentation procedures	*none*	*none*	*none*
Hybrid	*Internal audits (own staff)*	*Initial audit training* *Audits* *Review process (document review)*	*2 days (1200usd/day/per trainer)* *10 days over 12 month period* *2 days over 12 month period*

****Representative from the certification/accreditation + another assessor a (technical expert in the field, in the case of accreditation)*
***** Normal frequency for certification is 2 times a year and once a year for accreditation*

d) ***Study cases*** *- This valuable information was gathered from the respective genebank curators or heads of the respective laboratories. It was compiled to give an idea of the motivation, processes, benefits and current trends found on some major genebanks that opted for one or more of the four options of QMS discussed in this document*

Genebanks with Certification

Case study 1 – From partial Documented Procedures into ISO Certification (CGN) (information kindly provided by T. van Hintum)

Motivation:
- To create transparency of its organization, definition of responsibilities and operations.
- To improve the reliability of operations.
- To improve the efficiency of the organization.

Process:
- A quality manual was developed and many unknown gaps were identified where no internal rules had been discussed or agreed before. (No shared awareness existed on several practices.)
- With the help of an external specialized company the required documents were prepared and the certification was applied and achieved.

Benefits:
- It was highly rewarding and it gives a clear picture of how the organization is run (what is done and how)
- Procedures can be discussed and improved where appropriate
- New staff can easier be introduced in the procedures, and guests and colleagues can easily find out how things are done and organized.
- Funding agencies and external collaborators have guaranties for the quality of the genebank, and often donor agencies tend to require externally certified quality system to be implemented as a condition for funding.
- Facilitates effective collaboration between genebanks, since it creates a basis of reliability.

Trend: Help/convince other genebanks to follow similar routes.

Case study 2 – From partial Documented Procedures into full Documented Procedures and then into ISO Certification (IPK) (Information kindly provided by A. Graner)

Motivation:
- Write down all the procedures that existed, mostly in the genebank curator's personal experience.

Process:
Initially established a QMS in 2005 and about 30 months later decided to move into ISO certification and now holding an ISO 9000:2001 certificate for the whole genebank department (including the research groups) as well as for the administration of the Institute (which has 3 additional departments doing research only).

Benefits:
- QMS has become a centerpiece of the daily genebank management.
- The identification and description of all major processes of the management and research on genetic resources helped to secure know how, increase transparency, assign responsibilities and to initiate further improvements. E.g. one of the outcomes of the establishment of a QMS at IPK is the regulation of co-existence of genetic resources. The corresponding regulations prevent admixtures of transgenic seeds, pollination of genebank regenerations with transgenic pollen and minimize the risk of introducing transgenic seeds from abroad.
- While the QMS does not warrant superior quality per se, it represents an efficient mechanism to identify shortcomings within the system and provides appropriate tools for improvement. In this way the QM contributes to the sustainability and accountability of a genebank operation - two very important parameters essential for the implementation of international efforts towards the conservation of genetic resources.

Trend: Help/convince other genebanks to follow similar routes**.**

Comments on genebanks with Certification: Both organizations felt there was an obvious benefit from undergoing certification to ISO 9001 and the key motivation that was a very clear idea on how the whole organization operates and also identifying and resolving shortcomings in the operations. The IPK case is a good example of a stepwise transition to first documenting the processes and then eventually seeking third party verification through certification. Information from Table 1, mentioning certification of four genebanks in the islands linked to the Macaronesia region with ISO 9001 since 1996, shows the relevance of these procedures even for small operational genebanks like those.

Genebanks with Accreditation

Case study 3 – From partial Documented Procedures into full ISO accreditation (CIP)* (information kindly provided by D. Galsworthy)

Motivation:
- The initial objective of establishing a quality system was to formalize the CIP genebank systems for the acquisition, maintenance and distribution of germplasm in light of reducing the risk of distributing infected material and material of the wrong genetic source.

Process:
- CIP was advised that the workings of the genebank would lend themselves to the introduction of a quality system, the process of distribution and quality control could then be validated and that system subjected to third party verification through accreditation. CIP management took the bold and forward-looking step of agreeing to fund this project and hired a consultant for one year to lead the project in Lima.

- A careful choice of quality standards was done for the structure of the system at CIP and third party

verification was made. The technical competence and validity was demonstrated through the ISO Standard 17025 with the assessment and accreditation being carried out by expert technical assessors. This was agreed with the CIP management and the structure of the quality system was modeled on the contents of ISO 17025.

- The management of the project documentation was initially started through a web site, allowing easy access for staff of the 3 different areas of activities (genebank, administration and virology) as well as remote access for the Accreditation Body. This turned out to be an incredibly efficient way of working and was a major contributor to the success of the project as well as cost saving.

- The project built on the considerable work of the previous few years at CIP, formalizing workflows and information recording as well as the introduction of bar coding for scanning accession identities, describing all the activities of the germplasm acquisition, maintenance and distribution. Audit training for CIP staff was carried out and an audit programme introduced. The performance of the equipment and environment was then established and staff training and competence records were also established and all equipment brought within an equipment records system.

- The effectiveness of the pathogen screening process was validated; results were statistically analyzed and showed the effectiveness of the systems.

- Accreditation against ISO 17025 standards was sought after a year of work, from United Kingdom Accreditation Service (UKAS), assessed by two experts for two days and the accreditation was awarded after one month.

Benefits/keys for success:
- Systems in place were highly efficient and bureaucratically very lean
- Staff were involved totally with the documentation and implementation of the systems
- The validation of the processes immensely improved efficiency of the germplasm pathogen screening process
- Final system had complete staff ownership allowing sustainability and ability to drive forward future improvements
- Being granted accreditation from a highly respected body gives the users of the genebank a level of confidence that the material is clean and of the right genetic source that has never been possible before.

Trend: Provide guidance and support as a role model/case study for other CGIAR genebank initiatives.
* - see annex 2 for more details.

Comments on genebanks with Accreditation: This was the first case of ISO 17025 accreditation for an entire genebank operation in the world, proving that this was possible to implement in the complex system of genebanks. The decision to implement this quality system and gain accreditation was taken in response to a clear identified risk that would be minimized with the implementation of a quality system.

Genebanks benefiting from accredited portions of processes within the organization

Case study 4 – From partial Documented Procedures into a hybrid of ISO accreditation and full Documented Procedures (CIMMYT) (Information kindly provided by M. Mezzalama)

Motivation:
- The accreditation with ISO 17025 is a requirement of the Mexican Phytosanitary authorities for any

testing laboratory that operates in Mexico to certify seed health for importation and exportation, therefore also CIMMYT seed laboratory had to follow this regulation.
- Establish an ISO accreditation for the seed health laboratory, covering the procedures for all germplasm handled by CIMMYT, including genebank accessions (the laboratory is not part of the genebank system, but represent a point of control for the genebank system as well as for the breeding programs).

Process: The seed health laboratory was approved under the Mexican Phytosanitary norm *NOM-036-FITO-1995* since 1998 to be able to operate as seed testing laboratory. This means that operations and methods were already monitored at a national official level every two years for renewing the approbation and every year because of the external audit processes carried out by Mexican Phytosanitary authorities.
When the ISO requirements came into force as a condition to renew the approbation according to the Mexican norm mentioned above and to the *Ley Federal de Sanidad Vegetal* 1994, (Federal Law of Plant health) updated in 2007, CIMMYT Seed Health Laboratory started the accreditation process.
The preparation for applying to the ISO 17025 accreditation started in June 2006. The laboratory was already operating in a Standard Operational System (SOP) due to the reason explained above, but it was lacking of the documentation supporting it. Therefore the majority of the efforts went into the preparation of the documents supporting the quality system and training of the personnel to operate under ISO 17025 standards. The application was submitted to the Accreditation entity in October 2006 and accreditation was granted on April 10, 2007.

Benefits: The possibility to test all CIMMYT maize and wheat seed in house, under strict quality control measures; the guarantee for collaborators that the seed is tested under recognized and monitored procedures; the guarantee for Mexican government that CIMMYT operations do not jeopardize the phytosanitary situation of Mexico.

Trend: Maintenance of the accreditation, possibly upgrading of the actual accreditation with new detection methods (depending on funds available).

