ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

Review of published ACDP guidance

ISSUE

In February 2012 ACDP agreed to a review of its current portfolio of guidance and an outline of the structure for new guidance. Members are asked to consider more detailed proposals for taking forward the guidance review.

BACKGROUND

ACDP has an existing suite of technical guidance on the control of risks from exposure to pathogens at work (see full list in Annex 1). The users of this guidance are generally health and safety specialists or experts in the relevant field. They will often rely on it as the main source of information on what they or those they advise, must do to comply with health and safety legislation in the relevant specific application. It is therefore important that it remains proportionate, current and fit for purpose. ACDP has agreed that they will seek to ensure that their guidance is in accordance with the principles of good guidance outlined in the Government’s ‘Code of Practice on Guidance and Regulation’.

The existing documents each contain information and standards that are specific to the document, but also contain generic information mirrored in all the publications. For example, the law and its application, containment measures, fumigation methods, emergency procedures, waste disposal and disinfection.

The suite of ACDP guidance can be separated into two categories. Firstly, those that relate to laboratory-type work, i.e. activities involving the deliberate propagation of biological agents in contained use conditions (‘contained use guidance’). Secondly, those that deal with incidental exposure; where the work activity involves providing care for people, or work with contaminated materials. In this latter category, ACDP’s role in providing advice for healthcare workers is particularly important.

THE PROJECT OUTLINE

PHASE I

Phase I of the project will concentrate on ‘contained use’ guidance, which members agreed were the first priority for review. These include:

• The management, design and operation of microbiological containment laboratories (2001),
• Biological agents: Managing the risks in laboratories and healthcare premises (2005) (laboratories aspect only)
• Working safely with research animals (1997), part of which is a supplement document - Working Safely with Simians (1998)
• The large-scale contained use of biological agents (1998)
The following documents were not highlighted as the first priority by the ACDP committee but involve ‘contained use’ of biological agents and will be incorporated into the first phase of the project:

- **Biological agents:** The principles, design and operation of containment level 4 facilities (2006)
- **Vaccination of laboratory workers handling vaccinia and related poxviruses infectious for humans** (1990)
- **Revised advice on laboratory containment measures for work with tissue samples in clinical cytogenetics laboratories supplement to: ACDP guidance on protection against blood-borne infections in the workplace HIV and hepatitis** (2001)
- **Transmissible spongiform encephalopathy agents: safe working and the prevention of infection** (2003)

The intention is to use the model of the unpublished Biosafety Guidelines for Contained Use (2010) prepared by ACDP as the central core document. This was drafted by the committee some time ago in preparation for the single regulatory framework. ACDP incorporated updated information on laboratory containment issues, which we need to include in current guidance. The guide can be modified to fit the current regulatory landscape to form a central hub of core guidance.

In the framework of the proposed 2012/13 guidance review specialist topics will exist on the periphery of this central hub as a satellite topic (See Annex 2). The rationale used to decide on core and satellite topics within this framework are discussed in detail in Annex 3.

**PHASE II**

Phase II of the project will focus on the review of guidance relating to incidental exposure. ACDP has recently updated *Protection against blood-borne infections in the workplace: HIV and hepatitis* and the *Management and control of viral haemorrhagic fevers* and therefore these do not need further review.

The remaining documents for review in Phase II are:

- **Infection risks to new and expectant mothers in the workplace** (1997)
- **Biological agents: Managing the risks in laboratories and healthcare premises** (2005) (healthcare aspect only)
- **Infections at work: controlling the risk**

A similar approach will be taken in this phase to determine whether the material within these guidance documents still remains valid and whether information can be brigaded into the overarching document. Thus some of the Phase II guidance documents once reviewed may be better placed as satellite topics around the central hub. For example, elements of the guidance set out in “Infection risks to new and expectant mothers in the workplace”

**Resources required to carry out the Review**

Much of the current guidance due for revision is of a specialist nature. However, for most we are not proposing to make significant changes to what is required. Therefore it is proposed that the bulk of the drafting of new guidance can be done by HSE staff. It will be essential for ACDP to review the drafts.
In addition, for the following documents there is scope for update and consideration of whether the techniques and methodology employed are in line with the current standards:

- Working safely with research animals (1997)
- Working Safely with Simians (1998)
- The large-scale contained use of biological agents (1998)

We therefore propose to approach ACDP members before the next meeting to set up arrangements for review of draft documents and to arrange a working group(s) with the expertise to review the above 4 documents.

