



ISSUE 1 DECEMBER 2004

SCAHL S

NEWSLETTER

SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

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What is SCAHLS all about?

Welcome to the first edition of the SCAHLS Newsletter. SCAHLS is a committee of veterinary laboratory representatives, established by the Australian Federal and State governments, to foster a network of government, CSIRO, private and university laboratories with the specific aim of maintaining and improving technical and professional standards.

The committee seeks to achieve its objectives by improving communication between laboratories and with those who interact with laboratories in servicing the livestock industries of Australia and New Zealand.

The key strategy adopted by the committee is to promote a national system of quality assurance and standards. The strategic plan, therefore, involves a commitment to the following:

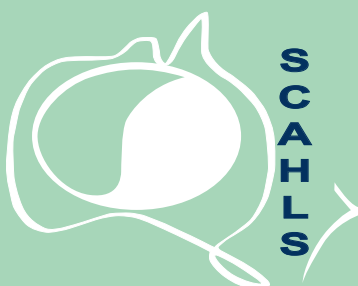
- Quality systems (NATA Accreditation to ISO/IEC 17025)
- National standards for diagnostic tests (ANZSDPs)
- Proficiency testing (e.g. ANQAP)
- National reference laboratories
- Development and validation of new diagnostic tests
- Continuing professional and technical education
- National and international collaboration

The committee has representatives from State and Federal governments, CSIRO, Animal Health Australia, NATA and private sector laboratories. It reports to Primary Industries Standing Committee (PISC) through Animal Health Committee (AHC). Details can be found on the SCAHLS website at www.SCAHLS.org.au

Syndrome Reporting

SCAHL S/AHC have agreed on a format for syndrome reporting by all veterinary laboratories in Australia. The concept involves listing the number of diagnostic outcomes for animal disease investigations, based on the presenting clinical signs. The procedure will allow retrospective reviews of the ability of the surveillance system to exclude potential exotic diseases and will identify syndromes not captured by the system. There are 24 syndromes (from abortion/still-

birth to weakness/depression) and 7 diagnostic categories (endemic diseases, new diseases and several categories of 'no diagnosis'). All species are covered, including feral and captive wildlife. Syndrome reporting data will be collated at State/Territory level and published through the National Animal Health Information System (NAHIS). Details of the scheme are available on the SCAHL S website – see 'Guidelines for Syndrome Reporting' in the 'Policy and Guidelines' folder.



Reference Laboratories

One of SCAHLS objectives is to encourage the establishment and recognition of Australian National Reference Laboratories that will be the reference points and centres of excellence for specified diseases. There are prescribed roles and criteria for recognition as a reference laboratory. Criteria for recognition as a reference laboratory for a particular disease are similar to those set by The World Organisation for Animal Health (OIE), the international organisation for animal health. These include having resident scientific staff who are acknowledged as experts in the specified disease and having a range of diagnostic tests for the disease including those not ordinarily available at other Australian animal health laboratories.

Other roles of reference laboratories are: supply of reference products and reagents used in diagnostic tests for the disease; development of new procedures for diagnosis, control and exclusion testing of the disease; maintenance of current epidemiological data for the disease; and, provision of scientific

and technical training for personnel at other laboratories in Australia. This is by no means an exhaustive list of the requirements and functions of reference laboratories but gives you an idea of the basics.

Currently there are seven SCAHLS-endorsed Australian National Reference Laboratories and you can check these on the SCAHLS website. The information in this is due for update by the end of November 2004.

If you want any more information about the criteria for qualification as a reference laboratory or their roles, functions and activities send your questions to Pritchard.david@saugov.sa.gov.au

National Veterinary Laboratory Specialist Competencies

Another service SCAHLS maintains for veterinary laboratories and all users of veterinary laboratories around Australia, is a list of scarce expertise in quite specialised areas. This is a resources database that facilitates access to advice, information and tests that are uncommon

or rare and often available at only one place in Australia.

