MANAGING QUALITY FOR QUALITY OUTCOMES

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Abstract

In today's competitive climate it is increasingly important for an organisation to foster client confidence in the products and or services that they provide. It is no longer adequate for an organisation to rely solely on its past record or reputation. An organisation may demonstrate its commitment to ensuring client confidence through:

(a) Implementation of a Quality Assurance Management System (QAMS)
(b) Certification of that system to a relevant recognised standard, and
(c) Subsequent management and monitoring of the system through formal documented procedures.

This paper will briefly discuss the initial steps of a QAMS such as development, documentation and implementation. However, the main emphasis will be directed towards the on-going management of the system to achieve quality outcomes.
A combination of formal and informal processes, including planning, auditing, observations and actions are employed to demonstrate compliance of the QAMS to the relevant standard. In addition, these processes verify that the documented procedures and processes are in place to deliver the quality goals desired by both organisation and client.
Managing quality for quality outcomes is the essential element for realising optimum benefit to all sectors of the organisation, its business partners and client relationships.

Key Words

Certification; audits; documentation; quality assurance management systems

Introduction

A Quality Assurance Management System (QAMS), certified to the ISO 9000:2000 standard, was developed and implemented into the Australian Malting Barley Centre (AMBC) and the Queensland Department of Primary Industries and Fisheries Barley Quality Laboratory (BQL) situated at the Leslie Research Centre Toowoomba. The QAMS covers the operations of both laboratories incorporating routine analysis as well as research and development activities.

The activities and outcomes of the laboratories assist breeders, growers and marketers, at a national (AMBC) and state (BQL) level, to make informed decisions on new varieties being developed in the various breeding programs. The BQL is responsible for material produced by the Northern Barley Improvement Program (NBIP), whilst the AMBC provides an independent assessment of elite barley lines developed by State and private breeding programs throughout the whole of Australia.

The development, implementation, and continued maintenance of a QAMS (1-4) demonstrates the commitment of the staff and the organisation to carrying out testing procedures and producing data that is of a high standard.

Methods

Managing the QAMS to ensure continued quality outcomes involves utilising a number of tools including auditing (5) and following the preventative and correction procedures that have been established within the system. A number of standards were assessed for suitability for the AMBC and the BQL, prior to the QAMS being developed.

The **ISO** 9000:2000 series of standards was chosen as it seemed to best fit the purpose of the operations of the laboratory and was subsequently utilised in the development of the QAMS. The **ISO** 9000:2000 series is generic in nature and this allowed for the degree of flexibility required to cover the operations peculiar to the laboratory, and, in addition, it is recognised at an international level. An assessment of the various certifying organisations was also undertaken with the decision being made as to which company would be the certifying body and hence carry out future external audits. Due consideration was also given to the various government standards and directives currently in place and the potential impact they might have on the QAMS. After consultation with relevant staff and management, a decision was made to apply for certification to the **ISO** 9001:2000 standard through SAI Global as this series of standards best suited the purpose and the level of critical control required by the laboratory.

Following these above assessments being satisfactorily completed, a critical appraisal was carried out of the existing methods and procedures currently employed in the laboratory including their compliance with the standard. The process of planning, developing, documenting, implementing and maintaining a QAMS was initiated. The system documentation was broken into four major components, Quality Manual, Methods Manual, Procedures Manual and Forms. The Quality Manual outlines the overall operations of the laboratory and is the document that would be given to prospective clients to demonstrate that management and laboratory personnel are committed to quality. The Methods Manual contains the specific instructions for the tests conducted within the laboratory whilst the Procedures Manual describes the procedures that are in place to address the various elements of the standard. Forms are used in conjunction with the procedures to validate the operations of the laboratory. Forms act as a reference tool for the auditors, management and laboratory personnel and provide evidence of the operations of the laboratory. When it was considered that the documentation was at a satisfactory stage of completion, a preliminary audit was conducted by the certifying body SAI Global. This preliminary audit was invaluable in identifying gaps or shortcomings in the system prior to the certification audit. A full audit was carried out at a later date with the system being deemed as "meeting all requirements of the Standard" and certification to the **ISO** 9001:2000 standard was subsequently granted to the laboratory.

The relevant standards and reference materials were sourced from Standards Australia. This organisation also has an extensive range of books and articles available to assist in the development, documentation and implementation of a quality assurance management system. It was also imperative that current government standards and directives were included in the reference materials as some of these standards had the potential to impact on any QAMS implemented within the laboratory.

Results and Discussion

As stated in the introduction, this paper is aimed at the steps and procedures that are involved in maintaining the quality assurance management system for optimising quality outcomes for the organisation. A number of tools are available to assist in the maintenance and continued improvement of a QAMS. The design and use of forms and procedures is imperative to the ongoing success of the system. When the AMBC and BQL system was being developed, critical control points were identified and procedures and forms that addressed these critical areas were produced. It was considered best to keep these procedures and forms as simple and concise as possible to facilitate the effective and efficient running of the system with a minimum of ongoing maintenance paperwork.

