

Health and Safety Executive		Operational Circular	
		OC 349/10	
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To
 AFQ Inspectors (Bands 0-4)
 HID Inspectors (Bands 0-4)
 SG Medical Inspectors (Bands 0-3)
 SG Specialist Inspectors (Occ Hyg) (Bands 0-3)
 Railway Inspectors (Band 2)
 TD6 Inspectors (Bands 0-4)

PRIMARY INSPECTION RESPONSIBILITIES AND THE USE OF SPECIALIST SUPPORT FOR WORK WITH BIOLOGICAL AGENTS

This OC, which cancels and replaces OC 349/8, provides information on new arrangements for the division of primary inspection responsibilities for work with biological agents, and describes the enforcement arrangements. It also advises on the use of TD6's specialist expertise to support FOD/HID's inspection responsibilities on biological agents.

INTRODUCTION

1 Exposures to biological agents (BAs) from work activities can be broadly categorised into firstly, those arising from deliberate working with BAs themselves, and secondly, those arising adventitiously from the work activity, either routinely (eg work with farm animals) or intermittently (eg dock work involving contaminated cargos). In the first category, primary inspection responsibility is divided between FOD/HID and TD6, while in the second, FOD and HID have sole responsibility. From April 2001 the demarcation arrangements in the first category changed to give TD6 increased responsibility. Details are given in the following text along with revised guidelines on the provision of TD6's specialist expertise to assist FOD/HID inspectors in their own inspections and investigations of work involving BAs.

TD6 PRIMARY INSPECTION RESPONSIBILITY

2 TD6, Dangerous Pathogens/Microbiology Section now has primary inspection responsibility for microbiological aspects of:

- (1) all deliberate work with Advisory Committee on Dangerous Pathogens (ACDP) Hazard Group 4 BAs;

(2) all deliberate work with ACDP Hazard Group 3 BAs; and

(3) all research activities with ACDP Hazard Group 2 BAs.

(Definitions of the hazard groups are given at the [appendix](#)).

3 Additionally, the TD6 Genetically Modified Organisms (GMOs) Contained Use and Biotechnology Sections have primary inspection responsibilities for work involving GMOs. Due to an unrelated development, TD6 is no longer involved in the inspection of deliberate release of GMOs related to crop trials, etc but this does not affect FOD/HID responsibilities. Full details of arrangements for the inspection of GMO work are given in OC 349/9 *The Genetically Modified Organisms (Contained Use) Regulations 2000* (to be issued shortly).

Advisory Committee on Dangerous Pathogens Hazard Group 4

4 The change of demarcation has no effect on the inspection of premises handling ACDP Hazard Group (HG) 4 agents. The total number is small and includes high security isolation disease units of which there are currently 2 in the country.

Advisory Committee on Dangerous Pathogens Hazard Group 3

5 TD6 have now assumed primary inspection responsibility for **all** deliberate work with HG 3 agents, regardless of the nature of that work. Previously HG 3 diagnostic work was FOD/HID's responsibility. This has involved the transfer of approximately 300 facilities to TD6, comprising mainly hospital pathology laboratories.

Advisory Committee on Dangerous Pathogens Hazard Group 2

6 TD6 have now assumed responsibility for all research work on ACDP HG 2 agents. This is largely carried out in similar types of premises where HG 3 research is performed, ie teaching hospitals, universities, research establishments and research facilities associated with the pharmaceutical industry, and will in many cases be subject to the same management. At the time of the change it was uncertain how many facilities would be affected. FOD/HID however, retain responsibility for all **diagnostic** and other routine work with HG 2 agents, which includes, except in rare cases, those laboratories undertaking criminal forensic work, food analysis and hospital pathology labs undertaking HG2 work even where these are closely associated with facilities working with HG3 BAs.

Advisory Committee on Dangerous Pathogens Hazard Group 1

7 FOD and HID have primary inspection responsibility for all work, except in relation to GMOs (see OC 349/9) in HSE enforced premises which involves BAs in HG 1 regardless of the nature of such work. In practice there are no laboratories carrying out work on HG 1 organisms and risks arising from exposures will generally be in relation to the non-infectious hazards arising from these agents.

DETAILS OF TD6 INSPECTED PREMISES

FOCUS recording

8 TD6 enter details of contacts and enforcement for those areas of premises where they have primary inspection responsibility on FOCUS under their own field management unit number, ie FMU 49. Most if not all facilities inspected by TD6 belong to premises for which FOD or HID have inspection responsibility as a whole and FOD inspectors can identify these contacts from the incumbent overview. Also to act as a 'flag' on the incumbent record, it is recommended that the words 'TD6 primary inspection' be entered onto the incumbent pen picture. This can be entered either by the individual FOD or TD6 inspector concerned, but an exercise to undertake this systematically may take place in the future.