This referral system differs from the Reference Laboratories in that the latter are providing a centre of excellence for a particular disease. Often the referral laboratory is the only one performing a particular test or set of tests and these are usually very much linked to a person who has taken an interest and/or developed expertise in a specific disease or group of diseases, for example, plant toxicoses, fungal and tropical infections. Although these specialised fields are not unimportant or insignificant, they may not be so widespread or sufficiently common or potentially dangerous on the national scale to be included in the major national or State disease control programmes. There is not sufficient call, nationally, to warrant all the work and rigorous scrutiny required to establish an Australian National Reference Laboratory for the disease, syndrome or test type. Nevertheless, there is sufficient reason for SCAHLS to promote and encourage access to them.

SCAHLs endeavours to maintain a database which is as up to date and complete as possible. All laboratory workers and users of laboratories are invited to access the database not only to locate a resource, but also to contribute by having specialist competencies added to it.

The National Veterinary Laboratory Specialist Competencies database, available at the SCAHLS website, is to be updated in November-December 2004. You can obtain further information on the Specialist Competencies and referral laboratories database, by contacting Pritchard.david@saugov.sa.gov.au

New committee to consider future laboratory services in Australia

Queensland CVO Kevin Dunn is heading a new group looking at what changes are needed by Australian veterinary laboratories following the 2003 Frawley Report on 'Rural Veterinary Services'. The Frawley review recommended a more strategic and national approach to diagnostic laboratory services including collaboration between institutions, the possibility of strategic alliances between organisations and training opportunities for laboratory specialists. It also called for a definition of the minimum needs of the laboratory system, given the requirements to handle a surge of activity in the event of an emergency, biosecurity issues and new and emerging diseases.

The group has representation from the States/Territories, Commonwealth, CSIRO, Industry, private laboratories and universities, and will report to the federal Minister for Agriculture, Fisheries and Forestry in 2005. Initial meetings have been held and a number of national models are proposed. The group is also seeking input from SCAHLS and welcomes submissions from all interested parties and individuals. Several SCAHLS members are in the group including Chairman Martyn Jeggo. Anyone seeking further information, or wishing to make a contribution, should contact their SCAHLS member directly.

Virus neutralisation tests – expression of serum dilutions

In Australia and New Zealand, when a serum sample is diluted for testing, the dilution is expressed as the 'starting' dilution, that is, the dilution of the serum prior to the addition of other test components (ie virus and cells). However, in 2003, the Standards Commission of OIE recommended that, for all virus neutralisation test methods, the dilution of the serum should be expressed in terms of the "final" dilution of serum in the test (ie, the volume of liquid in the virus and cell

suspensions should also be considered). Use of 'final dilution' terminology is scientifically inaccurate, misleading and inconsistent with the methods for all other serological tests. In fact, addition of other test components does not reduce the absolute number of antibody molecules in the test system.

OIE has recently agreed to allow countries to use either terminology. For the purposes of Australian and New Zealand Standard Diagnostic Procedures (ANZSDPs) SCAHLS has

decided that 'starting dilution' terminology will be retained. However, when testing for export it is important to determine whether an import protocol specifies the test 'cut-off' in terms of starting or final dilution. Biosecurity Australia and AQIS will endeavour to make this clear when new protocols are negotiated. Unless otherwise specified, all test cut-off points for VN tests are currently described as a 'starting' dilution.

Proposal to form an Australian Association of Veterinary Laboratory Diagnosticians

Continuing education of staff in diagnostic veterinary laboratories is problematic, particularly for non-veterinary staff. In North America the American Association of Veterinary Laboratory Diagnosticians (<http://www.aavld.org/aavld-3/>) provides such an opportunity for members. At recent meetings, SCAHLS and AHC have approved the conduct of a feasibility study to assess the possibility of an Australia/New Zealand version of the AAVLD.

The proposed Association would offer members annual or biannual conferences, an electronic listserve and teleconferencing. Activities could be run concurrently with related groups.

Background material and a questionnaire have been circulated to laboratory staff through ANQAP. Response so far has been sufficient to encourage further work and development of an inaugural conference to further test commitment of staff and employers. SCAHLS has appointed a small steering committee of proponents and respondents

to continue working to develop the agenda for the inaugural conference. Further information on the proposal can be obtained from the SCAHLS website (<http://www.scahls.com>).