Case study 5 – From partial Documented Procedures into a hybrid of full Documented Procedures compliance with requirements of ISO management standards (IRRI) (Information kindly provided by B. Marichu)

Motivation:
- Having achieved the first certification (ISO 14000 for Environmental Management System (EMS)) in 2007, IRRI will strive towards improving QM across the institute by using the framework of relevant ISO standards in a number of other operations, without necessarily seeking certification.

Process:
- Developing a QMS embracing the whole institution, applying different ISO standards for the different organizational units, according to their various specifications and requirements.
- The main criteria to choose the various types of ISO standard were the risk and quality requirements of each unit or activity.
- The first ISO certification was the ISO 14000 for Environmental Management System (EMS) on the Experimental stations.
- Currently in the process of deciding compliance with requirements of ISO 17025 for laboratories and all technical activities of the genebank as well as the ISO 9001 for all genebank management activities and any support/administration units, OHSAS 18001 for Occupational Health and Safety management systems; ISO 9003:2004 for Computer software, ISO 27001:2005 for the Information Security management system.

Benefits/disadvantages:
- The main benefit regarding the Environmental Management System (already accomplished), was the enhanced reputation among stakeholders in terms of providing quality support and services related to

Experiments Stations and farm processes.
- The high cost of implementation was the main disadvantage observed.

Trend: Improving internal quality assessment processes (possibly applying ISO) and practices according to each risk, quality requirements and opportunities. Leave less relevant areas with only full Documented Procedures (i.e. most process of the ISO certification without the final certification steps).

Comments on genebanks benefiting from accredited portions of processes within the organization:

In the CIMMYT case the primary driving force for the accreditation of the Plant Seed Health Laboratory was the Mexican Government demanding that seed testing laboratories be accredited to ISO 17025. This is an example of an external force compared to the previous cases of internal motivation. In the case of IRRI, feedback suggested that the organization has recognized the need to improve the quality systems across a whole range of activities including the genebank and they are looking to an institutional wide solution to this issue.

Genebanks looking at possible options

Case study 6 – Deciding where to go from partial Documented Procedures (Seed genebanks South Africa) (information kindly provided by A. Lezar)

Motivation:
- Establish an ISO certification or accreditation for the seed genebank, for better consistency, quality and performance.

Current situation and trends:
- The management of genebank collections is highly decentralized and closely linked to research institutes of particular crops. However at the national level measures have been taken moving towards ISO application on all their genebanks. In the ongoing development of the Draft National Gene Bank Management Strategy for South Africa, some of the key actions are recommending that:

a) All gene banks should have quality assurance systems, clearly documenting procedures and protocols to follow for each gene banking activity.

b) All gene bank managers (curators) should be in possession of an ISO 9000 qualification to enable them to implement and manage a quality assurance system.

The following areas of priority were defined (almost all the procedures of a genebank):
- Distribution (Access control)
- Archiving and core collections (large collections)
- Relationships between breeders' collections and active collections
- Procedures for maintaining the most original sample, seed processing (purity), drying and health
- Storage conditions, accession size in storage and viability testing
- Multiplication, regeneration, documentation and security of collections

Case study 7 – Deciding where to go from partial/almost full Documented Procedures (Vegetable and Ornamental Plant Institute - *In Vitro* Genebank - South Africa) (information kindly provided by A. Lezar)

Motivation:
- Establish an ISO certification or accreditation for the *in vitro* genebank, for better consistency, quality and performance.

Current situation and trends: They have no formal QMS in place at present, but have certain quality control measures already in place such as:

- Document control (records on: Orders, Written consent, Phytosanitary certificates, Import permits, Invoicing, Disease status)
- Records control (Personnel time sheets, Chemicals used, Media prepared, Production sheets, Validation/calibration certificates for equipment, Purchases)
- Processes control (Production sheets, Multiplication rates, Contamination rates, Production schedule, Consumables, Cross checks, Computerized labeling, Duplication, Visual checks, Rejuvenation (max 18 generations))
- Equipment control (Validation of benches, Calibration of balances, Calibration of pH-meters, Performance of autoclaves, Cleaning and servicing of air conditioners)
- Internal Quality control (Laboratory checks (Monitor growth rooms and growth chambers), Visual checks, Bacterial screening (Nutrient Broth Test))
- External Quality control (Disease testing (viruses), DNA profiling)

Case study 8 - Deciding where to go from full Documented Procedures (Australian Temperate Field Crops Collection (ATFCC) (information kindly provided by B. Redden)

Motivation: Reach a higher level of quality for genebank operational procedures

Process: ATFCC developed its operational procedures manual in 2007 partly modeled on CIMMYT and CGN genebanks.

Benefits: Writing down all the important procedures to carry out genebanks activities

Trends: Possibly seeking further ISO certification or accreditation if/when funds are available

Case study 9 – Keeping the Documented Procedures – Plant Gene Resources of Canada (information kindly provided by K. Richards and A. Diederichsen **and Nordic Gene Bank** (information kindly provided by Louise Bondo)

Motivation: Focusing their attention and limited resources on conserving and maintaining quality germplasm and relevant information updated.

Process: Following the standards documented in several publications e.g. by Bioversity (IPGRI, IBPGR), International Seed Testing Association, that provide advice and important information on relevant aspects of the genebank work. Currently in the process of implementing all administrative changes to comply with the International Treaty on Plant Genetic Resources. ISO possible alternatives discussed earlier and reached the conclusion that the guidelines were not so useful, since they only recorded how things were done but did not guarantee that the work was well done.

Benefits: Saving as much as possible the limited time, energy and resources.

Trends: Do not undergo any certification or accreditation, for the time being, due to limited resources

and other priorities.

Case study 10 – from a diverse status into a common platform – Quality Management System for AEGIS (A European Genebank Integrated System)* (information kindly provided by J. Engels)

Motivation: Establishment of a quality management system and the elaboration of quality standards across Europe, in order to allow the establishment of a virtual but integrated European genebank system that builds on task and responsibility sharing

Process:
- Initiate a wide discussion within ECPGR (European Cooperative Programme for Plant Genetic Resources) and its various bodies, actively participating in the shaping and establishment of AEGIS based on the signing of a Memorandum of Understanding with each country and within countries agreement between the National Coordinator and the collaborating genebanks/collections and subsequently the management of the European genebank system
- Draft and agree on crop specific technical standards and generic management standards
- Coordinate implementation
- Promote improvement and increased coverage
- Survey the institute's capacities and availability
- Delegate responsibilities for the implementation plan

Expected benefits:
- Increase transparency and mutual trust
- Increased collaboration and task sharing
- Collections managed more effectively and efficiently
- Improve the quality of conservation activities
- Re-allocation of funds to other pertinent but often neglected activities

Expected trend:
- Same quality level across institutes and countries, to allow trust and confidence on each others
- Sharing responsibilities between countries and associated institutions within and between countries

More information on their website
*(http://www.ecpgr.cgiar.org/AEGIS/Meeting_Poland0708/QMS_draft.pdf)

Comments on genebanks looking at possible options: There is a perception that either certification or accreditation are expensive and will divert resources away from key genebank functions. Many genebanks are looking for solutions requiring minimal resource input. Some genebanks have clearly expressed an interest in seeking certification / accreditation of the genebank activities but presently feel there are not the resources to support this. In the case of AEGIS platform there is a minimal standard to be reached by each of the member genebanks to ensure confidence on the future collaborative activities and to allow the establishment of a common platform of standards for genebanks collaborating as part of a Regional Network.

Laboratories with experience of dealing with similar issues to genebanks

Case study 11 - Central Science Laboratories (CSL) has ISO 9001 for the overall operation of the facility and the provision of research and development services. It has accreditation to ISO 17025 for specific testing methods covering chemical analysis and plant health diagnostic

(information kindly provided by D. Galsworthy and R. Weekes)

Motivation:
- CSL is an innovative and influential centre of excellence in the sciences underpinning sustainable land use, safe food supply and environmental issues, and a contractor of choice for a broad user community.
- The key motivation for QS implementation has been the demands of the users and the purpose of the work being carried out.

Process: Quality systems have been developed over a period of about 20 years. Food testing analysis carried out using test methods accredited to ISO 17025. Recently plant health diagnostic techniques have been added to the schedule of accreditation to ISO 17025, being one of the first laboratories in Europe to accredit these types of techniques. Research is carried out within an ISO 9001 certified quality system framework. Work carried out for safe registration of agro-chemicals is carried out to the requirements of the Good Laboratory Practices (GLP) legislation. Seed testing is now carried out under accreditation by the International Seed Testing Association (ISTA). The overall organization has been certified to both ISO 9001 and ISO 14001.
Benefits:
- Giving their customers complete confidence in the reported results.
- Satisfying specific customer requirements
- Improvements to existent Standard Operation Procedures (SOP), equipment files and processes such as Quality Control checks on reagents.