ACTION
Members are asked:

- To support the project proposal to review ACDP Guidance using the phased approach
- To agree with the rationale taken in regards to the core and satellite topics that will form the body of the project
- To provide the necessary expert input to the review process required by this undertaking
## ANNEX 1 COMPLETE LIST OF ACDP PUBLICATIONS

<table>
<thead>
<tr>
<th>Current ACDP publications</th>
<th>Date</th>
<th>Format</th>
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<tbody>
<tr>
<td>Vaccination of laboratory workers handling vaccinia and related poxviruses infectious for humans</td>
<td>1990</td>
<td>Hard copy</td>
</tr>
<tr>
<td>Microbiological risk assessment: an interim report</td>
<td>1996</td>
<td>Hard copy</td>
</tr>
<tr>
<td>Working safely with research animals</td>
<td>1997</td>
<td>Hard Copy</td>
</tr>
<tr>
<td>The large-scale contained use of biological agents</td>
<td>1998</td>
<td>Hard Copy</td>
</tr>
<tr>
<td>Working safely with simians: Management of infection risks</td>
<td>1998</td>
<td>Hard Copy</td>
</tr>
<tr>
<td>The management, design and operation of microbiological containment laboratories</td>
<td>1998</td>
<td>Hard Copy</td>
</tr>
<tr>
<td>Revised advice on laboratory containment measures for work with tissue samples in clinical cytogenetics laboratories supplement to: ACDP guidance on protection against blood-borne infections in the workplace HIV and hepatitis</td>
<td>2001</td>
<td>Hard Copy</td>
</tr>
<tr>
<td>Infection at work: Controlling the risks</td>
<td>2003</td>
<td>Electronic</td>
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<tr>
<td>Transmissible spongiform encephalopathy agents: safe working and the prevention of infection</td>
<td>2003</td>
<td>Electronic</td>
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<tr>
<td>Biological agents: Managing the risks in laboratories and healthcare premises</td>
<td>2005</td>
<td>Electronic</td>
</tr>
<tr>
<td>Biological agents: The principles, design and operation of Containment Level 4 facilities</td>
<td>2006</td>
<td>Electronic</td>
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<tr>
<th>Other titles</th>
<th>Date</th>
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<tr>
<td>Draft Biosafety Guidelines (CU2010) - drafted in anticipation of a new regulatory framework</td>
<td>2010</td>
<td>Electronic</td>
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<tr>
<td>Blood-borne virus web-based guidance</td>
<td>2012</td>
<td>Electronic</td>
</tr>
<tr>
<td>Management and control of viral haemorrhagic fevers</td>
<td>2012</td>
<td>Electronic</td>
</tr>
</tbody>
</table>
• The management, design and operation of microbiological containment laboratories (2001)
• Biological agents: The principles, design and operation of Containment Level 4 facilities
• Working safely with research animals (1997) with Working Safely with Simians (1998) as annex
• The large-scale contained use of biological agents (1998)
• Revised advice on laboratory containment measures for work with tissue samples in clinical cytogenetics laboratories supplement to: ACDP guidance on protection against blood-borne infections in the workplace HIV and hepatitis (2001)
• Transmissible spongiform encephalopathy agents: safe working and the prevention of infection
• Biological agents: Managing the risks in laboratories and healthcare premises (2005) (laboratories aspect only)
• Vaccination of laboratory workers handling vaccinia and related poxviruses infectious for humans(1990).

PHASE II - INCIDENTAL EXPOSURE

• Infections at work: Controlling the risks (2001)
• Infection risks to new and expectant mothers in the workplace (1997)
  • Biological agents: Managing the risks in laboratories and healthcare premises (2005) (healthcare aspect only)

Draft Biosafety Guidelines Prepared for SRF in 2010
ANNEX 3: RATIONALE FOR DECIDING ON CORE AND SATELLITE TOPICS

We have pinpointed commonalities across the ACDP suite of guidance. For example, areas dealing with Health and Safety Legislation, Risk Assessment, Training and Supervision appeared in most of the guidance documents. These would be included in the core of the project. Many of these key elements are not only in the ACDP guidance, but also form the foundation of all HSE’s guidance.