Interested laboratory staff are encouraged to complete the questionnaire available on line and submit it to Dr Peter Kirkland (peter.kirkland@agric.nsw.gov.au).

JD Quality Plan – Evaluation of ELISA Kits

Independent validation of tests for Johne's disease will increase the confidence of livestock industries, laboratories and regulatory authorities in the diagnostic process. Enzyme-linked immunosorbent assays (ELISA) are widely used for the diagnosis and screening of groups of animals as part of the National Johne's Disease Market Assurance Programs. The recently approved JD Quality Plan requires that new batches of ELISA kits for Johne's disease be subjected to testing prior to release for diagnostic purposes. A new batch is defined as a batch with a change in the source, production or processing of any biological component of the kit.

Pre-release evaluations of bovine kits for Johne's Disease are conducted by the National Reference Laboratory for Johne's Disease (located at PIRVic Attwood). A pre-release evaluation of a new batch generally involves testing of a minimum of 40 well-characterised positive sera, approximately 100 - 200 negative sera and M phlei control sera from the National Serum Reference Panel. The sera are run on assays performed on four to six different days over a two-week period followed by collation and analysis of results within a week after completion of laboratory testing. The laboratory maintains all laboratory records associated with testing. The cost of evaluating a bovine ELISA kit is \$2,800, chargeable to the kit distributor.

Transport of Diagnostic Specimens and Dangerous Goods

How does it work?

The 2004 edition of the IATA (International Air Transport Association) Dangerous Goods Regulations (DGR) is the 45th Edition. These regulations were largely based on the Technical Instructions 2003-2004 of the International Civil Aviation Organisation (ICAO). The Technical Instructions, in turn, were largely based on the 12th Model Regulations on the Transport of Dangerous Goods, developed by the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) in consultation with the World Health Organisation (WHO) where it concerns infectious substances. Within Australia, the Civil Aviation Act is enforced by the Civil Aviation Safety Authority (CASA). From 1 July 2004, commercial shippers of dangerous goods must be trained.

Diagnostic specimens are currently defined as any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigative purposes, but excluding live infected animals. There are three "levels" currently based on WHO laboratory biosecurity risk groups:

- a). **High level danger.** These diagnostic specimens must be assigned to UN Number 2814 (infectious substance affecting humans) or UN Number 2900 (infectious substances affecting animals only), must comply with Packing Instruction 602 and must be accompanied by a Shipper's Declaration.
- b). **Low level danger.** All other diagnostic specimens must be assigned UN Number 3373 (diagnostic specimens) and must comply with Packing Instruction

650 but a Shipper's Declaration is not required.

- c). **No danger.** Those diagnostic specimens known not to contain infectious substances (**Not Restricted**).

What's new?

Positive developments are:

- the granting of observer status to OIE at UNSCETDG allowing OIE to make submissions and proffer opinions
- the approval of OIE's submission to UNSCETDG to modify the list of organisms that must be transported as infectious substances (UN Numbers 2814 or 2900), unless they are sent as cultures. Once adopted by ICAO and IATA, many more diagnostic

specimens will be able to be transported as UN Number 3373 substances from 1 January 2005 (at the earliest – worst case scenario 2007)

- Standards Australia has issued a draft standard for surface transport of biological materials.

A negative development is that UNSCETDG has amended the model regulations so that virtually all biological specimens (fresh tissues, blood, urine, faeces, etc) must be transported as UN Number 3373 substances, whether they contain infectious substances or not. If adopted by ICAO and IATA, it would mean that all such substances would have to comply with Packing Instruction 650 and the "level C" diagnostic specimens (see above)

Export Testing

A SCAHLS workshop on export testing in Australian Laboratories was conducted in December 2003. The workshop highlighted a number of issues and offered some 37 recommendations. A summary of these recommendations and the SCAHLS actions can be found on the SCAHLS Website (www.scahls.org.au) under "Workshops".