Trends: It was the first group in Europe to have plant diagnostic methods accredited to 17025 and has established a strong training component providing training courses on relevant fields (pesticides residues in food; uncertainty of measurement and sampling GMO detection in food), providing in addition to the technical aspects of the detection, additional learning about the application of ISO 17025 standards to test protocols.

Case study 12 – From partial Documented Procedures into ISO certification and later on into ISO accreditation – (Rtech Laboratories, US) (information kindly provided by J. Honsa)

Motivation: They were first certified in 1996 to ISO 9002:1994 (there was no adequate accreditation standard available then) and later accredited to ISO 17025 in 2001, incorporating an overall system for an effective technical and quality management system, that resulted in daily benefits for laboratory practices (Honsa and McIntyre, 2003).

Process:

a) Implementation

1) Began with documentation of all analytical, administrative, and quality processes to meet the requirements of the ISO 9002 standard.
- Personnel was trained and written methods incorporated into a control system
- Equipment was identified and calibration requirements determined
- After all processes were documented the laboratory lived by the system
- Evidence of compliance was provided by the records
- Audits identified issues to improve compliance and documents were revised to accurately describe processes, as needed. After adequate evidence of quality system compliance an ISO 9002 registrar was chosen, the lab was certified and audits took place every 6 months to maintain the certified status

2) Upgraded to implement the ISO 17025, with an internal gap analysis of the current system (ISO 9002) against the 17025 standard.

- Most management requirements were fulfilled and necessary small changes were made (written response to clients; Results to include enough information to allow repetition, including equipment information, methods and conditions)
- Many more changes needed to meet the technical requirements:
  - o Review of analytical methods
  - o Sampling plan
  - o Quality control trending
  - o Method uncertainty procedures
  - o Template to approve new methods
  - o Procedures to report results

b) Maintenance

- Coordination and monitoring the completion of the required actions and meticulous record keeping

- Elements providing continuous improvement:

Corrective and preventive action
Internal audits at predefined schedules
Management review meetings
Document review and revision
Training status
Accessible records
Daily quality control
Proficiency testing of all process
Method approval
Equipment calibration and maintenance schedules
Purchasing and supplier performance

Benefits:
- Faster identification and resolution of issues regarding methods, personnel or equipment,
- Improved customer satisfaction, meeting quality requirements of specialized customers
- Overall increased laboratory business

Trend: The real benefits from operating a quality system begin after the certification process, were proper maintenance of the system is required to uncover relevant issues and constantly improve.

Comments on laboratories with experience of dealing with similar issues to genebanks: In the case of CSL, the organization would not be able to carry out the majority of its work without having fulfilled customer requirements for quality system implementation. The comment from both organizations is that without some form of external review and internal audit it is hard for an organization to maintain the discipline to achieve a high level quality of service and critically maintain that level consistently over a long period of time.

Discussion

This section discusses the PEST (Section a) and SWOT (Section b) analysis presented above, putting together the possible benefits (users comfort and satisfaction, external image, health and safety compliances) requirements (Section c: resources, time to achieve, maintenance costs, initial cost to implement) and obstacles, incorporating examples from case studies (Section d), from the perspectives of quality, costs, effectiveness and risks, which are the main areas of concern in the operations of any genebank or any other business.

Quality

Considering quality improvement and assurance as well as the routine of regular updates and efficiency, accreditation is the best option for genebanks (recently achieved for the entire genebank, shown in case study 3, of CIP), due to the fact that accreditation involves the assessment by technical experts in the specific field.

This is followed by the hybrid solution, providing the right choice of accreditation in critical areas in a genebank is adequately addressed and defined. Certification is the third best option in terms of quality, since this does not necessarily involve technical assessments, but generally mostly assures consistency on the methods and procedures over time. Feedback from genebanks study cases 1 and 2 (CGN and IPK) showed a high level of commitment to the ISO 9001 certification process with the feelings that certification has added great value to the quality of the service being provided as combined with a high level of satisfaction with the overall certification process. The Documented Procedures can generally be classified as the fourth best options for quality, because there are usually no regulatory bodies that would reinforce the routine implementation of predefined procedures and methods. Nevertheless, this would greatly depend on the commitment and capacity of each organization.

Costs

All organizations are constantly trying to improve quality while balancing efficiency and cost. The costs implied in Accreditation or Certification could encourage organizations to opt for intermediate solutions that combine the highest level of quality assurance for the most critical operations with some cost-savings by using documented processes for other procedures with lower levels of risk or costs. Care should be taken when considering the options available since specific costs are made on a case-by-case basis by the assessment bodies concerned and this depends on the level of effort required for the assessment process. Very often there is an efficiency saving if an overall assessment is made for the whole process rather than two or three individual units that operate separately. This is shown with similar running costs estimates from CIMMYT (hybrid accreditation only for the plant health unit) and CIP (entire genebank accreditation) in Table 9.

Accreditation and certification bodies operate a similar cost structure (Table 8 and 9) for assessment visits and fees that relates directly to the onsite effort of the assessment process. Regarding implementation costs in terms of time and possible resources, accreditation is probably the most costly. This is mostly due to the fact that validation data would have to be generated to demonstrate the performance of the processes concerned.

If long-term costs are considered, attention must be paid to the costs of potential upgrades from certification to accreditation or from Hybrid to full QMS implementation if these are envisaged in the near future. An apparent short term less costly solution could become a more costly in the long term. A good example of this stepwise process using the three options presented here is shown from the experience at IPK (case study 2) and Rtech labs (case study 12). Unfortunately it is difficult to estimate how much each upgrade would cost. However, regardless of the costs the final situation is beneficial and greatly improved their work and revenues. Table 8 shows estimates for initial costs for two distinct levels of accreditation from CIP (entire genebank accreditation) and CIMMYT (hybrid accreditation only for the plant health unit) that are not so different.

Effectiveness

Regarding the timely and efficient recording of all the processes of the genebank, either certification or accreditation is the best option to guarantee and enforce full and adequate implementation. This is followed by the Hybrid solution that will guarantee it but only partially. One of the possible disadvantages of using the Documented Procedures approach is the lack of a regulatory body to monitor full and timely implementation. Strong genebank management that enforces though regular checking adherence to Documented Practices can improve the QMS in resource poor situations where more effective methods cannot be employed. Case study 1 (CGN) is a good example of the benefits of 'being forced' to write and document all genebank procedures.

The Hybrid solution could be an effective option, where the accreditation of a few areas of the genebank could be in place for a while and more areas would need to be accredited in the future, allowing flexible/smooth and gradual stepwise upgrades. CIMMYT (case study 4) applied this approach to deal with the demands of the Mexico government.

Case study 9 (Plant Gene Resources of Canada and Nordic genebank) are examples of good systems already in place for documented processes and therefore they consider that there is no need (there are no obvious incentives to do it, considering the cost that is implied) to implement any further upgrades for the time being. In these two cases, the high level of resources estimated to be required for the implementation of ISO certification or accreditation did not justify the apparent potential improvements when compared with the Documented Procedures presently in place.

Another important aspect for the CGIAR, perhaps sometimes more important than or at least as important as the use of QMS in individual genebanks, is the establishment of a common platform of QMS. In these cases, the decision of which documented procedures to establish or the decision to use an ISO solution is a collective one. In this case the genebanks not only have to agree and comply with a specific (previously agreed) set of standards but also have to assure the sustainability of that decision for their collaboration in the future. Case study 10 (AEGIS network) is a pioneer to establish this platform that is still being discussed.

Risk assessment

It is the likelihood and impact of each possible risk (Insufficient funds available, insufficient human capacity, process stopping before reaching the end, more time than expected, social cultural barriers, anti-change reactions)

The risk in any of the four options is to decide to start a QMS but then not be able to finish the implementation process. It is very important to ensure that the quality system design and the plan of implementation is carefully considered in order to implement systems in the most efficient manner using the resources available for this task. In the case of ISO certification and accreditation, careful consideration should be given to the full range of options available for implementation. These will include sources of knowledge from already certified or accredited organizations and consultancies as well as the choice accreditation/certification body. This is particularly important for those genebanks that have not made a decision on their quality system implementation, as seen in the cases described from South Africa (case studies 6 and 7) and Australia (case study 8). Case study 5 (IRRI) is an example of distinct steps being implemented at different paces for each operation, not only in the genebank, but the whole research organization. This hybrid combination could have the advantage to be used for particular critical aspects like health and safety regulations. However, a major risk when deciding on a wide range application of ISO 9001 is the possibility of taking more time and resources than expected as well as lack of sustainability for the future.

