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Secretaries of Health Boards Secretary, Common Services Agency	Your reference	COMMON SERVICES AGENCY RECEIVED - 4 FEB 1985 FILED
	Our reference NLZ/11/1 pt 4 Date 4 February 1985	
Dear Secretary		RECEIVED
ADVISORY COMMITTEE ON DANGEROUS PATHOGENS (ACDP): INTERIM GUIDELINES ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)		
<u>Summary</u>		

This letter introduces interim Guidelines, drawn up by the Advisory Committee on Dangerous Pathogens, which set out the measures to be taken to safeguard the health and safety of people who, because of their work, come into direct contact with AIDS patients, or specimens from them.

Introduction

The emergence of AIDS as a newly recognised disease has given rise to concern among clinical and laboratory staff, other hospital workers and researchers who may have contact with AIDS patients or specimens therefrom. The ACDP has therefore drawn up interim guidelines which it recommends be adopted in all cases where AIDS is suspected or where antibody to HTLV III virus is diagnosed.

Status of the Guidelines

These guidelines represent the considered view of the ACDP at this time, in the light of the best available information, of the hazards, the level of risk associated with those hazards and the protective measures appropriate to those risks. However it is recognised that rapid advances are taking place in knowledge of the disease and of the one agent identified as responsible for it, and for this reason the guidelines should be regarded as interim.

The ACDP intends to review the measures recommended in the guidelines within the next 12 months, while in the meantime keeping itself informed of any scientific developments in this field. To this end Health Boards are requested to submit to the Department, within 9 months from the date of this circular comments on the content and practical operation of the guidelines. This information will be put to ACDP, along with the views of other interested parties, to assist in the planned review of the advice.

Content and Implementation

The guidelines make a number of recommendations relating to clinical and laboratory practice in relation to this disease, but the major recommendations discuss the prime need to avoid accidental self-inoculation or infection via mucous membranes or broken skin by splashing or by contact with contaminated surfaces. Limitation of preparative work and manual tests to a defined area of the laboratory is essential. While

transmission by the aerosol route has not so far been demonstrated, present uncertainty about this possibility indicates that the use of a microbiological safety cabinet to contain any dispersal is a wise precaution. Laboratories with ready access to a containment level 3 room or other room fully or temporarily dedicated and containing a safety cabinet (Class I or Class III depending on the level of dispersal anticipated) should have little difficulty in complying with the recommendations of the guidelines. A reassessment and modification of present work procedures may be all that is necessary. The need to use expensive non-dedicated analytical equipment is recognised but efforts must be made to select those machines in which splashing and aerosolisation of AIDS or AIDS related pathological material can be well controlled.

Many of the recommendations in the guidelines are in line with the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post Mortem Rooms (the Howie Report) which Health Boards have been progressively implementating since 1978. In view of the probable increase in the amount of clinical and laboratory work involving AIDS patients, the ACDP has suggested that consideration might be given to the designation of specific laboratories which are able to provide both the necessary level of support to clinical investigation and the appropriate level of containment for specimen handling.

AIDS is one of a number of diseases which disqualify potential blood donors. Advance warning is given via a Scottish National Blood Transfusion Service leaflet 'Important Message to Blood Donors' which lists the high risk groups.

Action

The guidelines currently have an interim status and will be revised in twelve months' time. However, Health Boards are asked to comply with the recommendations therein as soon as practicable. They should draw this guidance to the attention of all clinicians who might be involved in handling such cases, including consultants in charge of STD clinics and clinical laboratories. They are further asked to submit comments on the practical application of the guidelines to Dr A D McIntyre, Room 20, St Andrew's House, Edinburgh EH1 3DE (031 556 8501 Extension 2597), from whom further copies of the guidelines are also available.