SCAHLS Membership (Nov 2004)

Martyn Jeggo	Chair, Representing Animal Health Committee
Russell Rogers	Deputy Chair, Representing DPI Queensland
Andrew Gregory	Executive Officer
Gary Horner	Representing MAF New Zealand
Peter Daniels	Representing AAHL, Geelong
Anton Janmaat	Representing DBIRD Northern Territory
David Pritchard	Representing Primary Industries and Resources, SA
Stephen Pyecroft	Representing DPIWE Tasmania
Deb Cousins	Representing Department of Agriculture, WA
Malcolm Lancaster	Representing DPI Atwood
Peter Morcombe	Representing AHA
Barry Richards	Representing IDEXX
Mark Williamson	Representing Gribbles
Bettina Poxleitner	Representing NATA
Mike Nunn	Representing Office of the Chief Veterinary Officer, DAFF
Judith Bourne	Representing Biosecurity Australia, DAFF
Graeme Fraser	Representing NSW DPI

would no longer exist. In fact, all diagnostic specimens would be classified as dangerous goods, either as Category A Infectious Substances (UN Numbers 2814 or 2900, Packing Instruction 602 and Shipper's Declaration) or Category B Infectious Substances (UN Number 3373, Packing Instruction 650 but no Shipper's Declaration). Moves are afoot to try to have this modified at the next meeting of UNSCETG, to be held later this year.

The next edition of the ICAO Technical Instructions (2005-06) will be issued shortly and this will be based largely on the 13th Model Regulations developed by UNSCETDG. The 46th IATA regulations, valid for calendar year 2005, will also be based on these two documents.

It is clear from the above that the regulations for the transport of diagnostic specimens by air are in a state of flux. To avoid inadvertent errors, anyone transporting diagnostic specimens by air needs to follow the latest version of the IATA Guidelines.

Pathology Standards Program

The National Registry of Domestic Animal Pathology currently located at EMAI, NSW has been re-badged the "Australian Animal Pathology Standards Program" (AAPSP). PISC 6 (2004) agreed, subject to review in 2004-05, an interim business plan and budget (2004-09). The review was to introduce a higher level of cost-recovery from both public and private users of the Program as well as a review of the formula for attributing government's share of the funding. The review will be coordinated by AHA, in consultation with AHC, and AHA will report back to PISC in March 2005.

ASVP (Australian Society of Veterinary Pathologists) in conjunction with AHA and with SCAHLS

Test Validation and Measurement of Uncertainty

Diagnostic tests are important for population based veterinary medicine including research, surveillance, disease-free certification, prevalence estimation, epidemiologic studies, risk management and modelling of infectious diseases. Little attention has been given to the post-analytical phase of the diagnostic process e.g. data management, analysis and interpretation. The purpose of the diagnostic testing and the structure of the data determine appropriate methods for data analysis.

Recently OIE suggested that all veterinary diagnostic assays used to test for disease status in relation to international trade should be validated following the 'fit for purpose' principle. This includes eight categories and 12 parameters, covering assay characteristics such as test type, sensitivity, specificity, turn-around-time and reproducibility.

Additionally, Australia's National Association of Testing Authorities (NATA) is suggesting that veterinary diagnosticians include an estimation of measurement uncertainty (MU) in all diagnostic tests performed.

It is concluded that the relevant parameters of MU in Veterinary Diagnostic Testing are expressed by proper assay validation because: "A validated assay provides results within predetermined statistical limits" (Jacobson, 1998). The overall estimate for MU is precision. Reproducibility and Repeatability are measurements of precision e.g. Repeatability estimates (intra and interassay variation) are available through continuous monitoring of internal quality control data. Reproducibility estimates are available through participation in external proficiency test programs such as ANQAP. This principle is similar to the "top-down" approach, as it provides an overall measurement of precision. It does not include the uncertainty of individual steps during the diagnostic process or take into account pre- and post-analytical sources of error, e.g. sampling errors, transcription, transformation errors etc.