Once the system is implemented the risk is that the systems will not be followed effectively. ISO accreditation or certification provides regular monitoring and enforcement and therefore minimizes this risk.

The current trends in areas of technical service provision are to raise the level of assurance in the quality of services provided through third party verification. Therefore any choice of option for a quality system that has no or limited third party assurance may not in the future meet the demands of regulatory authorities, donors and users. The full commitment documented in Documented Procedures for example, would not be sufficient in the near future if tighter regulations are in place. However, with more time, work and resources most of the documentation already in place can be used to develop or implement an ISO compliant QMS. Case study 2 (IPK) is a good example of this situation, and although it was a risk, they do not regret implementing it.

Conclusions

A few genebanks have implemented either ISO 9001 or ISO 17025 compliant QMS. The ISO 9001 is more related to administrative and management matters and is being applied and improved all over the world in numerous fields; while ISO 17025 covers technical methodologies and procedures, and is widely implemented worldwide in laboratories. Experience on the implementation of this ISO is therefore available. This standard appears very suitable and applicable for many of the activities of genebanks, as many processes involve laboratory methodologies and procedures such as sample handling, routine analysis and testing as well as research experiments.

Regarding the PEST analysis of most important external factors, certification and accreditation were both grouped together for their political, economical, social (mostly outsiders like users, public opinion and donors) and technological (specifically from the users and donor perspective) distinct advantages, followed by the Hybrid solution.

However, the major social detrimental factor linked to the adoption of any of those four options (stronger for the accreditation) is the possible lack of support and time required to produce the documentation. This should be routine work of genebank managers that would ultimately be the main executors of any required changes. However, the perceived levels of documentation and surveillance needed for ISO accreditation and certification discourage some genebank managers to even consider these options. In this regard, the Documented Procedures could be the most easily applied solution for many genebank staff and managers.

Still within the PEST analysis, from the technological point of view (independent from any users or donor perspective), accreditation would be the best option. This would guarantee the highest level of quality implementation, maintenance and improvement. The Hybrid solution could the best next option, if accreditation would be applied to the most critical and risky procedures of a genebank system. From the same technological point of view, either certification or good Documented Procedures would be at the same level of last options to be chosen, although certification would have the additional assurance for consistency.

When weighing the strengths and weaknesses (Table 6) or the opportunities and threats (Table 7) (SWOT analysis) of the intrinsic characteristics of the four options, and looking at the various study cases already implemented, the following trend was observed:

- The highest level of quality assurance as well as the most prestigious is achieved with accreditation but that comes together with higher financial cost and a potentially heavier

commitment of human resources and time. An intermediate and possibly equally good option is the Hybrid option, with careful choices of critical areas.

- The least costly solution appears to be the Documented Procedures. This and the Hybrid solution have also the possibility to be upgraded into any of the other full certification and accreditation ISO solutions at a later stage, allowing for a gradual change.

- Both accreditation and certification warrant advantageous competition for funds availability and users trust and confidence and at a lesser extent the Hybrid solution as well, depending on how it is implemented.

Regarding risk analysis, all four have their own risks, depending on the particular conditions and status of each genebank and/or their laboratory related areas. Most risks relate to the availability of human resources and the ability to complete the implementation process as well as maintaining established commitments. Risk may be increased in the case of the Documented Procedures option since there is no drive towards a definite end point, such as gaining accreditation or certification. A further risk is the lack of funds available for the full implementation of ISO (certification or accreditation) or Hybrid solution.

As a general conclusion, the Accreditation would be the best option from the technical and social point of view, as long as sufficient and human resources are available and fully committed (mainly genebank staff), to minimize the risk of failure to accomplish and achieve the workload.

Certification or the Documented Procedures would be the more general options that would not be the best technical choices, especially for genebanks or laboratories with specifically critical and risky areas. The case studies 1 (CGN) and 2 (IPK) given in the document provide good evidence that the certification process has strengthened the quality of the operation of their genebanks. Depending on the commitment of each genebank and their interpretation/implementation of Documented Processes, it is possible to obtain a level similar to that achieved through certification. However, because there is no external verification process there may be less pressure to achieve the required standards.

The Hybrid solution would be a complicated solution, but with the possibility of flexibility through risk/vulnerability based choices. This is would be a gradual option to deal with issues of availability and commitment of human resources. This Hybrid solution could be a possible approach to start with the accreditation of some of the processes just not to embrace too much at the beginning when the experience with accreditation is limited, and this would be a flexible option, provided the other areas of the genebank have established Documented Procedures.

It is clear from the positive feedback from the examples and the potential risk of the distribution activities of the genebanks, that the choice of not implementing any form of quality system is not an option. Therefore all genebank operations need to meet a minimum requirement for quality assurance and the level of this assurance needs to be set taking into account risk as well as available resources.

Recommendations on the implementation of QMS

A) Genebank level

Although examples of ISO compliant QMSs are still limited for genebanks, we now know that certification to ISO 9001 (IPK and CGN) and accreditation to ISO 17025 (experience from CIP)

are possible. The feedback from IPK and CGN has been very positive about the benefits of formalizing the genebank systems in such a way that certification was possible. The same is also true for the CIP case, where it required commitments at all levels of the organization. In this case accreditation was achieved within the timeframe of one year. The adoption of a wiki knowledge management platform to gather all the information on the CIP genebank operation was a critical factor for their success. This emphasizes a key point of designing a system that is fit for purpose and it is not too bureaucratic.

The level of implementation of any quality system in a genebank is definitely dependent on the individual conditions of the genebank. This includes the staff, especially the manager, location, major limitations such as staff resources as well as main short, medium and long-term priorities. The time, efforts and costs that are required to establish any quality system in a genebank will be strongly dependent on how much of the system already exists. This varies greatly within not only CGIAR genebanks, but also other genebanks, as shown in Table 1. The fact that most genebanks only have partially Documented Procedures shows the urgent need to improve this situation. In order to minimize risks in conservation and management of germplasm one of the four options presented here must be applied.

Recommendation 1

The adequate and effective functioning of any genebank, particularly a CGIAR genebank can only be guaranteed on a long term basis if an adequate QMS is in place.

Recommendation 2

a. If a genebank has enough (or can raise enough) resources, it should opt for one of the ISO, preferably the ISO 17025 for the whole genebank system or at least for the most critical areas of the genebank.

b. If a genebank does not have enough resources (financial, human or technical), should at least opt for the full documentation of procedures and prioritize areas with higher risk and possibly implement an ISO hybrid solution (preferably for the ISO 17025) as a short term solution.

Recommendation 3

After taking in consideration recommendations above, it is recommended that the genebank community follows the stepwise approach:

1) Evaluate the external factors

Seek information regarding any possible external factors that can pre-impose certain rules (e.g. increasingly country and regional regulations on genetically modified crops or movement of germplasm) which can set the minimum criteria to follow or donor/user requirements for the near future in each genebank.

2) Evaluate the internal factors

Internal factors of relevance include: the present level of implementation of QMS, resources available for implementation and knowledge gaps.

3) Evaluate appropriate QMS model to apply

Evaluation will include: gathering experience of other genebanks, assessing the expertise of genebank staff, exploring the availability of consultants, opening the dialogue with relevant accreditation and certification bodies to assess their experience and reputation in terms of the capability to provide a good service for the assessment of the genebank system.

Part of the evaluation will involve gaining an understanding of the requirements of the quality standards. This may need the help of a specialist. It is extremely important to learn before the implementation of the QMS what the quality standards are asking for, in order to ensure compliance. This will determine the complexity and the amount of work required and may vary from genebank to genebank depending on the crop stored and on the desired quality level of the operations. This can also make a considerable difference in cost estimates for each genebank.

4) Decide on QMS options

Based on the above information, then the specific components of the quality system can be decided upon. A core component of this as a minimum would be a full documentation of the genebank operation. The other components of the QMS would align themselves with the content of the ISO 9001/ISO 17025 quality standards.

