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# SCA·H·L·S

## NEWSLETTER

SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

### CONTENTS

- 2 Beale Review of Australia's Quarantine and Biosecurity Systems

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- 2 Database Development – New Tests and Expertise

---

- 3 New Test Approval Developments

---

- 3 New Members

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- 3 SCAHLS Editorial Services

## ANQAP

Over the past year, there have been a number of changes to the Australian and New Zealand Quality Assurance Program (ANQAP) staff list. Sonia Rizzi was appointed as the Acting coordinator in August 2008 and a new technical officer is assisting her. Recently, NATA accreditation was temporarily suspended, however steps to regaining NATA accreditation are progressing well and re-accreditation is anticipated in the near future. ANQAP is continuing to run the program as it did for several years prior to attaining NATA accreditation and processes and procedures are exactly the same as they were under NATA accreditation. Your help and understanding are appreciated during this time. In addition, several practices have been implemented that will greatly improve the running of the program including the simplification of the results and reporting templates, and the creation of a database of sample information to allow better searching.

One of the obstacles has been locating enough reagents to fill gaps in the current stock list so that an entire year of the program could be adequately serviced. This is now almost complete and ANQAP would like to thank those participants that have been able to contribute. It is requested that any laboratories with access to bulk sera that might be of use contact the ANQAP coordinator, Sonia Rizzi (03 9217 4360 or at [Anqap.Quality@dpi.vic.gov.au](mailto:Anqap.Quality@dpi.vic.gov.au)).

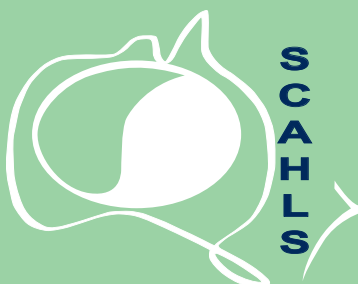
## Sample Tracking and Reporting System (STARS)

The STARS project, to enable electronic data exchange between laboratory information management systems (LIMS), has been under development for some time. The current phase of development began in June 2008 and has seen progress made towards this goal.

The development version is now on the public internet. Test cases have been submitted from several jurisdictions and successfully imported into the LIMS development environment at AAHL. The next phase of the project, to enable fully specified data to be imported into the LIMS production environment, remains on track for the target date of July 2009.

CSIRO-AAHL has submitted a pilot project proposal to the Australian Biosecurity Intelligence Network (ABIN), to provide funding for the development required in each jurisdiction to enable their respective LIMS systems to interface to the STARS system automatically.

Discussions are being actively pursued with the developers of BioSIRT (Biosecurity Surveillance Incident Response and Tracing) to enable STARS as the interface for laboratory data. The LEADDR working group has also agreed that STARS is the logical mechanism for aggregating QC data in a devolved testing network and work is in progress to specify the requirements for this functionality.



# Beale Review of Australia's Quarantine and Biosecurity Systems

In February 2008, the Australian Government announced an independent review into Australia's quarantine and biosecurity systems. The review panel comprised Mr Roger Beale AO (chair), Dr Jeff Fairbrother AM, Mr Andrew Inglis AM and Mr David Trebeck. The panel reported (*One Biosecurity: a working partnership*) in September 2008 and the Australian Government released its preliminary response in December 2008. The Government agreed, in principle, to the report's recommendations, and added that resources would be considered in the Budget process.

The review concluded that Australia operates sound quarantine and biosecurity systems that can be improved further to deal with increasing risks, such as climate change, globalisation and increased passenger and cargo movement. Key recommendations include:

- establishing a new national authority to bring together the functions of Biosecurity Australia, the Australian Quarantine and Inspection Service and some parts of the Product Integrity and Animal and Plant Health Division (including the Office of the Chief Veterinary Officer) of the Australian Government Department of Agriculture, Fisheries and Forestry;
- establishing a new Biosecurity Standards Commission to oversee the new authority;
- developing new biosecurity legislation to replace the *Quarantine Act 1908*;
- appointing an Inspector General of Biosecurity to audit the new authority's work;
- creating a new national agreement on biosecurity with the states and territories;
- moving from the mandatory intervention targets set in 2001, to a 'risk-return' approach; and

- increasing funding for biosecurity functions and upgrading information technology systems.

The Beale Review made a total of 84 recommendations but public and media interest and comment have been dominated by only three — the recommendation to import positive control samples for FMD (Recommendation 59), the proposal to increase the Passenger Movement Charge to help fund implementation of all the recommendations (Recommendation 73), and the endorsement that the 40% Export Certification Subsidy lapse, as scheduled, at the end of June 2009 (Recommendation 79).

Recommendations of particular relevance to laboratories include:

- developing an agreed national priority list of (exotic and endemic) pests and diseases and enhancing strategic surveillance for these (Recommendations 45 and 53);
- having the new 'National Biosecurity Authority' ensure that 'Australia has the laboratory capability and capacity to manage exotic pest and disease incursions of national significance' and 'improve the quality and use of state and territory laboratories to support national biosecurity priorities' (Recommendation 56); and
- developing agreed national

research priorities (Recommendation 59).