Yours sincerely

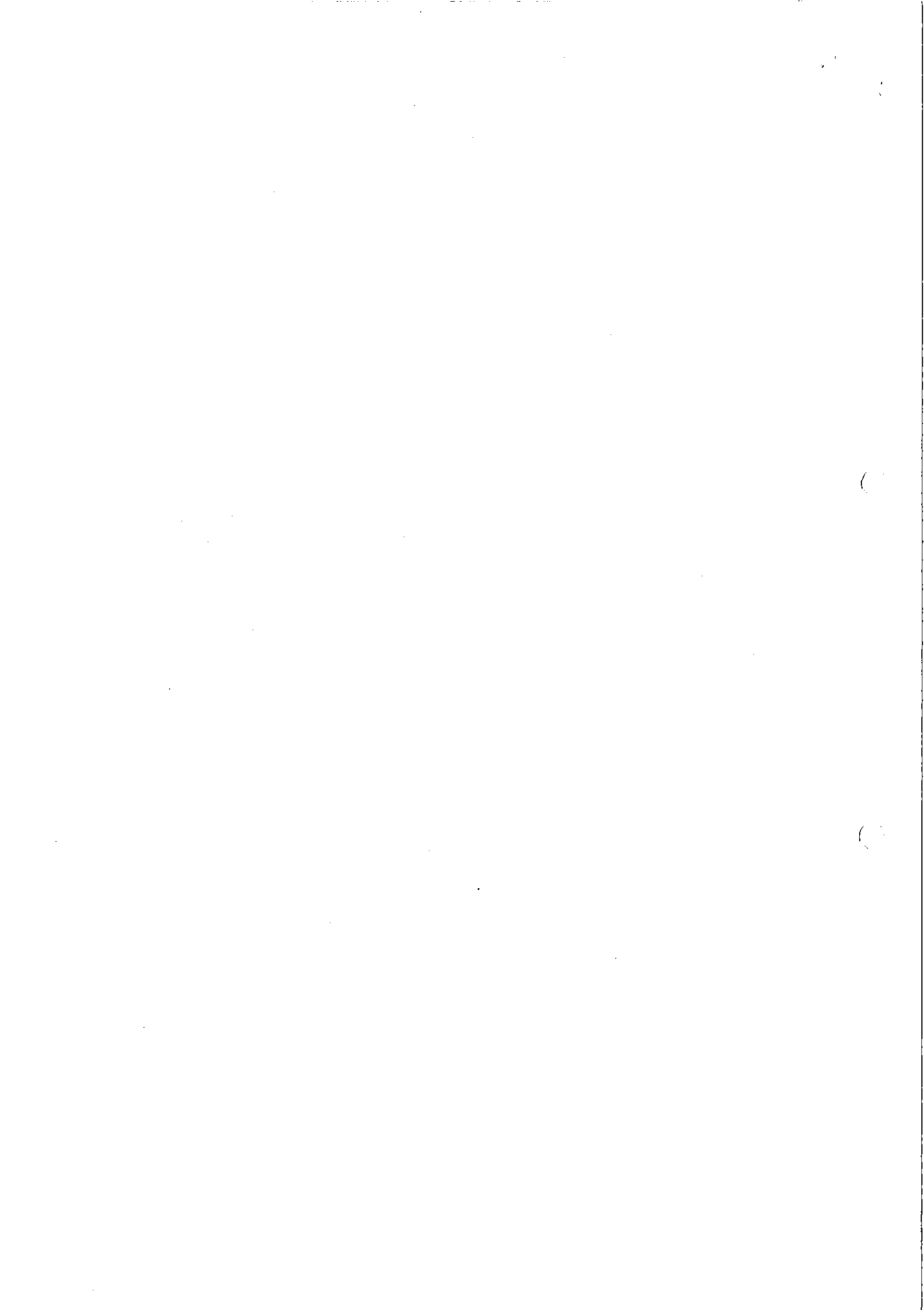
A. J. Murray

A J MURRAY

Advisory Committee on Dangerous Pathogens

**Acquired Immune Deficiency
Syndrome (AIDS) — Interim
Guidelines**

DECEMBER 1984

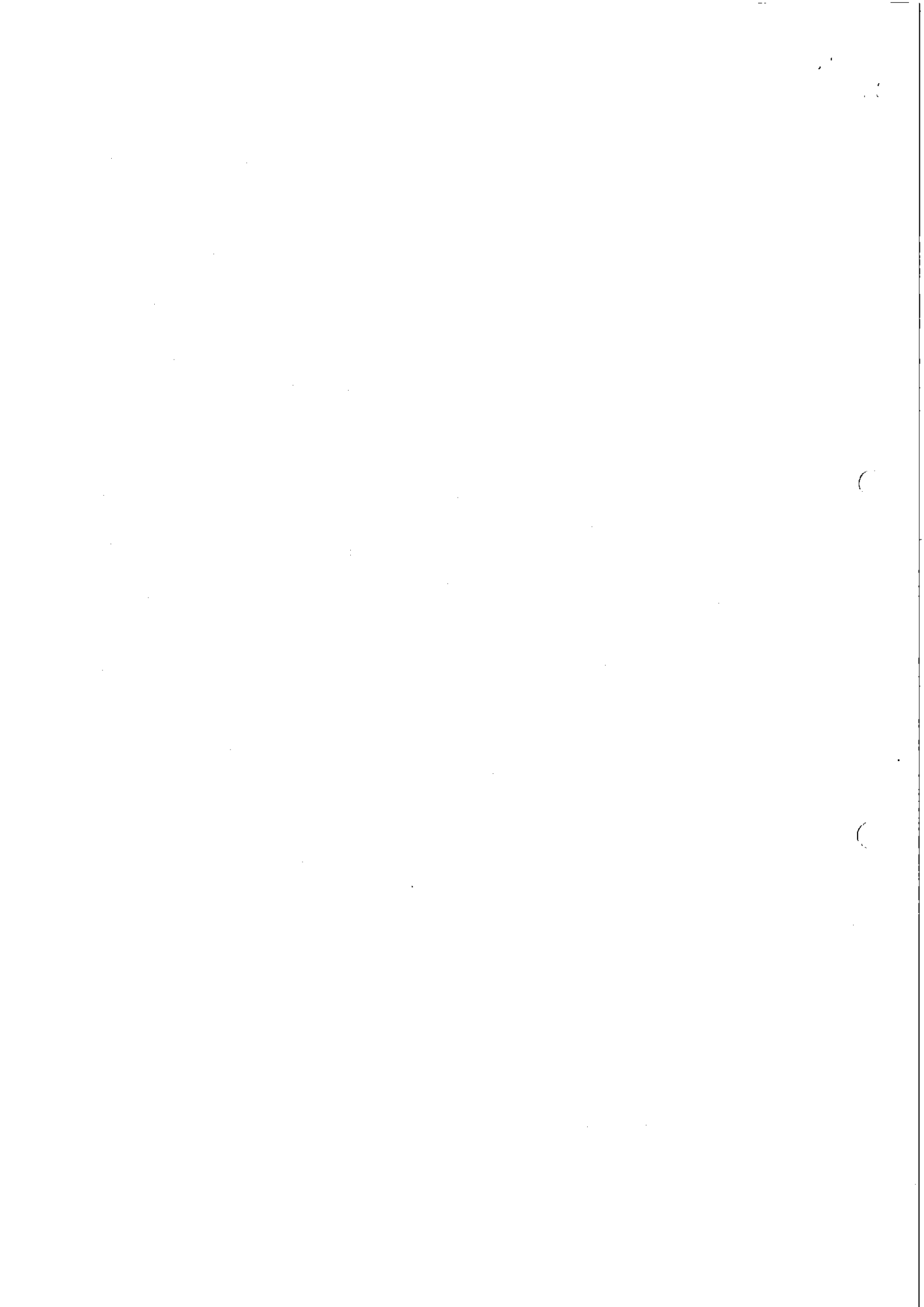


PREFACE BY THE
HEALTH & SAFETY
EXECUTIVE AND
THE HEALTH
DEPARTMENTS

1. The Advisory Committee on Dangerous Pathogens (ACDP) were asked by the Health Departments and the Health and Safety Executive for advice on the measures which should be taken to safeguard the health and safety of people who because of their work come into direct contact with patients with the Acquired Immune Deficiency Syndrome (AIDS) or specimens from them.
2. With the emergence of this serious and newly recognised disease, which is not yet fully understood, it is essential that those who might be occupationally exposed are provided with safeguards which take account of the hazard. These guidelines represent the considered view of the Committee at this time of how the balance between hazard, the risk, and appropriate protective measures should be weighed.
3. Rapid advances are however taking place in knowledge of the disease and the agent responsible for it, and these guidelines are therefore interim. The Committee will keep under continuous review any new information published in the scientific press. They will also welcome evidence or comments from health care workers, from researchers in the field or other interested parties, which will allow them to re-assess the measures they have recommended.
4. In presenting these guidelines, the Committee made two further points. First they recommended that those wishing to undertake research with viable HTLV III virus should notify the HSE. Second that with the likely increase of the number of cases of AIDS, Health Authorities might like to consider the designation of laboratories equipped to carry out necessary investigations at the appropriate level of containment.
5. Anyone wishing to comment or provide information should write to the Secretariat of the ACDP at either of the addresses shown below.