5) Formulate an implementation plan

The overall implementation plan should include: objectives, milestones and responsibilities for all the key areas of a QMS. The list below is given as an example of the overall plan for an organization seeking accreditation to ISO 17025.

- Overall system design
- Quality procedure production
- Documentation of procedures and workflows (ideally this should be already in place in any genebank system)
- Introduce record system to allow re-creation of all activities at a later stage
- Internal audit training
- Internal audit plan and implementation
- Production of training records
- Establish environmental controls as necessary
- Validate methodology of processes
- Produce equipment records and evidence of equipment control
- Produce evidence of compliance

6) Implementation

Implementation should be regularly reviewed to ensure milestones have been met.

7) Obtain 3rd party verification if desired/required

This is only applicable for the certification to ISO 9001 or accreditation to ISO 17025. The normal process would involve the initial dialogue with the certification/accreditation body, pre-assessment visit, then assessment visit and finally the award of certification/accreditation.

8) Ensure maintenance of the system

The system needs to be regularly reviewed to ensure it is being adequately maintained. This includes regular surveillance visits in the case of certification or accreditation.

Figure 1 shows a schematic decision tree to implement Quality management systems for genebank operations.

B) Overall genebank community (aspirations for the future)

CG genebank system

It has been generally agreed that some kind of quality management system needs to be in place to minimize risks as well as a providing a means of checking genebank performance indicators. The drivers to this within the system is the collective CG global conscience, striving for the highest standards possible for the services provided by the CG as well as meeting external demands from key stakeholders such as the donor community. This would elevate the genebanks to a higher level of recognition and respect.

Other genebank networks

Information gathered from the Study Cases show a trend towards genebanks restructuring and organizing as national or international networks. Examples of this include Europe (AEGIS), South Africa and Australia. The organization through a network gives a good opportunity to collaborate and harmonize around the implementation of an appropriate QMS.

An important area that needs increasing coordination and continual updating is new innovations and software. Common criteria for quality are essential for:

- Creating on-line search query databases linking evaluation data to accession entries - these databases can integrate data from other genebanks for a more complete file on phenotypic expressions in various environments.
- Evaluation databases can become a virtual world genebank, across world genebank inventories and multiple sources of data - a role suited to the CGIAR gene banks, but separately hosted for other crops e.g. *Brassica sp*, peas, etc.
- FIGS software matches accession GPS with associated climatic / soils data enabling searches for genetic variation tolerant of abiotic / biotic stresses.

- Establishing links to molecular databases, which are potentially so massive that they need to be separately managed, however a capability will be needed for phenotypic data bases to "talk" to molecular databases.

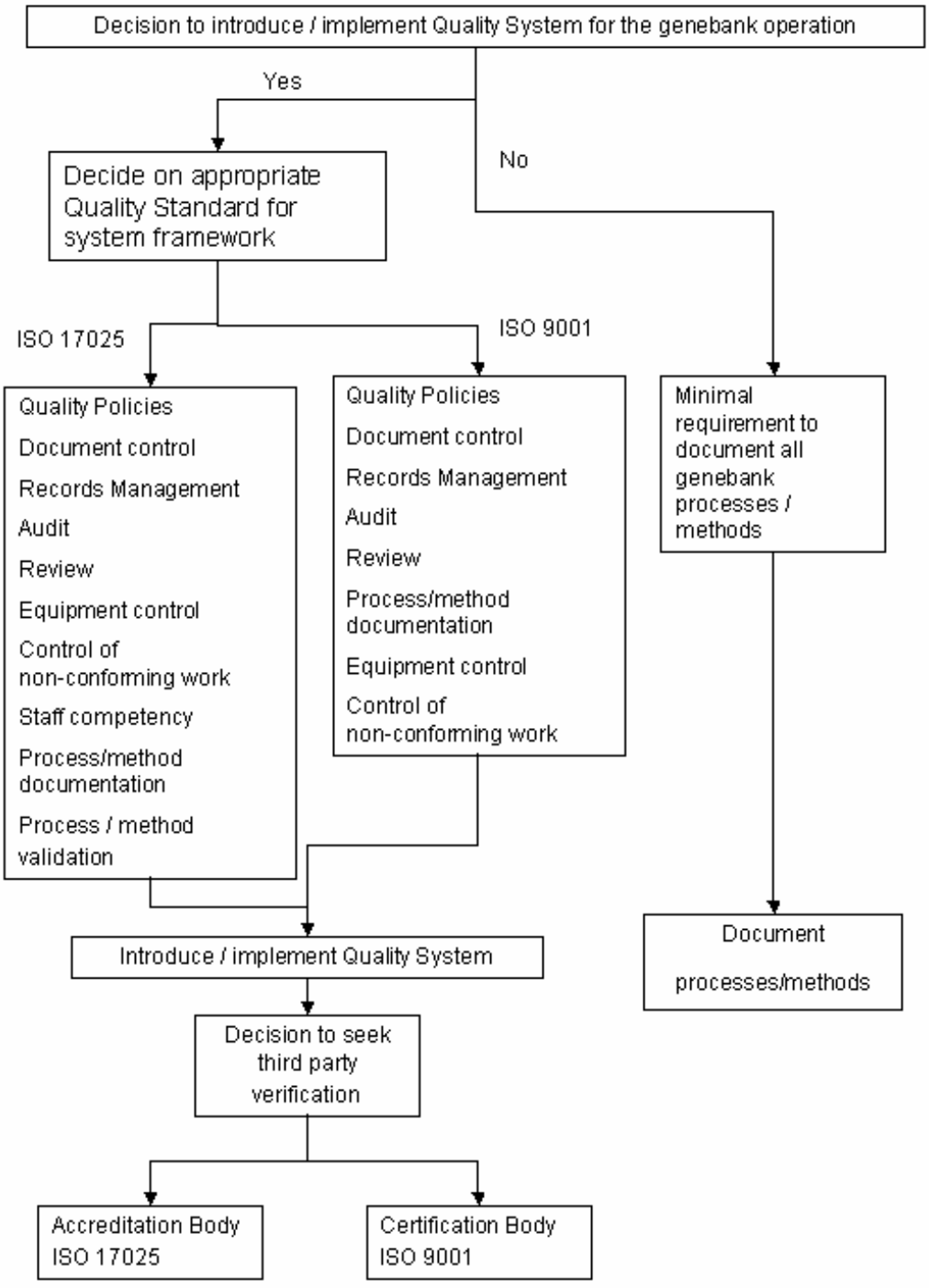

Figure 1. Decision tree to implement Quality systems in genebank operations.

Collaboration on quality system implementation

A clear identified risk in the report is the lack of resources for quality systems implementation. There are already examples of genebanks who have successfully applied ISO compliant QMS to the genebank operations. Therefore there is already a good knowledge base to utilize in order to help other genebanks to initiate the implementation of their systems. That would mean that implementation time / costs could be minimized and be focused on the specifics of the operation of the each of the banks (maybe utilizing common best practice procedures where appropriate).

Global approach to assessment of genebank quality systems

The operation of genebanks is highly technical. In order to ensure the assessment/accreditation process gives assurance of the technical validity of the genebank processes, the desired assurance to users as well as value added in improvement of operations a dialogue should be started with the organizations that oversee the accreditation / certification process. This includes organizations such as the global body International Laboratory Accreditation Cooperation (ILAC) and the European co-operation for Accreditation (EA) body. This dialogue would cover how the accreditation bodies could deal with the assessment of the global genebank community. Issues for discussion would include how to ensure appropriate assessor selection and ways of dealing with many organizations in developing countries that do not have a suitable national accreditation body.

Recommendation 1

It is essential that all the CGIAR genebanks implement a collective action to develop a quality system that is fit for purpose for the short and long term conservation of germplasm of the respective genebanks.

Recommendation 2

After reaching a common consensus, the CG genebanks should approach the relevant certification or accreditation bodies that can provide a formal quality assurance, looking for the adequate provider and the most appropriate quality system to implement the conservation of seed collections, *in vitro* collections field collections or other types of collections as a whole, but maintaining the necessary specificity for each crop or conservation method.

