

Report for QIS OQI as of 28/06/2022 11:03:31 AM

Report for QIS OQI -

20369 No Title Provided

OQI Details

Status	Closed Approved
Subject	<p>AUDIT 8227: Training and personnel related to the DNA IQ process.</p> <p>Points to be addressed from Audit 8227: 4.1-4.9, 4.28. Refer to hard copy Audit 8227 report (Cheng, Clausen & Muharam, 2008) in Quality Management DNA Analysis for full details.</p> <p>4.1. Add KPC?s for off-deck lysis and STORstar components into the DNA IQ training module (QIS 24896 R0).</p> <p>4.2. As part of DNA IQ? training delivery and the associated training module, incorporate more aspects into the background and theory of the system, including discussions on the composition and function of each buffer reagent.</p> <p>4.3. A Training Delivery Plan needs to be developed for training in the automated DNA IQ? extraction process. Note that a TDP already exists for training on the use of the MultiPROBE? II platforms (used in conjunction with QIS 24450).</p> <p>4.4. ?Statement of Competence to Train? records must be finalised for appropriate Automation Project team members.</p> <p>4.5. Review the expected timeframes to complete training modules QIS 24450 (Operation and Maintenance of the MultiPROBE? II PLUS HT EX Robotic Platform) and QIS 24896 (Automated DNA Extraction with the DNA IQ Kit).</p> <p>4.6. Trainers and supervisors need to progress the completion of training modules with staff. Consider adding progress reports as an agenda item in weekly team meetings or an appropriate alternative.</p> <p>4.7. Apart from staff identified as trainers, it is recommended that all DNA Analysis staff attend Trainer the Trainer. This will assist with 1) trainer and trainee responsibilities, 2) adult learning styles, 3) introduces the FSS Learning and Development Manual (QIS 23651).</p> <p>4.8. A re-evaluation of pipetting skills should be performed in order to benchmark and standardise techniques. The evaluation can incorporate demonstrations on differences in the pipetting behaviour of hot, warm and cool liquids; reagents containing a high proportion of solvents (e.g. ethanol), etc. A SOP and TM detailing and assessing pipetting techniques (e.g. forward versus reverse pipetting) should be created, if not yet available (e.g. see QIS 23899). The re-evaluation should also assess the use of multichannel and multistep pipettors in combination with various tip types.</p> <p>4.9. The issue of overworked staff in the Analytical Section needs to be investigated further.</p> <p>4.28. As a continuous QA/QC measure, the supervisor should observe the DNA IQ? protocols at regular intervals for critical assessment and</p>

	possible re-evaluation of the impact and suitability of changes in the methods.
Source of OQI	Audit
Date Identified	11/08/2008

OQI Creator Contact Details

Creator	Amy CHENG
Organisational Unit/ s	Analytical
Service/ s	
Site Location/ s	Coopers Plains

Investigator/ Actioner Contact Details

Actioner	Allan MCNEVIN
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Investigation Details

Investigation Completed	21/08/2008	Root Cause Type	Training Audit finding 4.1. KPC's relevant to the off-deck Lysis procedure were in development at the time of the audit. This has since been completed and revision 1 of the training module has been activated. Audit findings 4.2 & 4.3. A training delivery plan had been used by the trainer for most of the Analytical section staff, however this had not been incorporated into a QIS document (currently in process). A large amount of theory has been incorporated into this training delivery plan and into the SOP. Additionally, copies of the kit insert are constantly available (with every new kit) for staff to access at any time. The kit insert is also listed as a reference in the SOP Audit finding 4.4. Statements of competence, and competent to train have now been completed Audit findings 4.5 & 4.6. Completion of training modules is currently being managed by the Analytical supervising scientist. Time-frame for completion has not yet been evaluated, however it was felt appropriate at the time of the last revision by all approvers. This will be re-evaluated after discussion with trainers and for the next revision of the training module.
Investigation Details			
Performed By	Quality Information System		

Action Details

Action Complete	26/09/2008	Action Fix Type	Updated Documentation
Title	Action Description finding 4.7. All staff undertaking training delivery at the time of the audit had attended train-the-trainer courses. The two newest staff members who were not undertaking any training delivery had yet to do so, but will attend as soon as practicable. Audit finding 4.8. The quality team will be consulted to assess the NATA requirements for pipetting skills assessment for Analytical staff. It must be noted that each trainer assesses the pipetting skills each time an Analytical staff member is trained in a new process, therefore pipetting skills are evaluated many-fold throughout a staff members training. Audit findings 4.9 & 4.28. Attempts to reduce workload pressures within the Analytical section have been addressed prior to and since the audit. Analytical staff are		

continually encouraged to work standard working hours (7:15) with the levels of TOIL and OT worked being monitored. It is not feasible for the Analytical supervisor to regularly observe all analytical procedures. The Analytical supervisor relies therefore on feedback from competent staff to assess each process. Additionally, staff are encouraged to discuss processing issues in the weekly team meeting and an analytical log exists for concerns to be raised. Internal audits are also conducted to assess ongoing process improvements. Whenever an OQI is raised concerning a quality event related procedures are also investigated. Changes to methods are only implemented after documented testing.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	<u>8/12/2008 2:52:53 PM Amy CHENG:</u> Points in this OQI will be reviewed in an audit within 8 weeks after re-implementation of DNA IQ (date to be decided), followed by another audit 6 months later. These points are: 4.3, 4.8, 4.9, 4.28. With regards to 4.28, the Analytical Section Senior Scientist will be the key investigator for the post-implementation reviews and audits.
Approver	
Approval/ Rejection Date	11/12/2008
Approval/ Rejection Comment	<u>11/12/2008 12:00:00 AM Paula TAYLOR:</u> No comment was recorded

Associations

Module	Audit	
QIS Record	DNA Extraction Process (DNA IQ)	
QIS Record Number	8227	Associated Version Migrated Data from QIS
Status	Closed	Current Version version 1
Association Description		

Records

No Records found