The new concept for validation of diagnostic assays in veterinary diagnostic testing will considerably reduce the uncertainty of a test result and thus reflect a meaningful basis to comply with international regulatory standards. Providing diagnostic results within predetermined statistical limits enhances the client-service provider relationship and is a major precondition for an improved and competitive (inter)national trade.

For more information on this topic, see Test Validation and MU on the SCAHLS website.

Reference: RH Jacobson (1998) Validation of serological assays for diagnosis of infectious diseases. Rev sci tech Off int Epiz 17:469-486

overview will deliver continuing education and proficiency testing by a number of different contracts. The AAPSP will continue to be located at EMAI but continuing education services will be delivered via the internet (restricted access)

or by CD for members without appropriate internet access, and at the annual workshops around Australia for members. Proficiency tests will be forwarded directly to members, aiming for 2 cases every 3 months.

Audit of biological agents held in veterinary laboratories

Following a number of global and regional bio-terrorist activities, the formation of the Department of Homeland Security in the USA and the development of significant biosecurity programs in individual States there has been a number of initiatives to determine exactly what pathogens we have in our laboratories. In response to a SCAHLS paper submitted to the Animal Health Committee (AHC) entitled "Control of biological agents in Australian Veterinary Laboratories" at a recent AHC meeting, SCAHLS was asked to undertake a scoping study on the pathogens held in veterinary laboratories in Australia.

At the same time, the Commonwealth Government Department of Health and Ageing held a series of meetings around Australia to discuss how best to identify what biological agents existed in laboratories, what agents really need to be in such an audit and how best to manage any risks associated with these agents in the future. A full report of these discussions and the resulting conclusions will be available in November 2004.

It was considered useful if those laboratories represented on SCAHLS were to carry out a survey of biological agents currently held. A list of pathogens was prepared, based on the current HAZOP list, and circulated to all participating laboratories. The results of the survey will remain confidential, but they will be submitted to AHC with comment on issues of concern.

Clearly, there are biosecurity issues related to the holding of pathogens that could represent a risk to the livestock industries and could be used for agro-terrorist purposes. This risk needs to be properly assessed and managed. It is likely to affect the way some of these pathogens are managed, but there is a growing appreciation that this risk must be addressed. The solutions will be manageable and affordable and are likely to focus on enhancement of current procedures rather than a radical new way of doing things. We will keep you updated!

Plant Health To Copy SCAHLS Operations

In the Australian plant health diagnostic system there is no committee with an equivalent role to SCAHLS or that manages the type of work activities undertaken by SCAHLS. Plant Health Australia, in conjunction with the Office of the Chief Plant Protection Officer (OCPPO), has recently investigated the possibility that a similar model could work equally well for plant health laboratories. At a meeting in Melbourne it was agreed by all attendees that plant diagnostic laboratories should embrace the concept. PHA and the OCPPO have prepared a discussion paper for the forthcoming Plant Health Committee (PHC) meeting at which it will recommend the formation of a new PHC subcommittee. Terms of reference, a proposed work plan and membership will be discussed by PHC.

The proposed plant committee will cover the same issues addressed by SCAHLS such as identification of national reference laboratories, national diagnostic standards and laboratory accreditation.

Exercise Crucible

This three day exercise was designed to test the preparedness of NSW veterinary laboratories and AAHL to cope with an outbreak of foot and mouth disease. The exercise planners created a realistic scenario involving transmission from pigs to cattle which ultimately resulted in the northern third of NSW being in the affected area, with a large number of animals (including sheep) being included. Each day of the exercise dealt with different stages of the outbreak. Day 1 involved the initial diagnosis and investigation, day 2 revolved around confirmation of infection on a large number of holdings, and day 3 was concerned with testing for proof of freedom.

The exercise tested the readiness of the laboratory network and its integration with AAHL by evaluation of:

- Capability to deliver the necessary testing and scientific support for control and eradication operations;
- Capacity to complete the necessary testing;
- Administrative arrangements in support of and by the laboratories;
- Decision making by the laboratories;
- Policies and protocols as relevant and applied to the laboratories;
- Systems of the laboratories; and
- Communication between and within laboratories, and submitters.