Authors

This document was prepared by M.A. Jorge (Bioversity International/ILRI, Addis Ababa, Ethiopia) and D. Galsworthy (Central Science Laboratory, CSL, York, UK)

Acknowledgements

We would like to thank the invaluable help and commitment from Bernardo Marichu (IRRI), Bob Redden (ATFCC), Ian Barker (CIP), Jan Engels (Bioversity International), Jean Hanson (ILRI), Julie Honsa (Land O' Lakes Analytical Laboratories, US), Louise Bondo (KULUK consult ApS), Monica Mezzalama (CIMMYT), Rebecca Weekes (CSL), Theo van Hintum (CGN) as well as the exhaustive revision of D. Debouck (CIAT) and the many details and contributions provided worldwide for the current situation and study cases of laboratories and genebanks.

References and links of interest

A European Genebank Integrated System. http://www.ecpgr.cgiar.org/AEGIS/AEGIS_home.htm/

A European Genebank Integrated System. Meeting in Polland. http://www.ecpgr.cgiar.org/AEGIS/Meeting_Poland0708/QMS_draft.pdf

American Association for Laboratory Accreditation. http://www.a2la.org/

American Society for Quality. http://www.asq.org/

BCBA. http://pt.germobanco.eu/Bancos/Lists/Banco/DispForm.aspx?ID=4

Business Development Feasibility Studies. http://www.feasibilitystudyexpert.com/ data accessed: 19 Sep 08

Central Science Laboratories. http://www.csl.gov.uk/

CGIAR. www.cgiar.org/

CGN Plant Genetic Resources. http://www.cgn.wur.nl/UK/CGN+Plant+Genetic+Resources/

Chartered Quality Institute. http://www.thecqi.org/

CIMMYT. www.cimmyt.org

CIP. http://www.cipotato.org/

Complete collection of generic ISO 9000 standards. http://www.iso.org/iso/pressrelease.htm?refid=Ref1091

David Straker QW: What is Quality (part 1)? http://www.thecqi.org/qualityworld/c4-1-46.shtml

David Straker. QW: What is Quality (part 2)? http://www.thecqi.org/qualityworld/c4-1-51.shtml

EA. http://www.european-accreditation.org/default_flash.htm

Examples of feasibility reports. http://www.io.com/

FAPAS. http://www.fapas.com/

Feedback on ISO 9001:2000. http://www.bin.co.uk/info/9k2kfeedback.pdf

Honsa and McIntyre, 2003. ISSO 17025:Practical benefits of implementing a quality system. Journal of AOAC International 86 (5) 1038-1044.

ILAC. http://www.ukas.com/about_accreditation/International/ilac.asp data accessed: 19 Sep 08

INTA. http://www.inta.gov.ar/

International Food Safety & Quality Network. http://ifsqn.com/links.php

International Quality Management Programmes and Courses. http://www.aciglobal.com.au/Quality.html

IPK Genebank. http://www.ipk-gatersleben.de/Internet/Forschung/Genbank

IRRI. www.irri.org

ISOPlexis. http://www.uma.pt/Investigacao/Ccbg/swebs/germoplasma/index.html

Is ISO 9000 really a standard? http://www.bin.co.uk/info/IMS_May_2002.pdf

ISO 17025 Competence of Testing and Calibration Laboratories. http://www.quality.co.uk/custpage.htm

ISO 17025 Quality Manual template. http://www.e-shoq.com/?gclid=CKmq5_jYspUCFQnIsgodYQz_Pw

ISO 17025: Practical Benefits of Implementing a Quality System. http://www.atypon-link.com/AOAC/doi/abs/10.5555/jaoi.2003.86.5.1038?journalCode=jaoi

ISO forms, model agendas, standard letters. http://www.iso.org/forms

ISO templates. http://www.iso.org/templates

ISO/IEC directives and ISO supplement. http://www.iso.org/directives

Kuluk Consult ApS. http://www.kulukconsult.com/products.html

List of ISO standards. http://en.wikipedia.org/wiki/List_of_ISO_standards

Overview of ISO 9001. http://www.aciglobal.com.au/ISO9001_Overview.html

PhilRice. http://www.philrice.gov.ph/

PEST analysis. http://www.businessballs.com/pestanalysisfreetemplate.htm data accessed: 29 Set 08

Quality World selected articles. http://www.thecqi.org/qualityworld/c4-past.shtml

Quality World articles: Aiming for transparency. http://www.thecqi.org/qualityworld/c4-1-34.shtml

Reactions to ISO secretary-general's 'police yourselves' call to ISO 9000 community. http://www.bin.co.uk/info/Reactions_IMS.pdf

Royal Botanic Gardens, Kew. http://www.kew.org/press/iso_award.htm

Rtech labs. http://www.rtechlabs.com/

SWOT analysis. http://www.businessballs.com/swotanalysisfreetemplate.htm data accessed: 29 Set 08

System-wide Genetic Resources Programme. http://www.sgrp.cgiar.org/Default.htm

Table of comparisons of ISO 17025:2005 with the 1999 version. http://www.ukas.com/Library/downloads/News/News_2006/Lab%20assessment%20-%20a%20comparison%20of%20ISO%2017025%202005%20and%201999.pdf

The Business Improvement Network. http://www.bin.co.uk/

UKAS. http://www.ukas.com/

Acronyms

EA - European co-operation for accreditation

AEGIS - A European Genebank Integrated System

ATCFGRC - Australian Tropical Crops and Forages Genetic Resources Collection

ATFCC – Australian Temperate Field Crops Collection

BCBA – Genebank from the University of Açores, Portugal

BSI – British Standards

CAAS – Chinese Academy of Agricultural Sciences

CIAT – International Center for Tropical Agriculture

CIMMYT – International Maize and Wheat Improvement Center

CIP – International Potato Center

CGIAR – Consultative Group on International Agricultural Research

CGN – Centre for Genetic Resources, the Netherlands

CNRRI – China National Rice Research Institute

CSL – Central Science Laboratories

EMS – Environmental Management System

FAPAS - International Guidelines for Proficiency Testing

GPG2 – Global Public Goods – Phase 2

ICARDA – The International Center for International Research in the Dry areas

ICRAF – World Agroforestry Centre

ICRISAT – International Crops Research Institute for the Semi-Arid Tropics

IITA – International Institute of Tropical Agriculture

ILRI – International Livestock Research Institute

INIBAP – Banana Bioversity International (previously the International Network for the Improvement of Banana and Plantain)

INTA - Instituto Nacional de Tecnología Agropecuaria

ISO – International Standardization Organization

ISOPlexis – Genebank from the University of Madeira, Portugal

ILAC - International Laboratory Accreditation Cooperation

IPK – Institute of plant genetics and crop plant research.

IRRI – International Rice Research Institute

Lloyds – The Lloyds register group (a risk management organization)

NPGRC – National Plant Genetic Resources Centers

UKAS - United Kingdom Accreditation Services

OHSAS – Occupational Health and Safety Management Systems

PEST – Political, economical, social and technological

PhilRice - Philippine Rice Research Institute

QMS – Quality management systems

R & D – Research and Development

Rtech labs – Food testing laboratory, and research facility

SADC – Southern African Development Community

SARDI - South Australian Research and Development Institute

SGRP – System-wide Genetic Resources Programme

SGS – Inspection, verification, testing and certification company

SWOT – Strengths, weaknesses, opportunities and threats

WARDA – Africa Rice Center

List of contributors

Name	Affiliation	Email contact
Alice Muchugi	Molecular Genetics laboratory, Genetic Resources Unit, The World Agroforestry Centre, Kenya	a.muchugi@cgiar.org
Amri, Ahmed	ICARDA, Syria	a.amri@cgiar.org
Andre Lezar	ARC, South Africa	lezara@arc.agric.za
Andreas Graner	IPK, Germany	graner@ipk-gatersleben.de
Anna Small	Chartered Quality Institute, USA	asmall@thecqi.org
Axel Diederichsen	Plant Gene Resources of Canada	diederichsena@agr.gc.ca
Bernardo, Marichu	IRRI, Philipines	m.bernardo@cgiar.org
Bob Redden	Australian Temperate Field Crops Collection	bob.redden@dpi.vic.gov.au
Daniel Debouck	CIAT, Colombia	d.debouck@cgiar.org

