Ensuring reliability of test results through a quality assurance programme

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Abstract The Central Laboratory of the Sugar Industry Research Institute gained ISO/IEC 17025:2005 accreditation status, in May 2013, for the methods of sugar analysis in use. In an effort to show continuous improvement in the quality management system that had been developed, the laboratory has embarked on a programme to improve the quality assurance system to guarantee accurate analytical results. Several tools and techniques have been implemented to augment and maintain quality assurance and ensure continued approval from the accreditation body. These include internal assessment, external assessment, audits and management reviews, training, and staff development. These have proven to be effective as the laboratory has maintained its accreditation status for the testing of sugar.

Key words Quality assurance, quality control, quality assessment, ISO 17025, quality management system, continuous improvement

INTRODUCTION

On 28 May 2013, the Central Laboratory of the Sugar Industry Research Institute gained ISO/IEC 17025:2005 accreditation status for its methods of sugar analysis. This was given by Jamaica Agency for Accreditation (JANAAC), a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the scope of Accredited Laboratories since 2013. During the lead-up period, the laboratory demonstrated improvements in its quality assurance programme, an integral part of any quality management system (QMS) developed to meet the ISO/IEC 17025:2005 standard.

The quality assurance programme facilitates the documentation of analytical uncertainties and promotes confidence in analytical results. Quality assurance (QA) is the complete set of measures a laboratory must undertake to ensure that it can always achieve high quality output. This includes quality control and quality assessment. Quality control (QC) involves those laboratory practices that are undertaken specifically to achieve accuracy and reliability of analytical results, and may include the use of reference samples, replicate testing, repeatability and reproducibility, use of control charts, and the use of certified test pieces for instrument, among other practices.

Quality assessment comprises those processes that are undertaken to monitor and document the effectiveness of the quality control program, e.g. audits, trend analysis and participation in proficiency testing (PT). Regular assessment of quality control will document both accuracy and precision. Accuracy is defined as closeness of a measurement to the known or expected value. Precision is defined as the agreement or repeatability of multiple measurements on the same sample (van Reeuwijk 1998). Both accuracy and precision provide a good measure of analytical uncertainty.

Continuous improvement of the QMS is demonstrated over the period by incorporating important elements of organizational health and safety (OSHA). Procedures are in place to maintain safety, security and integrity of samples, and to ensure the confidentiality of clients’ results. Feedback is sought from relevant stakeholders to facilitate continuous improvement in customer service.

ELEMENTS OF THE QUALITY ASSURANCE PROGRAMME

The QA aspect of SIRI’s QMS, as adopted and implemented to ensure accuracy and reliability of results, are discussed below.
Choice of analytical method

The laboratory is required to use both internationally recognised methods as well as technicians trained to do them. The methods are appropriate for the testing undertaken and are usually the latest editions of valid methods. Non-standard methods are validated and the laboratory ensures that the range and accuracy of the values are relevant to the customer’s needs. All validation records are maintained.

Instrument calibration and equipment maintenance

Equipment and accompanying software used for testing are capable of achieving the accuracy required, all of which comply with specifications. Calibration/verification programs are established, and equipment calibration done to meet the laboratory’s specification, and to comply with the relevant standard prior to being commissioned. Equipment is operated by authorized personnel only. Current instructions on the use and maintenance of equipment are readily available.

Use of certified reference materials and test pieces

Certified reference materials are purchased from reputable sources. These are matrix-matched materials with assigned target values and ranges for each variable reliably determined from data obtained by repeated analysis. Currently, no certified reference sugar is available; hence the laboratory prepares its own. Test pieces for equipment and weights are calibrated to provide traceability of measurements to SI units.

Internal testing

Replicate analysis

The laboratory does routine replicate analysis to monitor precision of the method. Replicate analysis is useful where standard reference materials are unavailable.

Retained testing

The laboratory routinely conducts retained sample analysis (Fig. 1). The sample being retested should fall within expected limits, i.e. the upper and lower boundary that should contain the results. If results are out of range, corrective action is taken and a retest/audit carried out.

Fig. 1. Results for retained sample analysis.
Inter-lab testing

The laboratory participates in inter-lab testing of raw sugar. The results allow laboratories to detect unsuspected errors and deficiencies in the methods. Where deficiencies are detected, the corrective action procedure is implemented.

Reference material control chart and forecasting

Internal reference sample (house reference material, HRM) (Thompson and Wood 1995), a simple and effective aid to process control, is analysed monthly (Fig. 2) and plotted on a control chart. Internal reference sample is an inexpensive surrogate for standard or certified reference material. The scattering of the results around the target line is an indication of precision (Briggs 1996).

