



BIOLOGICAL AGENTS BULLETIN ISSUE NO. 5

CHANGES TO THE CIRCULATION OF BAB: A REMINDER

Welcome to the first electronic-only issue of the Bulletin. Thank you to all our existing readers for providing their e-mail address details. If you wish to change your details or to have an e-mail address added for direct e-mailing of future Bulletins please contact hsesubs@prolog.uk.com with your details. Photocopies of the Bulletin are also available if you want to forward it on to others without access to a PC who may be interested. Write to HSE HDB1 at the address at the end of this Bulletin if you would like to receive hard copies. Previous copies of the Bulletin are still available from HSE Books (contact details at the end of this Bulletin) or you can view or bookmark them online at <http://www.hse.gov.uk/biosafety/information.htm#a11>

PROGRESS REPORT ON FORTHCOMING GUIDANCE TITLES

❖ Biological agents: Managing the risks

Work is progressing with this new guidance. As the guidance will specifically advise on COSHH and biological agents in the healthcare setting, it has been agreed that early views on the general approach should be sought from the intended audience. Focus groups covering the human and animal health care sectors will be arranged later this year.

This approach has already proved useful in preparing the simple risk assessment guidance. Focus groups were held in

November last year. Representatives from a number of occupations attended, including: environmental health officers, park wardens, the fire brigade, nursery nurses and drainage workers.

❖ Containment Level 4

Work on preparing this new guidance entitled *Biological Agents: Managing the risks with Hazard Group 4 agents* is progressing well. It has been agreed that the design will follow the same format as the recently published Containment Level 2 and Containment Level 3 (CL2/CL3) guidance on *Management, design and operation of microbiological containment laboratories* (see Further reading) ie loose leaf, wipe clean, and with extensive use of colour and colour photographs. The content will be consistent and fit alongside the information and advice provided in the CL2/CL3 guidance. It is expected that employers in large organisations and Government bodies will make up the bulk of the intended audience, and it is likely to be circulated to the overseas market. The possibility of making the guidance available on the Internet via the HSE website is being explored.

CHANGES TO ACDP MEMBERSHIP

Two expert members of ACDP, Professor Catherine Peckham (epidemiologist), and Mr Martin Jones (laboratory health and safety expert) and employee representative, Ms Dee May, have recently resigned from the committee owing to other commitments. The terms of office for two of the employer representatives on ACDP, Mr Bob Clare and Miss Anne Harris, and employee representative, Mr Paul Taylor, have also come to an end. Warmest thanks are extended to all of them for the valuable contribution they have made to the work of the committee.

New appointments to serve on ACDP have been confirmed as follows – expert members: Dr Mike Painter, Mr Gordon Sutehall; employer representatives: Dr John Keddie, Dr Peter Wilson; employee representatives: Mr Peter Edge, Ms Susan Wiseman.

The terms of office of three other expert members - Dr Barbara Bannister, Professor Don Jeffries and Professor Brian Spratt, and another employer representative, Mr John Saxby, finished on 31 October. Our thanks also go to them for the important and very valuable contributions they have made to the work of the ACDP and its various Working Groups. A further three expert members – Dr Diana Westmoreland, Professor Colin Howard, Professor William Irving (to replace outgoing members), and a fourth expert member, Professor Colin Dixon (to enhance the range of expertise on the Committee) have been appointed to take up post with effect from 1 November 2002.

UPDATES

❖ POLIO

The UK panel for the certification of elimination of poliomyelitis recently prepared a final update report to be submitted to the European Regional Certification Commission (RCC). The national documentation on certification for all countries in the European Region will be reviewed by the RCC this year, and it is hoped that the region will be certified 'polio-free' by the end of 2002. The WHO global target for 2002 is to interrupt all transmission of wild poliovirus and reach certification of eradication by 2005.