9 HID Land Division use the Common Information System (CIS) for work recording. TD6 inspectors do not have access to CIS but they have been provided with electronic versions of CIS report templates. TD6 inspectors should complete a contact report template after each inspection and send it to the relevant HID site inspector. HID site inspectors are responsible for linking the contact report template to the relevant incumbent and indicating TD's role as a secondary enforcing authority on the additional details screen of the location module. Note that there is no need to complete a CIS timeline for TD contacts.

New facilities

10 Facilities where TD6 have primary inspection responsibility are established (and closed) fairly frequently. There is a requirement under the COSHH Regulations, Schedule 3 to notify HSE of the first use of all HG 2, 3 and 4 BAs, except where a diagnostic service is carried out with HG 2 and 3. TD6 manages the notification procedure on behalf of HSE and should get to know of new facilities by this route, except those purely involved with HG 2 and 3 diagnostic work. FOD/HID inspectors should inform TD6 if they come across facilities, which they believe should be their responsibility but which they may be unaware of. Similarly if FOD/HID inspectors identify facilities which have closed, they should inform TD6.

TD6 LIAISON AND JOINT VISITING BETWEEN TD6 AND FOD/HID INSPECTORS

11 For those parts of laboratories and facilities where TD6 has primary inspection responsibility, FOD/HID will **always** have responsibilities for non-microbiological aspects of health and safety, both within the laboratory/containment facility itself (but note the restrictions on entry; see [paras 17](#) and [30](#) and elsewhere on the site. It is therefore essential that there is good liaison between FOD/HID and TD6 to ensure that inspection arrangements are properly coordinated, and to avoid duplication of activity.

12 In all cases where TD6 has the primary inspection responsibility, prior notification of the intention to make an inspection should be made to the FOD/HID principal inspector (PI) for the premises, on form FI 2507, giving as much notice as possible and, in all cases, at least a week. The PI should advise TD6 promptly of any reason to defer a planned inspection, or of the need for a joint visit.

13 Management issues are as important to the inspection of biological risks as they are

with other health and safety matters. Therefore, when a FOD/HID inspection group intends to carry out a full management inspection of a site or premises where TD6 has a primary inspection responsibility, they should, as far as is practicable, involve them in a joint approach. In such situations, the FOD/HID PI should notify TD6, giving at least a month's notice. To assist this coordination, TD6 will provide, via the FOD Services Sector and relevant HID heads of field units, details of their annual inspection programme so that FOD/HID can plan management inspections accordingly. FOD Services Sector will publish the information concerning FOD premises in a SIM each year. If TD6 inspectors need to undertake follow up visits on purely microbiological matters, further joint visiting will not generally be necessary.

14 TD6 operate their own independent rating system for premises which is based on biological risk factors. In practice, this means that frequency of inspections will normally vary between 2 and 5 years depending on the nature of the work and the rating. Facilities working with HG 4 pathogens are inspected annually.

15 TD6 inspectors are responsible for making recommendations on improving standards in relation to their inspection activities. They will enter reports on FOCUS under FMU 49 which can be accessed by FOD inspectors. This will include, where relevant, references to management and other health and safety issues. A full report will be provided by TD6 on request. Arrangements for recording TD6 work at HID LD premises are described in [para 9](#).

16 For non-microbiological health and safety matters within the facilities which they inspect, TD6 inspectors will, as a general approach, note any apparent defects in compliance and bring these to the attention of the relevant FOD/HID inspection group as soon after their visit as possible. The FOD/HID inspector will follow these up as is appropriate. However, in circumstances where there is a risk of serious personal injury, the TD6 inspector may need to issue a prohibition notice. They will make every effort to contact and consult with the appropriate FOD/HID inspector before doing so, but if this is not possible they will act on their own initiative. FOD/HID inspectors should review their overall rating for the premises in light of non-microbiological matters brought to their attention in this way. No attempt should be made to do this in relation to microbiological matters, unless these concern management issues, as these are addressed by the TD6 rating system.

17 For any follow up action on non-microbiological matters, FOD/HID inspectors should note the restrictions on entry to facilities for which TD6 have responsibility stipulated in the FOD/HID Health and Safety Policy Supplement on *Hazards from Biological Agents*.

Enforcement

18 TD6 inspectors will issue notices concerning the microbiological aspects of the work. Before issuing any notice, they will, where practicable, contact the relevant FOD/HID inspection group and will, in all cases, send a copy of the notice to them. For potential prosecutions on microbiological matters, TD6 inspectors should jointly consider these with FOD/HID. The FOD/HID inspection group will be responsible for ensuring that the relevant enforcement action records are entered on the register kept under the Environment and Safety Information Act 1988. Enforcement action for

non-microbiological breaches is the responsibility of FOD/HID, but if this arises as result of matters brought to their attention by a TD6 inspection, then close liaison will be necessary.