The review recommended (Recommendations 73 and 75) that significant additional resources should be provided to implement its recommendations, and that the additional 'post-border' investment be tied to an agreement with State and Territory governments on 'appropriate matching commitments' (Recommendation 74). Government has indicated that it will consider the specific resourcing requirements as part of the Budget process. Clearly, this will be done in the light of the broader financial effects of the current global economic environment, so that it is unlikely that significant additional resources will be provided as soon as might be desired to implement all of the Beale Review's recommendations. Nonetheless, implementation of the review's recommendations should result in new opportunities for animal health laboratories in both diagnostic and research activities.

The full report of the review and the Government's response are available online (at [http://www.daffa.gov.au/\\_\\_data/assets/pdf\\_file/0009/111969/nairn\\_report.pdf](http://www.daffa.gov.au/__data/assets/pdf_file/0009/111969/nairn_report.pdf) and <http://www.daffa.gov.au/aqis/about/reports-pubs/nairn/govt-response>, respectively).

## DATABASE DEVELOPMENT – New Tests and Expertise

Following discussion on the SCAHLS test development and expertise registers, it was decided to explore the possibility of converting these registers to an online database to improve accessibility of the information as well as to simplify maintenance. CSIRO-AAHL has agreed to look into this under the aegis of the STARS project.

# New Test Approval Developments

The SCAHLS New Test Evaluation working group organises the peer review and assessment of the validation claims of new tests. During the last six months good progress has been made, with approval of a test for detection of bovine Johne's disease using pooled faecal culture, an assay for PCR detection of anthrax, a caprine Johne's disease pooled faecal

culture and an ELISA for *Chlamydomphilla abortus*. Several other assays are on their way through the review process, making this a busy time for the working group.

Also in the last six months, the working group has contributed to the review of a new draft of the OIE Terrestrial Manual chapter on validation of diagnostic assays. The new draft combines the previous chapters 1.1.4 "Principles of Validation of Diagnostic Assays for Infectious Diseases" and 1.1.5 "Validation and Quality Control of Polymerase Chain Reaction Methods". This challenging consolidation will need to produce guidance for a wide range of assays, from culture to serology (in its various forms), molecular tests and even point-of-care tests.

Three concepts are introduced in the new draft, that are particularly relevant to recognition of diagnostic tests as 'fit-for-purpose'. These are 'provisional assay recognition', 'equivalence' and 'adjunct tests'.

**Provisional recognition** is described as assessment through to early validation (including analytical sensitivity, analytical specificity, repeatability and preliminary reproducibility). It is intended to apply to tests for specific purposes

or situations, for specified periods, such as use in an emergency.

**Equivalence** is described as demonstrating that a technical modification of a test results in an assay that performs 'equal to, or better than, the reference procedure'. This is assessed by running the old and new procedures in duplicate. A point of discussion is the types of variations that would qualify as only requiring equivalence testing (e.g. equipment changes, different sample matrix or application to different species).

Adjunct tests are described as those that are used to further characterise an analyte detected by the primary assay. An example would be sequencing of a PCR product. Such adjunct tests may only require determination of their analytical characteristics. However, the use of such tests is variable. For some assays, these methods are an integral part of the test (for example, the use of PCR in culture of mycobacteria). In such cases, they need to be included in the overall validation pathway.

It is to be hoped that these developments will offer a way to reduce the time and workload required for assay validation and acceptance, while still ensuring the tests are 'fit for purpose'.

## New Members

SCAHLs has a continuing change of membership but there have been significant comings and goings in the last few months. Perhaps most significantly is the retirement of Barry Richards from SCAHLs after 19 years, not only as the representative from WA laboratories but in his role as Deputy Chair. I owe Barry a big vote of thanks for so much support over my period as Chair of SCAHLs but also for his very comprehensive responses to so many issues – thanks from everyone Barry. I extend a warm welcome to Lorne Melville who has agreed to take on the role of Deputy Chair of SCAHLs. We have also seen the retirement from SCAHLs of others who have significantly contributed, including Peter Daniels (AAHL), Graeme Fraser (NSW DPI) and Russell Graydon (DPI Victoria).

To our new members, I welcome Sarah Wylie (DAFWA), Les Gabor (NSW DPI), James Watson (AAHL) and Simone Warner (DPI Victoria). Also, a welcome to Lisa Crompton who is representing NATA whilst Nicole Bailey is on maternity leave. To all of you – welcome on board.

Martyn Jeggo,  
Chairman of SCAHLs

## SCAHLs Editorial Services

The current arrangements for editorial services for ANZSDP's and other SCAHLs documents are under review. It was decided at SCAHLs 25 (August 2008) that the National Animal Health Laboratory System (NAHLS), through Animal Health Australia, would coordinate a funding arrangement for the provision of editorial services to SCAHLs. Previously this had been undertaken through DPI Victoria.

As a result, SCAHLs has discussed the likely terms of reference (TOR) for a new editorial position. Through all discussions it was clear that the committee is keen to maintain the excellent standard that has been provided to date by incumbent editors. Applications will be invited once the TOR are finalised.