Health & Safety Executive
MD A2
25 Chapel Street
London NW1 5DT

Department of Health & Social Security
MED-SEB Room 1004
Hannibal House
Elephant & Castle
London SE1 6TE



ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) - INTERIM GUIDELINES

INTRODUCTION

1. In view of the concern among clinical and laboratory staff, other hospital workers and researchers who may have contact with AIDS patients or the AIDS agent (now generally accepted as being a retrovirus), ACDP has drawn up the following guidelines which should be adopted whenever AIDS or persistent generalised lymphadenopathy (PGL) is suspected or has been diagnosed.
2. Because of rapid advances in knowledge in this sphere, the Committee should reconsider the advice given in these guidelines 12 months after publication. In the meantime the Health Services Advisory Committee concerned as it is with evaluating the practicalities of implementation should be asked to review them.
3. The ACDP also strongly recommends that where there is an intention to conduct research work which involves the propagation of HTLV III virus or the use of high-titre viable stocks, the Health and Safety Executive should be informed if this has not already been done.

BACKGROUND

4. Certain retroviruses known as human T cell lymphotropic virus - (HTLV III Gallo et al)¹ and lymphadenopathy associated virus (LAV Barre-Sinoussi et al)² have been recovered from patients with AIDS. These two agents which are now believed to be identical* have also been isolated from patients with PGL, haemophiliacs and apparently healthy male homosexuals.
5. Further to this, evidence of infection as shown by the presence of antibody to HTLV III has been demonstrated in the following groups in the UK:

*Footnote: For the purposes of these guidelines HTLV III is taken to be synonymous with LAV.

1 Science 224 May 4 1984

2 Science 220 May 20 1983

<u>Categories</u>	<u>Number tested</u>	<u>% positive</u>
AIDS patients	31	= 97
PGL patients	124	= 89
Symptomatic homosexuals	69	= 59
Contacts of AIDS or PGL	36	= 42
Homosexuals at risk	308	= 17
Heterosexuals from genitourinary clinics	35	= 0
Haemophiliacs who have received pooled clotting factors	184	= 34
Intravenous drug abusers	269	= 1.5

Over one thousand unselected blood donors were also tested for antibody but none was positive. (Cheingsong-Popov et al)¹

6. The present situation with regard to the number of established cases of AIDS in the United Kingdom (and in the USA for comparison paragraph 7) is illustrated below. The clinical criteria used to make the diagnosis of AIDS are those provided by CDC and now adopted almost worldwide and given in appendix 1.

The first formal report of AIDS in the UK appeared in 1981 (Lancet December 12th). Since that time 88 cases have been identified (up to October 1984) one of which was diagnosed retrospectively as having occurred in 1979. Of the 88 reported cases 37 have since died.

Cases may be grouped according to their prime recognisable condition.

¹ Lancet September 1, 1984

Kaposi's sarcoma (KS)	30
Pneumocystis carinii pneumonia (PCP)	32
KS plus PCP	5
Other opportunistic infections	20
Cerebral lymphoma	1

88 CDSC October 1984

7. Of the 88 cases reported by October 1984, over 75 per cent were male homosexuals while the remainder were patients with direct or indirect contact with central Africa, recipients of pooled clotting factors and a small group with no recognised risk factor. The number of cases in the USA now exceeds 6,000 which, even allowing for population differences represents an incidence rate much higher than that in any other country. There are several hundred cases in Europe, the largest numbers being recorded in France and West Germany.

8. If the trend in the UK follows that seen in the USA we can expect an exponential increase in the number of cases of clinical AIDS diagnosed. Furthermore the serological studies referred to above seem to indicate that whereas the most severe outcome of infection with HTLV III is certainly AIDS, it cannot be assumed that all infections with this virus will necessarily lead to this disease, although the possibility cannot be ruled out.

9. Experience in the USA indicates that there is no evidence of the disease having been acquired through casual contact with persons with AIDS living in the community. Neither is there any satisfactory evidence of clinical AIDS developing in hospital or laboratory personnel through occupational exposure despite contact with over 6,000 affected patients and their specimens. However at the present time it is not possible to identify with certainty at which stage or stages of HTLV III infection the virus is transmissible nor are all possible routes of infection known. Until more is discovered about the natural history of HTLV III we cannot assess the true risk to laboratory and hospital staff. Consequently a clinician who has grounds to believe that a patient has been infected must ensure that appropriate warnings of hazard are always given. At the same time the doctor should avoid raising the fear of AIDS in the patient.

10. The prime risk of infection for clinical staff is parenteral transmission by accidental self-inoculation or entry of infectious material through broken skin or mucous membranes. The utmost care must therefore be taken to avoid needle injury, contamination of wounds, skin lesions and mucosal surfaces with blood, saliva or other potentially infectious material from any patient known or suspected to be suffering from AIDS or PGL. Written codes of practice designed to minimise these risks are essential. While an aerosol route of infection seems unlikely on the basis of current evidence it cannot as yet be completely ruled out, particularly during laboratory manipulations.

It must be assumed that tissues, body fluids (particularly blood and saliva), other secretions and excreta are capable of transmitting infection. Gloves must be worn and great care taken when handling these materials. Exposed surfaces and other soiled items are also to be considered as hazardous and will therefore require safe containment before disinfection or disposal.

The potentially serious consequence of an HTLV infection means that we must ensure that sound preventive steps are taken to protect against the possibility of occupationally acquired disease. As information becomes available it may be possible to define the risk more precisely.

11. Hazard Classification of Human Retroviruses

For the purposes of allocating particular pathogens to hazard groups the Advisory Committee on Dangerous Pathogens adopted the following definitions.

Hazard Group 3 - an organism that may cause severe human disease and present a serious hazard to laboratory workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment available.

Hazard Group 4 - an organism that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment.

12. As in some other instances HTLV III does not fit easily into either category. While there is no doubt that AIDS is a severe disease for which there is no effective prophylaxis or treatment, it does not present a high risk of spreading in the community except in the recognised high risk groups. This is supported by the results of serological investigation and the apparent lack of spread of infection through casual contact or by the aerosol route. Efforts should therefore be concentrated on protecting all those who handle infectious material in the course of their work.
13. In its report ACDP categorised the then known human T cell leukaemia viruses into Hazard Group 3 and HTLV III which has since been firmly associated with AIDS is also included in this group.
14. Staff must be made familiar with the precautions advocated in these guidelines and should be advised that providing these are followed there is believed to be no undue risk of infection. Local written codes of practice based on these guidelines should specify the use of an appropriate labelling system or colour code to be attached to all packages of contaminated materials and laboratory specimens (see para 25) from AIDS patients. The codes should also specify a requirement for recording details of accidents and equipment failures.
15. Those who may be directly exposed to the body fluids and tissues of AIDS patients and those undertaking laboratory work on viable HTLV III should be asked to volunteer serum samples. These should be taken before starting the work and at six-month intervals thereafter and be kept in long term storage. Arrangements should be made to test these sera for the presence of

HTLV III antibody and the results recorded as part of a surveillance scheme.