19 TD6 inspectors are responsible for any follow-up action in connection with microbiological notices they have issued. In relation to non-microbiological notices, discussion should take place with the relevant FOD/HID group to decide the most effective way to monitor compliance.

Accident or other investigation

20 Each directorate/division is responsible for microbiological incident investigations which occur in premises or parts of premises for which it has primary inspection responsibility. All incidents reported through RIDDOR are now received via the national incident contact centre. FOD/HID field offices should continue to forward to TD6 reports, received from the centre, of those incidents which are TD6's responsibility, although in future arrangements may be made for them to access these directly. Reports of incidents which are TD6's responsibility which reach FOD/HID offices from sources other than the employer, will always need to be forwarded promptly.

21 Following any investigation, TD6 should send details to the relevant FOD/HID PI and for FOD premises, should also record details on FOCUS. The investigation of incidents which are of interest to both TD6 and FOD/HID should be jointly investigated and for FOD, be recorded on FOCUS under both relevant FMU numbers. Arrangements for recording TD6 investigation work at HID LD premises are as described at [para 9](#), except that a CIS investigation (not an inspection) report template should be sent to the relevant HID site inspector.

Transport of dangerous pathogens

22 Responsibility for investigating incidents relating to the transport of hazardous biological agents falls to the directorate that has overall responsibility for enforcement at the relevant consignor's premises, ie FOD or HID. Where the consignor is outside Great Britain, the responsibility falls to the directorate that is responsible for enforcement at the relevant consignee's premises. In both cases FOD/HID inspectors should consult with their divisional specialist group (SG) occupational hygiene section to determine the need for specialist support from TD6, noting [paras 25-28](#).

FOD/HID emergency plans

23 In view of the greater number of premises in which TD6 have a primary inspection responsibility, it is advised that FOD divisions and HID units should review their emergency and major incident plans to cater for possible involvement of TD6.

Safety representatives

24 Safety representatives who raise microbiological safety matters with a FOD/HID inspector which relate to areas inspected by TD6, should be referred to TD6 and vice versa for non-microbiological matters.

TD6 SPECIALIST SUPPORT FOR FOD/HID INSPECTORS

25 To complement the available FOD SG expertise, TD6 staff are available to help FOD/HID field staff in the inspection or investigation of activities involving all biological agents, for which TD6 do not have primary inspection responsibility. Requests from FOD/HID inspectors for such support should initially be made through the SG occupational hygiene section. They will, in general, make their own judgement on whether there is a need to refer to TD6. However, in some specific situations, TD6 should always be consulted. This is to ensure that HSE correctly deploys appropriate specialist expertise. Details are given in paras 26-28 below.

Laboratory acquired infection

26 Because of their potentially complex microbiological nature, where cases of laboratory acquired infection occur in FOD/HID areas of responsibility, TD6 should always be informed and consulted at an early stage through the SG and, where necessary, as the investigation develops. TD6 will not necessarily need to be involved in the investigation, but may be able to assist in pointing out the line that it should take.

Situations of significant public concern

27 TD6 should also be informed of and consulted on those situations where there is judged to be significant public concern over infections from HG 3 pathogens, or HG 2 pathogens perceived as being particularly hazardous, arising in FOD/HID inspected premises, eg suspected E-coli infections on open farms.

Legionnaire's Disease

28 Revised arrangements for notifying and involving TD6 in investigation of outbreaks and single cases of Legionnaire's Disease are given in [OC 255/12 Control of Legionella: investigation of outbreaks \(and single cases\) from water systems incorporating cooling towers and evaporative condensers](#).

29 TD 6 will, in future, periodically review all cases of occupationally acquired infections reported through RIDDOR from whatever source with a view to identifying trends and patterns and will communicate issues of significant interest to FOD/HID for discussion and review.

FOD/HID HEALTH AND SAFETY POLICY

30 FOD/HID inspectors should refer to the FOD/HID Health and Safety Policy Supplement *Hazards from Biological Agents*. This places restrictions on entry into areas where work with high hazard biological agents is undertaken, as well as detailing other precautions. The supplement also gives procedures to be followed in cases where infections or other illnesses are contracted by inspectors which are suspected of being caused by exposure to biological agents, during visits to premises.

CANCELLATION OF INSTRUCTIONS

31 OC 349/8 - **cancel** and **destroy**.

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-- APPENDIX
(para 2)

HAZARD GROUP DEFINITIONS

1 The Advisory Committee on Dangerous Pathogens (ACDP) Hazard Groups are defined as follows:

(1) ACDP Hazard Group 1: a biological agent unlikely to cause human disease.

(2) ACDP Hazard Group 2: a biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available.

(3) ACDP Hazard Group 3: a biological agent that can cause severe human disease and presents a serious hazard to employees; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.

(4) ACDP Hazard Group 4: a biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment.

2 The biological agents listed in their respective categories can be found in the ACDP *Categorisation of biological agents according to hazard and categories of containment* published by HSE.

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