In general, the laboratories were able to meet all the challenges posed by the exercise planners. However, the exercise did reveal a number of potential problems and identified opportunities for improvement. It was obvious during the exercise that laboratories do not have sufficient staff to extend beyond the initial response and

cannot provide ongoing support for the diagnostic teams.

Communication from and between laboratories was not always sufficient and laboratory staff need to become more familiar with Ausvetplan and the state emergency animal disease protocols. Laboratories should have up to date contingency plans addressing amongst other issues, staffing, biosecurity, communications and triggers for responses.

Further information on the exercise can be obtained from Kevin Cooper (kevin.cooper@agric.nsw.gov.au).

ANQAP update

Two tests have been deleted from the ANQAP program for 2005. They are the CAE AGID and the B equi IFAT. The CAE AGID had one participant using the "W" antigen only and the B equi IFAT had two participants. One participant only did the test for ANQAP purposes.

Duplicate tests for the ANQAP program for next year will be: JD (bovine) CFT, JD ELISA, JD (ovine) AGID, Aino VNT, Akabane VNT (new), NDV, HI (new), and the Avian influenza AGID (new)

ANQAP Review

The roles and functions of ANQAP are to be externally reviewed. Since its inception in 1990 the program has expanded and established itself nationally and internationally in external proficiency testing. The review will assess the scope and objectives of ANQAP, communications, clients, ANQAP endorsement processes, and the terms of reference for the program. When the review is under way, all laboratories will be invited to make submissions.

Australian & New Zealand Standard Diagnostic Procedures

The complete set of Australian and New Zealand Standard Diagnostic Procedures (ANZSDPs) was last published in 1993. ANZSDPs are progressively being reviewed and updated. As part of this process, all methods will be listed at the SCAHLS website (www.scahls.org.au) and can be downloaded as pdf files. This will allow changes to be made rapidly in future.

It has been decided that ANZSDPs will only be prepared/revised for:

- Testing for regulatory or industry-driven disease control programs.
- Testing for the export of animals or animal products.
- Testing for major endemic diseases affecting a significant proportion of national herds and flocks.

Some of the existing ANZSDPs (and ASDTs) describing test methods for minor endemic diseases, will not be revised. However, all old procedures will be archived and available for reference through the SCAHLS website.

In addition to redefining the purpose of ANZSDPs, the actual content of ANZSDPs will be limited to those test methods that are used for official purposes and where they are used in more than one laboratory. Where methods are only used for follow-up testing, research or reference purposes, they will not be included in detail in revised ANZSDPs.

The format of the ANZSDPs will also be changed. In particular, there will be a section that clearly documents the performance of test kits and reagents. In the past, there were few test kits available commercially and there was no reference to product names. In the new format, all new test kits will need to be approved by SCAHLS, in the same manner that new test methods are approved. The performance of kits and methods will be described in the ANZSDP in terms of their fitness for the purpose for which they have been approved by SCAHLS. A test method or kit must not be used as an official test for a purpose, or in a manner, for which it has not been approved. For example, if a test method or kit has been validated for testing of one sample type, it cannot be used officially (ie for a purpose approved by SCAHLS) to test a different type of sample. Any extension to the scope of use of a test/kit must be reviewed and approved by SCAHLS.

Australian Reference Laboratories

- John's Disease Reference Laboratory, (DPI Atwood)*
- Australian Reference Laboratory for Bovine Tuberculosis, (Department of Agriculture, Perth)*
- Footrot Reference Laboratory, (Department of Agriculture, Albany)
- Anthrax Reference Laboratory, (Elizabeth Macarthur Agricultural Institute, NSW)*
- Newcastle Disease Reference Laboratory (Australian Animal Health laboratory, Geelong)*
- Avian Influenza Reference Laboratory (Australian Animal Health Laboratory, Geelong)*
- Bluetongue Reference Laboratory, (Australian Animal Health Laboratory, Geelong)*

*Note: *Also OIE Reference Laboratories*