David Galsworthy	Central Science Laboratories, UK	d.galsworthy@csl.gov.uk
Edwin Rojas	CIP, Peru	e.rojas@cgiar.org
Ehsan Dulloo	Bioversity International, Italy	e.dulloo@cgiar.org
Elvio Nunes	Isoplexis, Madeira, Portugal	elviosn@gmail.com
Hazel Jane Orge	Philrice, Philipines	hjorge@philrice.gov.ph
Ian Barker	CIP, Peru	i.barker@cgiar.org
Ioane Beenna	National Genebank, South Tarawa, Republic of Kiribati, South Pacific	beenna_ti@yahoo.com
Jan Engels	Bioversity International, Italy	j.engels@cgiar.org
Jean Hanson	ILRI, Ethiopia	j.hanson@cgiar.org
Julie Honsa	Land O' Lakes Analytical Laboratory, USA	jdhonsa@landolakes.com
Kalyani Srinivasan	Germplasm Conservation Division, NBPGR, India	kaliamma98@yahoo.com
Ken Richards	Canadian Genetic Resources Program, Canada	richardsk@agr.gc.ca
Louise Bondo	KULUK consult ApS	louise.bondo@kulukconsult.com
Manuela Veloso	INRB, Portugal	mveloso_ean@hotmail.com
Marcelo Ferrer	Instituto de Recursos Biológicos (INTA), Argentina	mferrer@cnia.inta.gov.ar
Maurice Wong	Service du Développement Rural Département de la recherche agronomique, Papeete, Tahiti	maurice.wong@rural.gov.pf
Miguel Carvalho	Isoplexis, Madeira, Portugal	quercus@uma.pt
Monica Mezzalama	CIMMYT- Seed Health Laboratory, Mexico	m.mezzalama@cgiar.org
Olga Romanova	VIR, Russia	o.romanova@vir.nw.ru
Rebecca Weekes	Central Science Laboratories, UK	r.weekes@csl.gov.uk
Richard Snowball	Australian Trifolium Genetic Resource Centre, Australia	rsnowball@agric.wa.gov.au
Sally Dillon	Australian Tropical Grains Germplasm Centre	sally.dillon@dpi.qld.gov.au
S. K. Sharma	NBPGR, India	director@nbpgr.ernet.in
Steve Hughes	PIRSA – SARDI, Australia	hughes.steve@saugov.sa.gov.au
Tang Shengxiang	China National Rice Research Institute	sxtang93@163.com
Theo van Hintum	CGN, the Netherlands	theo.vanhintum@wur.nl
Thomas Payne	CIMMYT, Mexico	t.payne@cgiar.org
Xiaoling chen	CAAS, China	xlchen@caas.net.cn

Annex 1 - Need for quality control and quality management

The 3 pillars

Current globalization and also competition for better and more efficient and more economical products and processes has been requiring the establishment of standards for management systems at various levels in any category. Quality management has becoming one of the infrastructure professions for any organization structure such as information technology, human resources or finance. The only difference is that unlike those, quality is hard to define, due to its numerous ramifications (www.thecqi.org). At a basic level, quality can however respond to two basic questions: what is wanted and how do we do it? Quality in business terms (but also not so different for other areas) means staying in business, not how big it gets but how long it survives, focusing on both short term and long term perspectives. It means (extracted from two excellent articles from David Straker) playing a dynamic balancing game, optimizing value exchange, having in mind the real limitations with whom we work with. It means therefore, optimizing the whole system, making compromises so that the whole system continuous to operate. In a more define statement quality is the understanding and optimization of the whole system, with three main pillars: *Understanding*, *improvement* and *assurance*.

- *Understanding* our external business environment (including what is needed and how to satisfy these needs), our internal capabilities and desires leads to changes that enable us to sustain and grow our businesses (Quality World arcticles). Understanding includes present and future needs and capabilities, with a consideration of external forces such as competition and legislation.

- Most decisions to achieve new business goals lead to necessary changes in the business system. Understanding is then the foundation for *improvement* and according to David Straker, competences can take years to develop and often tomorrow's competitions are won or lost in improvements we make today. This can be so true for genebank systems too!...

- When the needs and capabilities are understood and the system improved, all is needed is to make sure it works. The previous stages (understanding and improvement) ensured that definitions of what was to be done were optimal and clear. The following stage is about *assurance* that things happen on time, the same way, every time.

These three pillars fit together to form the basis for survival of any business or organization. The job quality requirements are simply to understand, improve and assure the operation of the whole business system, regardless of its field of expertise. The quality of assurance is about meeting stated or implied promises for products or services. It is about consistency. Improvement is not longer just to design products or services (as it was mainly before) but it also requires new levels of knowledge and skills to understand the way to design processes and broader organizational systems. Improvement, being initially about changing processes has evolved into changing organizational systems.

The quality of improvement is therefore building a system to keep the promises (defined by quality assurance). Understanding is the critical challenge for quality in the new millennium. Understanding is the underpinning that enables both improvement and assurance. The quality of information, the quality of understanding and the quality of decisions are as critical as the quality of the products and services that flow from them. In addition to understanding machines and processes we must as well understand people and complex systems in order to make the right promises and to ensure we keep them. The need to work at three levels of assurance, improvement and understanding is true at all levels of business, regardless of the scope of work, such as understanding the materials, improvement of processes and assurance of deliveries,

either in limited domains or in broader business processes. The understanding of the broader context into which work fits has becoming also increasingly important.

The four steps

It has been widely recognized (www.iso.org) that management systems standards can provide a model to follow in setting up and operating any management system using the following operating principles:

Plan - Establish your objectives and make plans

Do - Implement your plans

Check - Measure your results

Act - Correct and improve your plans and how to put them in practice

Although this principles sound very basic and simple, they are often not in place nor being implemented. Very small organizations may not have a "system", but just "their way of doing things", and "their way" is probably not written down, but all in the head of the manager or owner. The larger the organization, and the more people involved, the more the likelihood that there are written procedures, instructions, forms or records. These help ensure that everyone is not just "doing his or her own thing", and that the organization goes about its business in an orderly and structured way. This means that time, money and other resources are utilized efficiently. To be really efficient and effective, any organization should manage its way of doing things by systematizing it. This ensures that nothing important is left out and that everyone is clear about who is responsible for doing what, when, how, why and where. This process also assures an important parameter, consistency on the final results or products. This is extremely important in the area of research, as well as essential to assure good quality of any product or service delivered.
Large organizations, or the ones with complicated processes, could not function well without such management systems, so often these have been operating with management systems for years (regardless of being certified or not).

The written systemization of the processes is normally captured in standard operating procedures that can be made individually for each process or globally for the whole system. The existence of these quality documents is essential to inspect the compliance of the procedures or the failure to adhere to them. It is also essential that the staff involved in the process is aware and knows well what the procedures are and why they must be followed. Any good quality system must be based on its standard operating procedures (SOPs), not excluding natural sciences and research organizations. This will allow the achievement of maximum safety and efficiency of any performed activity.

Current business and also research Institution trends demand increasingly greater quality of products ad services, with a full justification/explanation of the processes used to achieve them. This is true not only for costumer satisfaction but also as important donor requirements. This later requirement is a particularly important incentive for research to upgrade their standards of operation, once most research programs are heavy dependent of donor supported budgets.

ISO has developed so far over 17000 International Standards on a variety of subjects and about 1100 new ISO standards are published every year. The online ISO Standards list (http://en.wikipedia.org/wiki/List_of_ISO_standards) integrates both the ISO Catalogue of published standards and the ISO Technical programme of standards under development. They

are maintained by ISO, the International Organization for Standardization and it is administered by accreditation and certification bodies. Although these standards originated in manufacturing businesses, they are now employed across a wide range of other types of organizations. The standards are regularly reviewed every few years by the International Organization for Standardization.

Definitions of other relevant quality terms

Quality is a very subjective, perceptual and conditional term that can vary from person to person, and refers to the perception of the degree to which a product or service meets the customer's expectations. The general sense and previous definitions range from: the non-inferiority, superiority or usefulness of something to products or services that meet or exceeding customer satisfaction, the fitness for use usually defined by the customer or conformance with requirements (http://www.asq.org/glossary/q.html). *Quality* has no specific meaning unless related to a specific function or object. Jim Wade recently defined quality as: 'in any organization, at any one time, quality is precisely defined by the organization's current measurable objectives' (http://www.bin.co.uk).

There are two technical applications of the term quality:

- One is *Quality Assurance* which is the prevention of defects, such as the deployment of a *Quality Management System*. It implies a characteristic of a product or service bearing on its ability to satisfy stated or implied needs. It is the planned or systematic actions necessary to provide enough confidence that a product or service will satisfy the given requirements for quality.
- The other is *Quality Control* which is the detection of defects, most commonly associated with testing that takes place within a *Quality Management System*, referred as *Verification* and *Validation*. It assumes a final product or service free of deficiencies. It is the ongoing effort to maintain the integrity of a process to maintain the reliability to achieve an outcome.