![Control Chart](image)

**Fig. 2:** Control chart for Pol analysis.

The control chart shows the action limits for each parameter based on one, two or three standard deviations from the mean. The chart is analysed according to the rules that govern the use of control charts. This method is simple and effective in aiding process control. According to Taverniers et al. (2004), an analytical system is under control provided no more than 5% of the measured values exceed the warning limits. If statistical control is considered unacceptable based on the laboratory’s system, a retest or audit is deemed necessary. The addition of trend line on the control chart allows for forecasting for the next three periods, and provides the laboratory with an efficient means of determining when the reference sample would deteriorate. This was found to be about 4 months after its first use.

External testing and assessment

Proficiency testing (PT)

The Laboratory participates in Sugar Proficiency Testing Scheme (SUPS), LGC Standards Proficiency Testing Scheme Coordinators (ISO/IEC 17043:2010 accredited), UK, which facilitates periodic assessment of competency and suitability of methodology (Table 1) of participating laboratories. This testing is done twice per year. The ISO/IEC 17025 standard does not mandate participating in PT, but is done to allow for assessment of the entire system and caters for corrective and preventive actions to be implemented as the need arises. The participants’ results are converted to Z scores. The absolute value of the Z score is used for the evaluation of the results. A Z score < 2 is acceptable, 2 < Z < 3 is considered questionable and Z>3 is considered an outlier. If the laboratory receives a score ≥2, the procedures for dealing with non-conformances are implemented.
Table 1. SIRI’s results for proficiency testing.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Method</th>
<th>Unit</th>
<th>Z score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ash</td>
<td>GS1/3/4/7/8-13</td>
<td>% m/m</td>
<td>0.00</td>
<td>Accepted</td>
</tr>
<tr>
<td>Colour</td>
<td>GS9/1/2/3-8</td>
<td>IU</td>
<td>0.00</td>
<td>Accepted</td>
</tr>
<tr>
<td>Colour</td>
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</tr>
<tr>
<td>Dextran</td>
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<tr>
<td>Moisture</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Reducing sugar</td>
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<td>Accepted</td>
</tr>
<tr>
<td>Starch</td>
<td>GS 1-17</td>
<td>mg/kg</td>
<td>0.00</td>
<td>Accepted</td>
</tr>
</tbody>
</table>

Surveillance visits

The Jamaica National Agency for Accreditation (JANAAC) has been a signatory to International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the scope of Accredited Laboratories since 2013. JANAAC’s program of accreditation has a 4-year cycle during which there are yearly surveillance visits. A re-assessment visit is done in the fourth year. The surveillance visits are conducted to verify the maintenance, extension, reduction or withdrawal of the laboratory's scope of accreditation.

Trend analysis

The laboratory uses both quantitative and qualitative methods of analysis to determine trends from data gathered from customer feedback, training, evaluation of supplies, evaluation of suppliers, auditors, use of reference materials, replicate testing, retained testing, and changes in the volume of work, etc. The use of trend analysis allows the laboratory to forecast projected changes, and enables implementation of preventive measures to mitigate adverse impacts on the quality management system.

Internal audits and management review

The internal audit addresses all elements of the management system and is carried out by trained personnel who, where resources permit, are independent of the activity to be audited. The results from internal audits are used to improve the quality management system (QMS). Where non-conformances are detected, improvements are made by implementing effective corrective actions. Concerns and comments from audit reports are addressed and the process also allows for implementing preventive actions to reduce the opportunities for non-conformances. The management review is conducted by top management once per year. This is done to review the laboratory’s management system and testing activities to ensure continuing suitability and effectiveness.

CONCLUSIONS

The QMS developed in the Central Laboratory was effectively implemented, and meets all the elements of the ISO/IEC 17025:2005 standard. The improvement in the quality assurance programme emanating from quality control and quality assessment measures has contributed to the continuation of the accreditation status. The overall quality assurance programme is a commitment towards the laboratory producing accurate and reliable results.

REFERENCES

Assurer la fiabilité des résultats des tests grâce à un programme d'assurance de la qualité


Mots-clés: Assurance qualité, contrôle et évaluation de la qualité, ISO 17025, système de gestion de la qualité, amélioration continue

Garantizando la confiabilidad de los resultados de pruebas a través del programa de aseguramiento de la calidad

Resumen. El laboratorio central del instituto de investigaciones de la industria azucarera obtuvo la certificacion de ISO/IEC 17025:2005, en Mayo 2013, para los metodos de analisis de azucar en uso. En un esfuerzo por mostrar avances continuos en el sistema de administracion de la calidad que fue diseñado, el laboratorio se embarco en un programa para mejorar el sistema de aseguramiento de la calidad para garantizar resultados analiticos de precision. Muchas herramientas y tecnicas fueron implementadas para aumentar y mantener el aseguramiento de calidad y garantizar la aprobacion continua de la entidad certificadora. Esto incluye verificaciones internas, auditorias y revisiones gerenciales, entrenamiento, y desarrollo del personal. Estas acciones han demostrado ser eficientes y el laboratorio ha mantenido su status de certificacion para el muestreo de azucar.

Palabras clave: Aseguramiento de la calidad, control de calidad, verificacion de calidad, ISO 17025, sistema gerencial de calidad, avance continuo