A requirement for completion of the certification process is that, upon global eradication, the laboratory containment level of wild poliovirus should change from CL2 to CL3. The post-global

eradication phase begins one year after detection of the last wild poliovirus anywhere in the world. Latest advice from the WHO indicates that this phase may take place as early as 2003.

It is expected that this issue will be discussed further at the December meeting of the ACDP.

❖ COSHH

The consultation on proposals to amend the biological agents provisions of COSHH ended in January this year. HSE is drafting amendments to address a number of comments received. Although no significant changes will be made, the amendments will provide more clarity in the text of the ACOP and guidance. The amended proposals were submitted to HSC in July for agreement.

❖ EVALUATION OF THE LEGIONELLA ACOP AND GUIDANCE

Work has been initiated to review the effectiveness of the new aspects of the revised HSC *Approved Code of Practice (ACOP) and guidance on the control of legionella in water systems* (see Further reading). HSE is overseeing a competitive research tender to evaluate the relevant sections of the ACOP and guidance.

A video related to the ACOP and guidance is currently in preparation. This will complement the existing guidance and will also include a self-audit proforma to assist the responsible person (as required by the ACOP) audit the arrangements they have in place to control legionella, and so assess their level of compliance with the ACOP and guidance. It is hoped that this will be released later this year.

❖ CHANGES TO THE APPROVED LIST

ACDP has discussed the outcome of the consultation to review the UK Approved List of Biological Agents. They have agreed a number of changes to the contents of the List, in particular the case for removing certain agents and increasing the Hazard Group of one agent: Duvenhage virus. This agent will be the subject of a limited consultation exercise to assess the impact of moving from HG2 to HG3. The revisions proposed will be recommended to the Health and Safety Commission (HSC) for approval. Publication of a new edition of the UK Approved List is expected to follow this approval.

If you have any comments on the proposed change to the Hazard Group of Duvenhage, please let us know. Contact:

Jillian Deans Tel: 0151 951 4528 e-mail:

jillian.deans@hse.gsi.gov.uk.

THE ROLE OF THE MEDICAL DEVICES AGENCY

What do you do if an adverse incident occurs in your laboratory?

The MDA (Medical Devices Agency) is an executive agency of the Department of Health. Its primary role is to ensure that all medical devices, including *in vitro* diagnostic (IVDs) medical devices such as HIV tests, automated immunoassay analysers and blood collection tubes, meet appropriate standards of safety, quality and performance and that they comply with relevant directives of the European Union.

As part of their overall role, MDA relies on clinical laboratory staff, doctors, nurses and other IVD users to report adverse

incidents to their adverse incident centre (AIC) for investigation. This provides an ongoing post-market surveillance system for IVDs, which contributes to the quality of these devices, the results that they produce and therefore patient care.

What is an *in vitro* diagnostic (IVD) medical device?

Broadly, a 'device' is described as an IVD when the manufacturer intends it to be used for the *in vitro* diagnostic examination of specimens derived from the human body. This includes:

- reagents, calibrators and control materials;
- analyser systems;
- point of care testing devices;
- specimen receptacles (including blood collection tubes).

NB: Items of general laboratory equipment (such as glassware, pipettes, and ovens) that are not specifically intended by their manufacturer for *in vitro* diagnostic use fall outside the MDA remit.

What is an adverse incident?

An adverse incident is any incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. Adverse incidents in IVDs devices may arise from shortcomings in the device, its operating instructions, user practices or conditions of use. Unwanted effects may include misdiagnosis or inappropriate treatment.

How do I send the reports to MDA?

All reports should be made either on-line via MDA's website (which is the preferred method) or using the IVD reporting form which should be sent to: MDA Adverse Incident Centre, Medical Devices Agency, Hannibal House, London SE1 6TQ, Tel: 020 7972 8080, Fax: 020 7972 8109, e-mail: mb-mba-aic@doh.gsi.gov.uk.