Internal Audits

An internal auditing schedule is drawn up each year with the whole system being internally audited over a 12 month period. The audit schedule must include the critical control points of the laboratory's operations. These areas, which have the potential to have a negative impact on the quality outcomes for the laboratory, are audited more frequently in line with their degree of criticality. The schedule should also take into account the work cycle of the laboratory. If the laboratory is involved in testing regimes that are seasonally based, these seasonal requirements must also be allowed for in the auditing schedule. An example of how an audit schedule may be set up is shown in **Table I**.

External Audits

External audits are carried out by the certifying body on an annual basis with one third of the QAMS being audited each time. At the end of the 3 year period, when the system is due for recertification, the system has been fully audited in all its operations and processes. A full report is issued by the certifying body on

completion of the final recertification audit. This report contains a full account of what the auditors observed along with suggested corrective or preventative actions and improvements identified by the auditor. It is important not to be too focused on the regulatory aspect of these audits as they are in effect a unique way to get constructive and often innovative ideas for the improvement and continued growth of the organisation.

Table 1. Audit Schedule Example

Date	Procedure / Activity to be Audited	Auditor(s)	Result
October	1.Sample receival 2.Document Control 3.NIR procedures	Mr Fred Blamey	1.Procedues verified 2.Corrective action request issued – see audit report and CAR for details 3.Procedures Verified
January	1.Calibration Schedule 2.Preventative and Corrective action procedures	Ms Julia Faulty	1.Schedule procedures verified 2.Procedures checked and verified

Maintenance of the QAMS.
Forms are used to monitor and validate the QAMS. They provide both management and auditors with tangible evidence of the operations of the laboratory. In addition, forms allow any non-conformity noted as a result of an audit to be actioned and tracked in order that the non-conformity is corrected. An example of an internal auditing form is given in **Figure I**.

Managing change is an important aspect of the ongoing maintenance and improvement of the QAMS. However if changes are to be instigated they must be of benefit to both personnel and the organisation. Nomura (6) discusses change management in her paper on "Building a Quality Assurance System into a GLP Laboratory" and its importance to the ongoing maintenance and improvement of the system. Managing change within the system involves managing any conflicts that may arise from the proposed changes as well as ensuring that all personnel are made aware of the changes and that all documentation relating to the changes is updated. In particular, if a critical part of an operation is to be altered, it is imperative that the changes be discussed with key personnel prior to the change being made. Communication is of utmost importance in the maintenance of the QAMS.

In his paper "The Human Factor in Quality Management" Ortner (7) stresses that quality management is more of a new way of working and thinking rather than simply a business strategy. He concludes that the human factor is of eminent importance to the success of a QAMS. This has also been the findings within the AMBC and BQL system. Ideally the Quality Assurance (QA) group in an organisation should be independent from the operations group. However, in a small organisation, this is not always possible. In these situations a team approach can be utilised with members of the team being responsible for auditing sections in which they are not directly involved. Good communication is crucial to positive outcomes for the laboratory regardless of the type of auditing process employed.

Improvements to the QAMS and hence the outputs of the laboratory are identified in a number of ways, for example, formally through the audit process, or informally through the observations of staff. It is, in fact often the latter that provides the catalyst for change. Areas that are identified through the audit procedures must be discussed with the relevant staff and management prior to any changes being made. In the less formal process, issues identified by key staff are discussed with all relevant personnel and changes made accordingly, as often these changes relate to processes being carried out in the laboratory that require adjustments or correction in a timely manner. These changes are usually communicated to management at the Management Review meeting or as required.

Figure 1. Internal Auditing Form

DATE OF AUDIT:	**AUDIT NUMBER:**
WORK GROUP:	**ACTIVITY AUDITED:**
AUDITOR(S):	**REPORT DISTRIBUTION DATE:**
SUMMARY OF OBSERVATIONS OF AUDIT:	
Corrective Action Requests (CARs) ISSUED:	
Verification that CARs have been satisfactorily resolved:	
Auditor or audit team leader: **Signature:** **Date:**	**Management Representative or delegate:** **Signature:** **Date:**

Conclusion

Quality Assurance was initially introduced into the manufacturing industries in the early 1900's. Due to the very nature of these industries, the Quality Assurance Systems were heavily regulatory and limiting in their scope. Unfortunately, this regulatory and limiting reputation is, to a large extent, still associated with QA today. The new standards that operate in today's climate encompass a diversity of organisations and companies that include everything from the local corner store to the multinational manufacturing corporations of the world. QAMS, when designed and implemented in accordance with the organisations operations, culture and personnel can be a mechanism whereby an organisation can not only monitor its performance and achieve its goals but also have processes in place that identify opportunities for growth and continual improvements. Until recently, the use of QA systems in Research and Development (R&D) activities has been limited as some scientists believed it to be too restrictive. However, with more flexible standards now available the scope of a QAMS can be broadened to cover the R&D area. Furthermore, with increased competition for project funding, the QA system can give a distinct advantage over competitors as the system demonstrates the organisation is committed to producing quality research that can be verified and validated through the QA processes. Overall, planning, developing, documenting and implementing a QAMS is a complex task. However, when properly maintained, the QAMS can deliver many benefits to the organisation, including savings in time and money through increased efficiency and decreased downtime, as well as in staff morale, as roles and responsibilities are clearly defined within the system.

References

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