GUIDELINES FOR MEDICAL AND NURSING STAFF AND OTHERS WHO MAY HAVE CONTACT WITH AIDS PATIENTS, INCLUDING STAFF WORKING IN THE COMMUNITY

16. The following protective measures are required for the prevention of infection which might arise from direct or indirect patient contact when a diagnosis of AIDS or PGL has been made or is suspected.
17. All AIDS patients must be counselled by a physician concerning the risk of transmitting infection.
18. Hospitalised patients in whom AIDS has been diagnosed or is suspected should be nursed in isolation; this will ordinarily imply the use of a single room. Isolation techniques involving the use of disposable gloves and plastic aprons will be necessary when invasive procedures are to be undertaken and when patients are too ill to use good hygiene, such as those with profuse diarrhoea, faecal incontinence, or altered behaviour secondary to central nervous system involvement.
19. The clinician in charge or the designated deputy must ensure that the Control of Infection Officer and all staff who have direct dealings with such patients (or materials arising from them) are aware of the risk. As far as possible this should be done in a way that preserves confidentiality.
20. Protective clothing, soiled linen and bedding for laundering must be double bagged and disposed of in accordance with approved practice. Grossly contaminated items should be incinerated. Surfaces and objects soiled by blood, saliva, secretions or excreta must be treated immediately with a fresh preparation of one of the following disinfectants.

Hypochlorite solution containing 1,000 ppm available chlorine, or freshly activated 2% glutaraldehyde. For blood spills and gross contamination with organic matter a higher concentration of hypochlorite (10,000 ppm) should be used.

21. All materials leaving the patient's room must be handled in accordance with the policies of the Control of Infection Committee. Non-disposable items which cannot be autoclaved, such as lensed instruments, should be washed in freely running water to dislodge contaminating matter, and must be disinfected before re-use. Precautions must be taken to avoid personal contamination during this cleaning process.
22. It may be necessary for patients to go to specialist departments for investigation or treatment such as x-ray, dentistry or surgery, but this should be allowed only after prior arrangement so that the control of infection policy for that department can be operated. Request forms must always indicate the hazard so that precautions can be taken. In some cases it may be necessary for a trained nurse to accompany the patient.
23. It must be borne in mind that patients with AIDS may also have other infections which present hazards demanding additional precautions.
24. Where it is necessary to attend AIDS or PGL patients at home these precautions should be adapted to fit the circumstances.
25. Clear instructions must be given to clinical staff on how best to complete laboratory request forms so that an awareness of the hazard associated with handling the specimens is constantly maintained. The use of a distinctive colour code different from that used for hepatitis risk specimens may be an acceptable signal. Whatever system is adopted it must be firmly agreed between clinical and laboratory staff so that appropriate containment measures can be taken as a matter of routine.
26. When blood or other specimens are to be taken gloves and a disposable plastic apron and/or gown must be worn and discarded safely after use. Eye protection is recommended.

27. Only the minimum essential quantity of blood should be drawn and then only by designated staff who are trained and experienced. Those who withdraw blood or other body fluids must ensure that the outside of any specimen container is free from contamination.

28. Disposable units must be used for blood collection. Needles must be removed from syringes before the blood is discharged into the specimen container and immediately discarded into a puncture proof disposable bin used solely for that purpose and designed for incineration. Only needle-locking syringes or similar units should be used to aspirate fluid from patients. Accidental puncture wounds in staff must be treated immediately by encouraging bleeding and liberal washing with soap and water. Any such accident or contamination of broken skin or mucous membranes must be promptly reported to and recorded by the person with overall responsibility for the work.

29. Specimens must not be sent to the laboratory without a standing agreement between the clinician and senior laboratory staff. They must be in robust screw-capped and leak-proof containers (evacuated or not) bearing a hazard warning label as indicated above (para 25). Securely capped specimen containers should be sent in separate sealed plastic bags, kept upright if possible and transported to the laboratory in a sound secondary container which can be disinfected. The accompanying request forms must be kept separate from the specimen to avoid contamination and also clearly indicate the hazard. Pins, staples or metal clips must not be used to seal the bags and for safety, the carrying handles of the secondary container should not be attached to the lid.

GUIDELINES FOR LABORATORY STAFF

30. The general recommendations of the Advisory Committee on Dangerous Pathogens on levels of containment are set out in paragraph 27 of their Report.

'Work with pathogens and materials known to contain them must be conducted at the appropriate containment level indicated in the model Code of Practice, but the level may be altered to provide more stringent containment conditions depending upon the local assessment of risk. Less stringent conditions must not be adopted before a full risk assessment has been made and agreed by the local safety committee and in the case of Group 3 and Group 4 pathogens until consultation with the HSE has taken place'

Therefore work with viable HTLV III must be conducted in a containment level 3 laboratory (see Appendix 2).

31. A written protocol should be drawn up for all work with HTLV III virus including material from patients with AIDS. This must cover the procedures for handling of materials including transport to the laboratory, reception, storage and all matters related to the disposal of waste. All staff involved in the work must be named and clear instructions laid down for contacts in an emergency. Such protocols must be produced with the full participation of the local safety committee, the safety representatives and all staff concerned.
32. Work involving the inoculation of experimental animals with unactivated virus or AIDS material must be undertaken only at ACDP's Animal Containment Level 3.

Microbiological safety cabinets

33. It is now clear that infection with HTLV III may result in a fatal disease for which there is no effective prophylaxis or treatment. While there is still uncertainty about all the possible routes of transmission in the laboratory environment, care must be taken to avoid the dispersal of aerosols and for some work microbiological safety cabinets will be required.

Because there are reservations about the level of operator protection which can be maintained by Class II cabinets under working conditions, for the time being, they must not be used for work with materials which contain the virus.

34. Where there is an intention to carry out any operation with high-titred viable virus and there is a probability that the level of airborne dispersal may exceed the protection offered by a Class I safety cabinet then a Class III cabinet must be used. A thorough risk assessment of particular operations is therefore essential and in making an assessment it may be helpful to remember that high concentrations of virus may be produced in cell culture eg 10^8 particles per ml although not all of these are necessarily infectious.