For further information on the MDA, copies of SN2002 (01) giving further guidance or to report an adverse incident visit the MDA website: <http://www.medical-devices.gov.uk/>

PHLS (PUBLIC HEALTH LABORATORY SERVICE) INTERIM GUIDELINES ON DELIBERATE RELEASE

ACDP has reviewed the Interim Guidelines issued by the PHLS for the following biological agents that could be used in a deliberate release:

- smallpox;
- anthrax;
- plague;
- botulism;
- tularaemia;
- viral haemorrhagic fevers (VHF).

Members' contributions have been fed back to the PHLS for inclusion in revisions as appropriate. For the latest information on the deliberate release guidelines go to the PHLS website at <http://www.phls.org.uk>

CMO'S INFECTIOUS DISEASE STRATEGY: GETTING AHEAD OF THE CURVE

The report from the Chief Medical Officer, *Getting ahead of the Curve: A strategy for combating infectious diseases*, was published in January of this year. This is available on the Department of Health website at <http://www.doh.gov.uk/cmo/idstrategy/index.htm>

The strategy describes the scope and nature of the threat posed by infectious diseases to public health, and establishes priorities for action to combat present and possible future threats posed by infectious diseases. These include the threats from new and emerging diseases and zoonoses. The report highlights the need for good surveillance to identify new infectious disease threats and monitor serious outbreaks, and emphasises the need for proper co-ordination of infectious disease surveillance systems.

The strategy proposes a number of actions to further these aims, including the establishment of a new National Infection Control and Health Protection Agency. This agency will combine the functions of The Public Health Laboratory Service (PHLS), The Centre for Applied Microbiological Research (CAMR), The National Radiological Protection Board (NRPB) and the National Focus for Chemical Incidents (NFCI). Key professionals working in health protection – consultants in communicable disease control, health emergency planning advisers, microbiologists and infection control nurses – will be drawn together to provide a dedicated field service and an integrated approach to protecting the public against infectious diseases and chemical and radiation hazards. It is also proposed in the strategy that a national expert panel is formed, to assess the threat from new and emerging infectious diseases.

The ACDP, with its remit to advise Government Departments generally, rather than just DH, on the risks and hazards from dangerous pathogens, and its specific remit to advise on occupational risks from dangerous pathogens, is seen as vital in providing independent expert advice. There are no plans to subsume its role into the Agency.

For the latest news see relevant pages of The Department of Health website and links at <http://www.doh.gov.uk/cmo/hpa/index.htm>. A comprehensive website for the new Health Protection Agency (HPA) is now under development.

DECONTAMINATION REPORT

The Department of Health has published the results of a national survey of decontamination services for surgical instruments in the NHS. The survey follows advice from the Spongiform Encephalopathy Advisory Committee (SEAC) that a key factor in reducing the theoretical risk of person-to-person spread of variant Creutzfeldt–Jakob disease (vCJD) is a high standard of decontamination of surgical instruments. Further information, including a summary report of the comprehensive review, is available for downloading at

<http://www.decontamination.nhsestates.gov.uk>

PET TRAVEL SCHEME: EXTENSION TO NORTH AMERICA

To help decide whether the Pet Travel Scheme can be extended to include North America in the list of qualifying countries, risk assessments, commissioned by DEFRA, have been prepared as follows:

- a re-assessment of the risks of importing rabies if pet animals from North America were eligible for the Pet Travel Scheme (Centre for Tropical Veterinary Medicine, University of Edinburgh); and
- an assessment of exotic agents of cats and dogs that could, potentially, be imported into the UK from North America if the Pet Travel Scheme were to be extended in that direction (Department of Veterinary Pathology and Centre for Comparative Infectious Diseases, University of Liverpool).

The ACDP Working Group, which previously considered the risk assessment on diseases, other than rabies, which could be brought into the UK with pet cats and dogs travelling from those countries which are now included in the scheme, met to consider the Liverpool report. Their conclusions were that the revised risk assessment did not indicate any reason why the scheme should not be extended to North America. The group also concluded that the risk assessment on exotic diseases had thoroughly covered all exotic agents that cats and dogs could potentially import from North America, although they thought that existing tick and tapeworm treatments should remain to prevent the importation of *Rhipicephalus sanguineus* and *Echinococcus multilocularis* in view of the infections they can carry.