A technical *Standard* is an established norm or requirement. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices. Some standards are mandatory while others are voluntary.

Standardization is the process of developing and agreeing upon technical standards. It is the process of establishing a technical standard, which could be a standard specification, standard test method, standard definition, standard procedure or others.

Standard operating procedures (SOPs) are sets of instructions describing how tasks of operations should be handled by staff assigned to those specific responsibilities, without loss of effectiveness. Standard Operating Policies and Procedures can be effective catalysts to drive performance improvement and improving organizational results. Every good quality system is based on its SOPs.

Quality management is a method to ensure that all the activities necessary to design, develop and implement a product or service are effective and efficient within a system and its performance. It is focused not only on the product quality but also on the means to achieve it. It comprises three major components: *quality control*, *quality assurance* and *quality improvement*. It uses quality assurance and control of processes as well as products to achieve more consistent quality.

Quality improvement is the purposeful change of a process to improve the reliability of achieving an outcome. It covers the product improvement, process improvements and people based

improvements. Any improvement (change) takes time to implement, gain acceptance and stabilize as accepted practice. Improvement must allow pauses between implementing new changes so that changes are stabilized and assessed as real improvements before the next improvement is made. Improvements that change the culture take longer as they overcome greater resistance to change. It is easier and often more effective to work within the existing cultural boundaries and make small improvements than major transformational changes. On the other hand, transformational changes works best when responding to a crisis and needs to make changes in order to survive. Any well organize quality improvement program takes all these factors into account when selecting quality improvement methods.

In the management of any operation, the dimensions of quality have five main different attributes: Quality, dependability, speed, flexibility and cost. In the past, when trying to improve quality typically producing less defective parts, this was done at the expense of increased costs and less productivity. However, today, when modern quality techniques are correctly applied to business, engineering manufacturing or assembly processes, and all aspects of quality (customer satisfaction, defects, productivity and total costs) must improve or at least stay stable and not decline.

Total Quality Management is a management approach for an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society. It requires that the company maintain this quality standard in all aspects of its business, ensuring that things are done right the first time and that defects and waste is eliminated from operations.

Management System refers to the organization's structure for managing its processes - or activities - that transform inputs of resources into a product or service which meet the organization's objectives, such as satisfying the customer's quality requirements, complying with regulations, or meeting environmental objectives.

Quality Management Systems is a formal system that documents the organization, responsibilities and procedures required to achieve maximum effectiveness at the lowest overall cost to the organization. Independent certification bodies may perform quality audits based on a QMS and the set of norms to which the QMS should comply.

Annex 2 – the latest case study - CIP towards ISO accreditation for genebanks

(Information kindly provided by D. Galsworthy and E. Rojas)

Preliminary considerations

Initial objective of establishing a quality system: formalizing the CIP genebank systems for the acquisition, maintenance and distribution of germplasm in light of reducing the risk of distributing infected material and material of the wrong genetic source.

Summary - CIP was advised that the workings of the genebank would lend themselves to the introduction of a quality system, the process of distribution and quality control could then be validated and that system subjected to third party verification through accreditation. CIP management took the bold and forward-looking step of agreeing to fund this project and hired a consultant (Dr. David Galsworthy, CSL, UK) for one year to lead the project in Lima.

Background - Quality Systems such as this need very careful structuring. The concept of Quality / Management Systems have been used in many areas of modern society to control risk and provide a mechanism for quality improvement. Manufacturing, food production, environmental controls, information technology are just some of the areas that rely on the application of quality standards and systems to support business. However, the biological / agricultural sciences have been slow to recognize the benefits of these systems and so there has been limited application in these fields.

Decisions made - A careful choice of quality standards was done for the structure of the system at CIP and third party verification was made. The most widely applied quality standard is ISO 9001. This is a generic standard and looks at the *control of the key processes of an operation*. A 3rd Party Certification Body such as Lloyds or SGS assesses it. The operation of the genebank could have been incorporated within an ISO 9001 system in the way the genebank at Wageningen (CGN) has successfully done. However, I felt because of the deeply technical and specialist nature of the genebank operation more value would be added to 3rd party assessment process if *the technical competence and validity was demonstrated* through the ISO Standard 17025 with the assessment and accreditation being carried out by expert technical assessors. This was agreed with the CIP management and the structure of the quality system was modeled on the contents of ISO 17025.

Implementation of the Quality System

Establishing a wiki web site

The management of the project documentation was initially started through a web site, allowing easy access for staff of the 3 different areas of activities (genebank, administration and virology) as well as remote access for the Accreditation Body. A Wiki content management style website (run through Confluence software) was established for the project and this turned out to be an incredibly efficient way of working and was a major contributor to the success of the project. The website was organized in terms of distinct layers – information about CIP and the genebank, obligations for CIP under International Treaties, Policies covering all aspects of ISO 17025, Work flows visually describing activities, Operational Procedures and Records (audits, training, equipment). All sections of the website were linked to easily move from policies to workflows to procedures and records.

Some of the more useful menus were the “Workflows” and the “Operational procedures”
The workflows are the flow of activities of different genebank process, that allowed:

- To have a map of view of all activities
- Promote scientist/assistants participation in the workflow documentation because they are designed in Power Point
- To monitor activities: detecting long path, see bottlenecks and select activity to be improved (automated with pockets + barcodes)
- This is also useful for new staff, practitioners and visitors

The Wiki structure allowed the system to be built with contributions from a number of staff involved in different aspects of the work as well as easy update to reflect changes. The website also had the ability to record the complete history of all amendments. By the time the project was ready for assessment the site had grown to nearly 300 WebPages linked to many hundreds of relevant attachments. All this without a single piece of paper! The website also allowed the remote initial assessment by the Accreditation body – saving CIP both 2 airfares from Europe as well as the considerable cost of the travel and assessment time for the team. This CIP genebank quality manual is still on-line based on ISO 17025 and being implemented in a commercial Wiki (Confluence).

Documenting existing procedures

The project built on the considerable work of the previous few years at CIP. This covered formalizing workflows and information recording as well as the introduction of bar coding for scanning accession identities. Work flows and operational procedures were fully documented to describe all the activities of the germplasm acquisition, maintenance and distribution. Audit training for CIP staff was carried out and an audit programme introduced. The performance of the equipment and environment was then established and conditions / settings altered to ensure the appropriate tolerances were met. Staff training and competence records were established and all equipment brought within an equipment records system.

Validation of pathogen detection systems

Along side this work, the effectiveness of the pathogen screening process was validated by passing infected and clean material through the screening process and recording the results at all stages of the screen. Results were statistically analyzed and the probability calculated of infected plant material escaping the screening procedure. The low probability recorded showed the effectiveness of the systems and was the first time that the pathogen screening procedures were tested in this way. Results were collated into a 71-page report to be published in the future.

Assessment and Accreditation Grant

Accreditation against ISO 17025 standards was then sought from highly respected United Kingdom Accreditation Service (UKAS). Implementation of the system by December 2007 was very advanced and the assessment visit by UKAS arranged for January 2008. Two experts carried out the assessment, Dr Colin Jeffries, from the Scottish Agricultural Science Agency and editor of the FAO guidelines for the safe movement of potato germplasm and Dr Sally Higgins, a quality system expert from UKAS. The visit lasted for 2 days and both assessors were extremely complimentary about the very effective structure of the system as well as the technical competence and experience of the staff. A total of 6 non-conformances were raised – an

incredibly small number of non-conformances for an initial assessment. After the visit, the non-conformances were addressed and CIP was awarded the accreditation in mid-February 2008!

Highlights

The project met and widely exceeded expectations of consultant. The key aspects of the success were:

1. The systems in place were highly efficient and bureaucratically very lean

2. The staff were involved totally with the implementation of the systems and contributed widely to the documentation involved

3. The validation of the processes helped immensely with improving the efficiency of the germplasm pathogen screening process

4. The final system had complete staff ownership to allow sustainability and the ability to drive forward improvements for the future

5. Being granted accreditation from a highly respected body gives the users of the genebank a level of confidence that the material is clean and of the right genetic source that has never been possible before.

CIP was very innovative in not only establishing the first quality system in a CG genebank but also being the first genebank in the world to gain accreditation to the highest level possible through implementation of ISO 17025.