CORE TOPIC AREAS:
- Health and Safety Legislation
- Management Issues
- Risk Assessment
- Training And Supervision
- Containment Tables
- Emergency Procedures / Accident Reporting

SATELLITE TOPIC AREAS:
The satellite topic areas, set out below, are mostly specific to work with dangerous pathogens. This guidance will be reviewed to ensure it is clear and that it focuses on providing advice on what duty hodlers must do to comply with the relevant legislation and standards. Where detailed information already exists elsewhere there will be clear electronic links so users can access the information without having to search through entire documents for the relevant section.

Containment Level 4: A small proportion of laboratories within the UK operate at Containment level 4, consequently the information here will only apply to a minority of users. However, as this is the highest hazard work it is important that the Biological agents: The principles, design and operation of Containment Level 4 facilities (2006) is retained. This will be an abridged technical supplement.

Waste Management: This section details the management of waste across the sector and would conceivably include information relating to autoclaves. As a satellite topic it would link electronically to relevant supporting bodies e.g. the Environment Agency and the Department of Health where further details relating to waste management and waste transport are available. It would useful to include in this section various methods of disposal such as incineration and alkaline hydrolysis etc.

Transport: In relation to the transport of samples, specimens and culture material from both the Hospital laboratories perspective and academia - this topic was less evident throughout the guidance but nonetheless contains important information that is relevant to a majority of dutyholders. As a peripheral document this section would provide users with minimal information (hence its inclusion as a satellite document) as this information already exists through the Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste via the Department of Health website.

Decontamination: The supplement will include the cleaning methods employed at all containment levels detailing disinfection requirements with more specialised information relating to fumigation - this topic could bring together the alternative methods used across the sector and link to useful information relating to efficacy of chosen methods.

Working with animals: In a similar vein to the Containment Level 4 guidance; this document and the supplementary information provided in the Working Safely with
Simians guidance applies to a more specialist line of work. Containment issues relating to animal work will continue to reside in the Containment tables within the core of the guidance document. However more specific instructions e.g. relating to work with Simians, Animal Welfare, disposal of carcasses, non biological hazards that arise from working with animals and specific RPE requirements (e.g. whether suited systems are employed) will be brigaded into a specialist supplement document.

**Microbiological Safety Cabinets (MSC’s) and Isolators:** Specific technical details relating to Microbiological Safety cabinet and Isolators will be incorporated here. Information will include the performance criteria for MSC’s and practical recommendations for safe use. The section will also contain information relating to the testing parameters for MSC’s e.g. In Use Operational Protection Factor Testing and details regarding maintenance regimes in line with (and electronically linked to) British Standards BS EN 12469:2000.

The same will apply for the use of Isolators electronically linked to the HSE guidance document “Guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents”

**Containment Measures for tissue samples in cytogenetics laboratories:** This document is highly specialised with specific information relating to the manipulation of specific tissue types. Before it is included in the project it will need reviewing to ensure it is in line with current procedures - we would require ACDP to decide whether this document is still relevant.

**Large scale work:** This document predominantly relates to the industrial sector and provides advice on the safe standards of operation for the large scale use of biological agents in Hazard Groups 2, 3 and 4 particularly in relation to fermenter systems.

**Health Related Issues:** Information here would include Health Surveillance, Screening and Vaccinations for staff working in the laboratory environment however it may be logical to include within this satellite those that could be termed “vulnerable employees” e.g. those that are immunocompromised and pregnant women which will incorporate some aspects of the document Infection risks to new and expectant mothers in the workplace.

**Maintenance of Containment Facilities:** Sealability Testing incorporating the current HSE guidance and other testing methods / Issues, including pressure decay testing.

**Design Issues:** Relates to specialist information relating to the construction of CL3 and CL4 facilities.

**Miscellaneous Topics:** Includes information that does not fit within the scope of the aforementioned satellites:

- Permit to work
- Visiting workers
- Lone working
- Shared facilities
- PPE