Clinical Laboratories

35. The following measures are required for laboratories handling materials for clinical investigation from patients in whom AIDS or PGL is suspected or has been diagnosed.
36. We consider that laboratories which can reasonably predict the need for AIDS specimens to be handled on a regular basis should have Containment Level 3 facilities for manual work on these specimens and the preparation of samples which have to be tested in automated equipment which cannot be dedicated for AIDS work.
37. However it is recognised that there may be circumstances in which a regular need for laboratory examination of AIDS specimens cannot be foreseen. In these cases manual tests and preparative work should be performed in a Class I microbiological safety cabinet sited in a room dedicated for this purpose (but see para 34). There must be adequate space ($24m^3$) for each worker. If it is decided to temporarily dedicate a routine laboratory for this purpose no other work should be conducted at the same time and to maintain a high level of supervision and microbiological security, only those involved should be present. In either case on completion of the work, the safety cabinet and any other areas which may have been contaminated must be thoroughly disinfected.

38. Each clinical laboratory should draw up a local code of practice stating how it is proposed to implement the recommendations in these guidelines according to the workload that is anticipated. Such codes must be produced with the full participation of the local safety committee, the safety representatives and all staff concerned.
39. Laboratories which do not have appropriate containment facilities to investigate specimens from these patients may not require such a detailed code but must make provisions for the safe handling and transfer of AIDS specimens to another laboratory equipped for this work.
40. From receipt, all specimens from patients in whom AIDS or PGL is suspected or has been diagnosed must be unpacked and prepared in the designated room by trained and experienced staff. Gowns, disposable plastic aprons and gloves must be worn for this work and in subsequent procedures. Eye protection will be required when splashing is a possibility.
41. Protective clothing must be used for no more than one day and always dealt with safely after use. When contamination is known to have occurred clothing should be discarded immediately. A fresh supply must be available at all times and clothing for laundering or disposal must be made safe to handle before despatch (eg by autoclaving or by the use of an approved double bagging system for infected linen). Disposable clothing and gloves for incineration must be placed in a yellow bag (see 'Safe Disposal of Clinical Waste' Health and Safety Commission - Health Services Advisory Committee 1982).
42. Users should ensure that protective clothing to be worn more than once in the course of a working day is hung on coat hooks rather than left on bench surfaces, and that gowns and aprons are not inadvertently reversed when re-used.
43. The receipt of a leaking specimen container should be notified to the head of the laboratory or designated deputy, and the person responsible for its despatch. A leaking specimen container should normally be sent for autoclaving or incineration

but when it is not possible or practicable to obtain a repeat specimen it may be necessary to rescue the material. This must be attempted only by an experienced member of the laboratory staff and then only under conditions of containment in a microbiological safety cabinet.

44. Great care must be taken to avoid contamination of equipment control knobs and surfaces during work with AIDS specimens. These should be routinely disinfected (2% glutaraldehyde) as soon as possible after use and immediately if contamination is suspected.
45. Full attention must be given to containment and disposal measures at all work sites and arrangements made for autoclaving, chemical disinfection or incineration of discarded materials and work surfaces as appropriate.
46. The use of sharp instruments must be avoided wherever possible but any puncture wound which does occur must be immediately treated by encouraging bleeding and liberal washing with soap and water. Any such incident or contamination of broken skin or mucous membranes must be promptly reported to and recorded by the person responsible for the work.
47. For roller-mixing specimen containers should be enclosed in another screw capped or stoppered vessel.
48. When centrifugation is necessary, sealed buckets must be used. The buckets must be opened in the microbiological safety cabinet by an operator wearing gloves and a disposable plastic apron. If it is seen that the specimen container is broken or leaking then the complete unit should be autoclaved with the lid of the bucket loose (but see para 43). Buckets should be routinely disinfected at the end of the day whether or not breakages have occurred.
49. All specimens, extracts of specimens or passage material to be retained must be separately labelled and placed in a secondary transport container capable of disinfection and of sound construction; carrying handles should not be attached to the lid.

The container must be clearly marked with a hazard label according to the locally agreed system and surface decontaminated. Specimens for disposal must be autoclaved or incinerated.

50. Equipment used for transport, processing, preparation and testing of AIDS specimens should be regularly disinfected by whatever means is appropriate and safe to use. Used pipettes and dispenser tips must be totally immersed in fresh hypochlorite solution (2,500 ppm available chlorine) overnight before draining and autoclaving or disposal by incineration. Glass pipettes must not be used for dispensing AIDS materials.
51. All personnel engaged in handling AIDS specimens in the laboratory must immediately remove their gloves and protective clothing following completion of work and wash their hands before moving on to other activities.
52. Specimens and request forms to be sent by post to other laboratories eg for specialised investigations must be clearly labelled. The inner wrapping, the specimen container and the request form should all be marked with an agreed warning label or colour code. No material should be sent without the agreement of the receiving laboratory. In any case it must then be packed in accordance with the recognised regulations for the postal transmission of any pathological specimen. Details of the packing and outer labelling required for inland postage are given in the Post Office Guide and the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms (HMSO 1978), Section 17 and later Bulletin No 2 (DHSS 1981) Section 2bi and iv. It is prudent to take note of any change in requirements by regular reference to the latest edition of the Guide. For international postage, the revised conditions required by the Perishable Biological Substance Service (jointly agreed by the International Air Transport Association (IATA) and the Universal Postal Union (UPO) must be observed. Details may be obtained from Postal Headquarters, St Martin's le Grand, London EC1A 1HQ.

53. General recommendations for the external transport of specimens other than by post are given in Section 16C of the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms. The special requirement for labelling as described above applies here also.

Clinical Specimens and Automated Equipment

54. All manipulations in manual tests and the preparation of material for analysis in enclosed analytical equipment must be performed either in a Containment Level 3 laboratory or in a room dedicated for the time being for the purpose (see paras 36 and 37). The batching of high risk specimens is now an accepted practice allowing for their separate treatment and the decontamination of equipment before resuming routine work. Specimens from AIDS patients must be handled in this way unless the volume of work is such that equipment can be dedicated. Samples to be transferred from the preparation area to automated equipment must be safely contained during transit.
55. Tests should wherever possible be confined to those which can be performed in an enclosed system eg an automatic analyser, or cell counter which can be easily disinfected and which operates without aerosol or droplet dispersal. The system, where possible should be treated after use with 2% glutaraldehyde or hypochlorite solution containing 1,000 ppm available chlorine. In each laboratory an assessment should be made of the ways in which the automated equipment in use there is liable to give rise to environmental contamination. Some machines have a reciprocating sampling probe which may give rise to local splash. Measures should be taken to limit the spread of splash by the provision of shields around the appropriate parts. Any surface which is subject to splash and to which the operator has access during work must be disinfected immediately after the AIDS samples have been processed. All splash shields and adjacent surfaces must be disinfected at the end of each day's work.
56. When a fluorescent activated cell sorter is to be used, a model incorporating an enclosed analytical channel should be chosen. Alternatively a suitable method of inactivation using eg para-formaldehyde may be adopted.