TSEs: SAFE WORKING AND THE PREVENTION OF INFECTION: WORKING WITH LOW RISK SPECIMENS IN A DIAGNOSTIC LABORATORY

Overview

Having been asked to advise in this area and to ensure ongoing patient care is not compromised, ACDP has decided to prepare some interim guidance covering the issues pending the completion of a full update of the main ACDP document:

Transmissible spongiform encephalopathy agents (TSEs): Safe working and the prevention of infection. The interim guidance is set out below:

A range of laboratory tests may be required for the clinical management of patients with known or suspected CJD. This interim guidance outlines what steps should be taken when working with low risk TSE samples. This information should help to ensure that patient care is not compromised when laboratories are asked to process such samples. As published in the guidance document *Transmissible spongiform Encephalopathy agents (TSEs): Safe working and the prevention of infection*, low risk specimens include cerebrospinal fluid (CSF), blood, urine, faeces and swabs from peripheral sites destined for routine clinical analysis. The situation has been kept under continuing review and the lack of evidence of infectivity in these body fluids, in faeces, and in swabs from peripheral sites means that they continue to be regarded as low risk.

TSEs are categorised as Hazard Group (HG) 3, therefore the baseline containment level (CL) required for such work (as defined by the Control of Substances Hazardous to Health Regulations) is CL3. However, because of the unique properties of the agents and the type of work that is being considered here,

not all the containment measures normally required by CL3 may be necessary. A similar situation arises when considering the containment measures required when performing diagnostic work on specimens known to contain HG3 blood-borne viruses (eg Hepatitis B).

Given the range of diagnostic techniques that might be used, it is not possible to indicate the appropriate measures for every situation. These must be selected on the basis of a risk assessment of the work to be carried out. The assessment should take into account:

- the potential for dispersal of the agent – for example, does the process involve mixing, stirring or manual dispensing of fluid?
- the potential for contamination of workers, equipment or surfaces; and
- the potential for contamination of automated equipment and how this will be addressed in terms of routine cleaning, making 'safe' for servicing and disposal of effluent.

Although not all the containment measures may be necessary in any particular instance, this does not mean that the work can be carried out under CL2 conditions. But, subject to following the guidance set out below, a CL2 laboratory may be appropriate for this work.

Before considering what CL3 measures may not be required when working with low risk TSE specimens in a CL2 diagnostic laboratory, it is important to be familiar with CL3 measures including that:

- the workplace must be sealable to permit disinfection (fumigation);

- extract air from the workplace must be HEPA filtered (or equivalent);
- the workplace must be separated from other activities in the same building;
- the workplace is to be maintained at an air pressure negative to atmosphere;
- there must be some means of viewing the occupants; and
- the laboratory must contain its own equipment, so far as is reasonably practicable.

What to consider before dispensing with containment measures

Although in many respects the requirements of a CL3 laboratory are outwardly similar to CL2 laboratories, because of the more hazardous nature of the agents, the standards that must be achieved are higher. The key differences between CL3 and CL2 laboratories relate to the way in which they are managed and the degree of supervision, in addition to the physical requirements of the laboratory itself. In terms of the work under consideration here, managers should ensure that:

- staff are competent to carry out the work;
- they have received suitable information, instruction and training about the risks; and
- there is appropriate supervision of the work in question.

Further detail on these issues can be found in the ACDP guidance *The management, design and operation of microbiological containment laboratories*.