57. Effluent from analytical equipment must either be trapped in bottles containing hypochlorite or glutaraldehyde or discharged directly into the waste water plumbing system. In the latter case a discharge tube should project at least 25 centimetres into the pipe-work. Water must flow down the waste pipe while the machine is operating and the waste system (preferably plastic or glass to avoid corrosion problems) must be treated with a solution of hypochlorite (2,500 ppm available chlorine) when the work is finished.
58. Gloves should be worn when dismantling or servicing equipment used for processing or analysing AIDS materials and a 'Permit to Work' system instituted for service engineers. A permit should be issued by a senior member of staff who has the responsibility for thorough disinfection of the contaminated parts of the equipment.

Histopathology

59. Arrangements should be made for most specimens from AIDS or suspected AIDS patients to arrive at the histopathology laboratory in a fixative solution. Examination and cutting up of specimens should be delayed to minimise operator exposure to unfixed or partly fixed material.
60. Wherever possible whole organs or large tissue masses should not be examined in the laboratory except under the conditions of containment recommended above. Pathologists should wear suitable protective clothing (gloves, gowns, plastic aprons and eye protection). Due attention must be paid to disinfection and disposal of these items along with instruments and cutting boards in accordance with local rules for the handling of infectious materials and the general recommendations outlined above.
61. Particular care must be exercised in this work to avoid cuts and puncture wounds, skin or mucous membrane contamination or splashing. Any such incident must be promptly reported to and recorded by the person with overall responsibility for the work.

62. Frozen sections should not be made on unfixed material from patients with AIDS. However, where the examination of unfixed material is essential for special staining procedures the work must be carried out using dedicated equipment sited in an area which allows containment and which receives particular attention as regards safe operation and disinfection (glutaraldehyde or formaldehyde); disinfection must be carried out immediately after use.

Requirements for Post-mortem Examination

63. When a diagnosis of AIDS has been established during life a full scale post-mortem examination should not be undertaken merely to confirm the cause of death.
64. It is recognised that AIDS as a disease is under intense investigation and that the post-mortem examination of confirmed or suspect cases may be required for research purposes. However, a limited examination involving discrete tissue sampling may suffice for this purpose. Full scale post-mortem examination if held to be imperative must be conducted only under the condition described on pages 41-43, Section g iv of the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms (HMSO 1978). All staff involved must be fully informed about the diagnosis and the risk of infection before the examination begins.

Precautions for Body Handling and Disposal

65. Recommendations appropriate for handling bodies of AIDS patients are contained in Appendix 12 of the same Code of Practice.

Maintenance Staff

66. The written code of practice must specify the protection required for all maintenance and service staff working in patient facilities and laboratories. It is the responsibility of the head of the department to ensure that all equipment is decontaminated before service or repair work is carried out whether or not the equipment is to be removed from the area for these purposes. The permit to work procedure described in para 58 should be adopted.

Cleaning Staff

67. The written code of practice must specify the protection required for all cleaning staff working in patient facilities and laboratories. It is the responsibility of the head of the department to ensure that the accommodation to be cleaned is in a safe condition before cleaners start work and that they have specific instructions on what they should or should not do in each area.

SURVEILLANCE OF AIDS IN THE UK

For their purposes, the Communicable Disease Surveillance Centre at Colindale had adopted, from the Centers for Disease Control, the following definition as the criterion for acceptance of a genuine case of AIDS:

"..... for the limited purposes of epidemiological surveillance a case of acquired immune deficiency syndrome is defined as one in which a person has a reliably diagnosed disease that is at least moderately indicative of an underlying cellular immune deficiency (such as an opportunistic infection, or Kaposi's sarcoma in a person aged less than 60 years) but who, at the same time, has had no known underlying cause of cellular immune deficiency nor any other cause of reduced resistance reported to be associated with that disease."

CATEGORISATION OF PATHOGENS ACCORDING TO HAZARD AND CATEGORIES OF CONTAINMENT
(ADVISORY COMMITTEE ON DANGEROUS PATHOGENS - 1984)

Containment level 3

34 Containment level 3 is suitable for work with pathogens in hazard group 3. Laboratory personnel must have had training in handling pathogenic and potentially lethal organisms, also in the use of safety equipment and controls. A high standard of supervision of the work must be maintained.

- 1 The laboratory must be easy to clean. Bench surfaces and the floor must be impervious to water and resistant to acids, alkalis, solvents and disinfectants.
- 2 The laboratory must be sealable to permit fumigation.
- 3 There must be adequate space (24m³) in the laboratory for each worker.
- 4 The laboratory should be sited in an area away from general circulation. Access to the laboratory must be limited to authorised personnel. The laboratory door must be locked when the room is unoccupied.
- 5 A specific biohazard sign must be posted at the entry to the laboratory and the door must contain a glass panel so that the occupants can be seen.
- 6 A continuous airflow into the laboratory must be maintained during work with pathogens by one of the following means:
 - (a) extracting the laboratory air through independent ducting to the outside air through a HEPA filter;
 - (b) extracting the laboratory air to the outside air with a fan and HEPA filter sited in a wall or window of the laboratory;
 - (c) ducting the exhaust air from a microbiological safety cabinet to the outside air through a HEPA filter;
 - (d) a safe variation of these provisions. Provisions should also be made for comfort factors e.g. fresh-air, temperature control.

In laboratories which have a mechanical air supply system, the supply and extract airflow must be interlocked to prevent positive pressurisation of the room in the event of failure of the extract fan. The ventilation system must also incorporate a means of preventing reverse airflows.

- 7 A wash hand basin must be provided near the exit of the laboratory. Taps must be of a type which can be operated without being touched by hand.
- 8 An autoclave for sterilisation of waste materials should be situated preferably within the laboratory, but one must be readily accessible in the laboratory suite.
- 9 Laboratory doors must be kept closed when work is in progress.
- 10 Side or back fastening gowns must be used in the laboratory and they must be autoclaved before removal for laundering. These gowns must not be used outside the laboratory suite.
- 11 Gloves must be worn for all work with infective materials and the hands must be washed before leaving the laboratory.

- 12 Eating, chewing, drinking, smoking, storing of food and applying cosmetics must not take place in the laboratory.
- 13 Mouth pipetting must not take place.
- 14
 - (a) All laboratory procedures with infective materials must be conducted in a microbiological safety cabinet (class I or class III BS 5726: 1979, or unit with equivalent protection factor or performance) except where the equipment to be used provides containment of the potential aerosol.
 - (b) The cabinet must exhaust through a HEPA filter to the outside air or to the laboratory air extract system, and in other respects such as siting, performance, protection factor and air filtration, it must comply with the specifications detailed in BS 5726: 1979. When laboratories are faced with a major problem because of difficulties in arranging for the cabinet to exhaust to the open air, recirculation of exhaust air through two HEPA filters in series may in exceptional circumstances be considered as an alternative. In these cases the maintenance of a continuous airflow into the laboratory during work with pathogens (see 34(6) (a) and (b)) will be of particular importance and such an option must not be adopted without prior consultation with the HSE.
- 15 The laboratory should contain its own equipment e.g. centrifuge in which sealed buckets must be used, incubator, refrigerator, deep-freeze, vapour phase liquid nitrogen chest etc so that all infective group 3 pathogenic materials are held within the laboratory and nowhere else. Where this is not reasonably practicable (see para 27) material must be transported and stored without spillage in properly labelled robust containers which must be opened only in containment level 3 accommodation.
- 16 Effective disinfectants must be available for routine disinfection and immediate use in the event of spillage.
- 17 Materials for autoclaving must be transported in robust containers without spillage to the autoclave.
- 18 All waste materials must be made safe before disposal or removal to the incinerator.
- 19 All accidents, spills and exposures to infective materials must be immediately reported to and recorded by the person responsible for the work.

1981 No. 1011

HEALTH AND SAFETY
The Health and Safety (Dangerous Pathogens)
Regulations 1981

Made - - - - - 13th July 1981
Laid before Parliament 20th July 1981
Coming into Operation 1st September 1981

ARRANGEMENT OF REGULATIONS

Regulation

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SCHEDULES

- Schedule 1 List of pathogens the keeping or handling of which is to be notified
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- Schedule 3 Particulars to be notified in respect of laboratories providing a diagnostic service
- Schedule 4 Particulars to be notified in respect of transportation of a listed pathogen

In exercise of the powers conferred on me by sections 15(1), (2), 3(b), (5)(b) and (6)(b) and 52(2) of, and paragraphs 1(1), 3(1) and 15(1) of Schedule 3 to the Health and Safety at Work etc. Act 1974(a) and of all other powers enabling me in that behalf and for the purpose of giving effect with modifications to proposals submitted by the Health and Safety Commission under section 11(2)(d) of the said Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act and after consult-

(a) 1974 c. 37; section 15(1) was amended by the Employment Protection Act 1975 (c. 71), section 116 and Schedule 15, paragraph 6.

ing with the said Commission in accordance with section 50(2) of that Act, I hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Health and Safety (Dangerous Pathogens) Regulations 1981 and shall come into operation on 1st September, 1981.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“listed pathogen” means—

- (a) a pathogen listed in Schedule 1,
- (b) a derivative of a pathogen listed in that Schedule which is capable of causing disease in humans,

but does not include any substance in respect of which there is in force a product licence granted under the Medicines Act 1968(a) or a clinical trial certificate or animal test certificate issued for the purposes of section 31 or 32 of that Act.

“diagnostic service” means any activity carried on with the intention of—

- (a) identifying a listed pathogen,
- (b) isolating or identifying other organisms from specimens or samples suspected of containing a listed pathogen,
- (c) analysing specimens or samples from a patient known to be, or suspected of, harbouring a listed pathogen for purposes relating to the assessment of the clinical progress or assistance in the clinical management of that patient,

and “diagnosis” and “diagnostic work” shall be construed accordingly.

(2) In these Regulations, unless the context otherwise requires, any reference to—

- (a) a self-employed person includes a reference to any person who keeps or handles a listed pathogen and who is not an employer or an employed person in relation to that keeping or handling;
- (b) a numbered Regulation or Schedule is a reference to the Regulation of, or Schedule to, these Regulations bearing that number;
- (c) a numbered paragraph is a reference to the paragraph bearing that number in the Regulation in which the reference appears.

Notification of the keeping or handling of listed pathogens

3.—(1) Subject to paragraph (2), on or after 1st November 1981 an employer or self-employed person shall not keep or handle nor cause or permit the keeping or handling of a listed pathogen unless at least 30 days in advance he has given to the Health and Safety Executive notice in writing of the particulars set out in Schedule 2 in respect of each activity involving that pathogen.

(2) Paragraph (1) shall not apply where—

- (a) the keeping or handling is solely for the purposes of transportation; or
- (b) the listed pathogen is in a human or animal body (whether live or dead) or in any part thereof but this exception shall not apply to any specimen or sample; or

(a) 1968 c. 67.

- (c) the listed pathogen is in the bedding of an infected person or animal or in the clothing of an infected person or in any waste material kept or handled in the course of clinical treatment or post-mortem examination of such a person or animal; or
- (d) the listed pathogen is in a specimen or sample being taken or sent for diagnosis; or
- (e) the keeping or handling is in the course of diagnostic work; or
- (f) the employer or self-employed person, as the case may be, does not know and could not reasonably be expected to know that a listed pathogen is being kept or handled.

Provision relating to laboratories providing a diagnostic service

4.—(1) Subject to paragraph (2), on or after 1st November 1981 an employer or self-employed person shall not carry out a diagnostic service in relation to a listed pathogen unless at least 30 days in advance he has given to the Health and Safety Executive notice in writing of the particulars set out in Schedule 3.

(2) Paragraph (1) shall not apply where the listed pathogen or suspected pathogen is in a human or animal body (whether live or dead).

Changes in particulars to be notified

5. Where—

- (a) there is a change in any of the particulars which have been notified in accordance with Regulation 3(1) or 4(1), or
 - (b) the activities which have been so notified cease to be carried on,
- then the employer or self-employed person, as the case may be, shall notify the Health and Safety Executive forthwith in writing of that change or cessation; but this shall not apply to the completion of a particular activity in accordance with the notification under sub-paragraph (f) of Schedule 2.

Transportation of listed pathogens

6.—(1) Subject to the following provisions of this Regulation, on or after 1st November 1981 a person shall not consign a listed pathogen unless at least 30 days (or such lesser period as the Health and Safety Executive may allow in a particular case) before the pathogen is transported he has notified the Health and Safety Executive in writing of the particulars set out in Schedule 4.

(2) Paragraph (1) shall not apply where—

- (a) the listed pathogen is being consigned—
 - (i) for the purposes of diagnosis, or
 - (ii) within the curtilage of any premises; or
- (b) the consignor did not know and could not reasonably be expected to know that he was consigning a listed pathogen.