The main physical containment measure that might be dispensed with after a risk assessment (ie as long as other risks do not warrant such measures, for example if other biological agents are likely to be in the sample) are:

- the need for the laboratory to be sealable to permit fumigation as the TSE agents are not affected by normal fumigants. Therefore, the means of decontamination for TSEs, in particular in the event of a major spillage, will need to be addressed in the local code of practice/Standard Operating Procedures;
- subject to the local assessment, it may not be necessary for the laboratory to be maintained at negative pressure. For example if the work only involves the handling of small volumes of liquid, the work could be carried out within the confines of an appropriate microbiological safety cabinet – all such devices will have HEPA filtered exhausts. Other activities may have the potential to disperse material that could be a risk. The risk assessment should be used to decide if negative pressure is required to prevent this. If a cabinet is used this will mean that the laboratory is under negative pressure to some extent. However, given that there is likely to be increased traffic in and out of such a diagnostic laboratory, this negative pressure will not be constant and so the work should remain within the confines of a cabinet (see also guidance for work with low risk samples in autoanalysers). If a cabinet is used, consider the routine disinfection of surfaces and also the action to be taken when the cabinet requires servicing.

Alternatives to required containment measures

When conducting work on low risk TSE specimens, the risk reduction afforded by the specified CL3 measures in certain areas may also be achieved by other means. **This should not be interpreted as a means of carrying out any other work with TSEs, or any other HG3 agents, under such conditions.**

- The need to separate the work from other activities does not necessarily mean having a separate laboratory, although this would be the preferred solution. Work could be separated temporally, ie samples could be handled at the beginning or ending of a work period.
- If an observation window, or alternative is not present so that occupants can be seen, then there will need to be some means of checking on staff, for example using CCTV or else regular phone calls/agreed check-ins. Such measures will ensure that adequate supervision is in place when individuals are working alone.
- In terms of equipment used for the handling of **infectious** material, this should be disposed of as clinical waste using standard procedures. The transport of infectious material also needs to be considered. Ideally, it should be stored within the room where it is to be handled. If this is not the case, it should be transported in robust, properly labeled and secure containers, which should only be opened within the confines of a microbiological safety cabinet.

Automated analysis of CSF, blood and other low risk specimens from known or suspect patients

One example of work where reduced containment measures may be considered is when 'low' risk samples from patients with known or suspected CJD are analysed in automated systems. The assessment for this work may indicate that it can be done in a fully enclosed automated system at CL2 providing any manual processing such as decanting is carried out within a microbiological safety cabinet. The low risk of infectivity together with the use of a fully enclosed system is considered to reduce any risk of exposure to the laboratory worker to a very low level. A local risk assessment should still be performed to determine what additional precautions might be required to control exposure (eg Can automated system contain spillages? How will waste be disposed of? Are suitable maintenance and emergency procedures in place?).

If you are not sure of the appropriate containment measures that should be in place for the risks identified, then you should **consult HSE on the risk assessment.**

FURTHER READING

Current ACDP publications and other free and priced publications relating to working with biological agents may be obtained from HSE Books, the Department of Health or the Stationery Office (TSO) (details at the end of this Bulletin).

HSE Books

Management, design and operation of microbiological containment laboratories HSE Books 2001 ISBN 0 7176 2034 4

Legionnaires' disease. The control of legionella bacteria in water systems. Approved Code of Practice and guidance L8 (Third edition) HSE Books 2000 ISBN 0 7176 1772 6

TSO publications

Transmissible spongiform encephalopathy agents (TSEs): Safe working and the prevention of infection TSO 1998 ISBN 0 11 322166 5

ADDRESSES FOR OBTAINING PUBLICATIONS

HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165 Fax: 01787 313995 Website: <http://www.hsebooks.co.uk> (HSE priced publications are also available from bookshops)

Department of Health, PO Box 777, London SE1 6XH Tel: 08701 555455 Fax: 01623 724524 Website: www.doh.gov.uk/acdp/publications.htm

The Stationery Office, PO Box 276, London SW8 5DT Tel: 0870 600 5522 Fax: 0870 600 5533 Website: <http://www.tso.co.uk> (TSO publications are also available from bookshops)

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