(3) In the case of a listed pathogen imported into Great Britain, the consignee shall give the notice required by paragraph (1), and paragraph (2)(b) shall have effect as a reference to the consignee not knowing or not reasonably being expected to know that a listed pathogen was being consigned to him.

(4) In this Regulation “consign” includes send to any other place whether or not it is in the same ownership or control.

Notification to the Health Ministers

7.—(1) Where any notice required by Regulations 3, 4, 5 or 6 is received by the Health and Safety Executive, the Executive shall forthwith give notice in writing of all the particulars included in such notice to the Health Minister for any country within which it appears, from those particulars, that a diagnostic service is to be, or is no longer to be, provided or that a listed pathogen is to be, or is no longer to be, kept or handled or is to be transported.

(2) In this Regulation "Health Minister" means, in respect of England or of Wales or of Scotland, the Secretary of State concerned with health in that country.

Defence in proceedings for contravening Regulation 3

8. In any proceedings for an alleged contravention of Regulation 3 it shall be a defence for the employer or self-employed person, as the case may be, to prove that on discovering that he was unintentionally keeping or handling a listed pathogen or causing or permitting it to be kept or handled, as the case may be, he notified the Health and Safety Executive forthwith.

Meaning of "work" and "at work"

9. For the purposes of Part I of the Health and Safety at Work etc. Act 1974 the meaning of the word "work" shall be extended to include any activity involving the keeping or handling of a listed pathogen and the meaning of "at work" shall be extended accordingly.

Modification of section 3(2) of the Health and Safety at Work etc. Act 1974

10. Section 3(2) of the Health and Safety at Work etc. Act 1974 shall be modified in relation to any person who keeps or handles a listed pathogen so as to have effect as if the reference to a self-employed person included a reference to any person who is not an employer or an employed person in relation to that keeping or handling.

Exemptions

11.—(1) Subject to paragraph (2), the Health and Safety Executive may, by certificate in writing, exempt any person or class of persons, from any of the requirements of these Regulations, and any such exemption may be granted subject to conditions and to a limit of time and may be revoked at any time.

(2) The Executive shall not grant any such exemption unless, having regard to the circumstances of the case, and in particular to—

- (a) the conditions, if any, which it proposes to attach to the exemption, and
- (b) any other requirements imposed by or under any enactments which apply to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it.

Patrick Jenkin,
One of Her Majesty's Principal
Secretaries of State.

13th July 1981.

SCHEDULE 1

Regulation 2(1)

LIST OF PATHOGENS THE KEEPING OR HANDLING OF WHICH IS TO BE NOTIFIED

Crimean Haemorrhagic Fever virus (Congo)	Marburg virus
Ebola virus	Rabies virus
Junin Haemorrhagic Fever virus	Simian Herpes B virus
Lassa Fever virus	Smallpox virus
Machupo Haemorrhagic Fever virus	Venezuelan Equine Encephalitis virus

SCHEDULE 2

Regulations 3(1) and 5

PARTICULARS TO BE NOTIFIED IN RESPECT OF THE KEEPING OR HANDLING OF A LISTED PATHOGEN

The particulars to be included in the notice mentioned in Regulation 3(1) shall be—

- (a) the name of the employer or self-employed person responsible for the keeping or handling of the listed pathogen;
- (b) the address of the premises where the pathogen will be kept or handled;
- (c) the location within those premises where the pathogen will be kept or handled;
- (d) the name (including, where relevant, the strain) of the pathogen to be kept or handled;
- (e) the name of the person from whom the pathogen will be obtained and the address of the premises from which it will be obtained;
- (f) particulars of the work to be undertaken, its proposed dates of commencement and completion and whether the listed pathogen is likely to be propagated;
- (g) the name, qualification and relevant experience of—
 - (i) the individual who will be directly in charge of the work,
 - (ii) any other individual who will be personally supervising the work,
 - (iii) any other individual who will be directly involved in the work;
- (h) whether the safety representatives, if any, appointed under the Safety Representatives and Safety Committees Regulations 1977(a) to represent any person who will work with the listed pathogen have been informed of the foregoing particulars.

SCHEDULE 3

Regulation 4(1)

PARTICULARS TO BE NOTIFIED IN RESPECT OF LABORATORIES PROVIDING A DIAGNOSTIC SERVICE

The particulars to be included in the notice mentioned in Regulation 4(1) shall be—

- (a) the name of the employer or self-employed person responsible for carrying out the diagnostic work;
- (b) the address of the premises where that work will be carried out;
- (c) the location or locations within those premises where that work will be carried out;
- (d) the listed pathogen in respect of which it is intended to provide a diagnostic service;
- (e) whether the safety representatives, if any, appointed under the Safety Representatives and Safety Committees Regulations 1977 to represent any person who will be employed in the diagnostic service have been informed of the foregoing particulars.

(a) S.I. 1977/500.

SCHEDULE 4

Regulation 6(1)

PARTICULARS TO BE NOTIFIED IN RESPECT OF
TRANSPORTATION OF A LISTED PATHOGEN

The particulars to be included in the notice mentioned in Regulation 6(1) shall be—

- (a) the name (including where relevant, the strain), the volume of the consignment and the estimated titre of the listed pathogen;
- (b) the address of the premises from which it will be transported;
- (c) the address of the premises to which it will be transported;
- (d) the name of the consignor;
- (e) the name of the consignee;
- (f) the name of the carrier or other transport operator responsible for the transportation;
- (g) the name of any individual who will accompany the consignment;
- (h) the route which will be taken;
- (i) the method of transportation;
- (j) the packaging and any containment precautions which will be taken;
- (k) the proposed date of the transportation.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations relate to certain dangerous pathogens (listed in Schedule 1).

The Regulations prohibit the keeping, handling and transportation of a listed pathogen unless notice is given to the Health and Safety Executive at least 30 days in advance; and the carrying on of a diagnostic service, likely to involve a listed pathogen, is prohibited unless similar notice is given. The particulars to be included in a notice are set out in Schedules to the Regulations. The Regulations also require the Executive to pass the information it receives to the appropriate Health Minister.

In addition, for the purposes of Part I of the Health and Safety at Work etc. Act 1974 they extend the meaning of work to include any activity involving the keeping or handling of a listed pathogen; and in relation to such activity provide that section 3(2) of the Act (which relates to general duties of employers and self-employed persons to other persons who are not their employees) shall have effect as if the reference to a self-employed person included a person who is neither an employer nor an employee (Regulations 9 and 10).