Health Service
Guidelines

NHS Management Executive

Decontamination of equipment prior to inspection, service or repair

Executive summary

Safe systems of work should be implemented to protect all staff, including those not employed within the Health Service, from the transmission of infection from medical devices (medical and laboratory equipment, consumables and materials used in the treatment, diagnosis and care of patients) and other equipment which come into contact with patients or their body fluids.

This notice highlights:

- the legal requirements;
- the features of an appropriate system of work;
- the documentation necessary.

Failure to comply with the legislative requirements would leave a health authority liable to prosecution.

Action

A written safety policy is a requirement of the Health and Safety at Work, etc, Act, 1974. This should contain or reference procedures to ensure that:

- hospital staff;
- representatives of suppliers or service organisations;
- recipients of items dispatched from hospital premises;

involved in inspection, service, repair or transport of medical devices or other equipment are not placed at risk by being exposed to contaminated items.

Individuals should be nominated with responsibility for implementing a safe system of work.

The Annex to this notice gives guidance on features of a suitable system of work.

This notice should be brought to the attention of all staff who need to be aware of its contents. This will include general managers, scientific officers, sterile services managers, medical, dental, laboratory and nursing staff, staff in pharmacy, medical physics, audiology, physiotherapy, imaging, engineering and maintenance departments, infection control personnel, supplies officers, safety officers and surgical appliance officers.

HSG(93)26

Decontamination of equipment prior to inspection, service or repair

17 June 1993

This notice replaces HN(87)22, which is cancelled.

Addressees

For action:
Regonal Health Authorities
District Health Authorities
Directly Managed Units
NHS Trusts
Special Health Authorities
Postgraduate Teaching Hospitals
Public Health Laboratory Service Board
Family Health Services Authorities
Local Authorities

For information:
Community Health Councils

From

Department of Health
Medical Devices Directorate
Room 222
14 Russell Square
London WC1B 5EP
Tel: 071-636 6811

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Background

The Department continues to receive reports that medical devices and other equipment are being presented for inspection, service or repair without documentation to indicate their contamination status.

There is legislation concerned with this situation and further regulations have been implemented during 1993. The Health and Safety at Work, etc, Act, 1974 places a number of duties upon employers. In addition, the Control of Substances Hazardous to Health (COSHH) Regulations (1988) are applicable both to chemical hazards and biohazards. Furthermore, European Directives on protection against biological agents and the management of health and safety are to be implemented in legislation within the UK during 1993.

An employer has a duty of care towards his employees and is required to ensure that they are not put at risk, for example, from medical devices or other equipment contaminated from or during use in healthcare or laboratories. Furthermore, employers must conduct their undertakings in such a way as to ensure that, as far as is reasonably practicable, persons not in their employ are not exposed to such risks. The Management of Health and Safety at Work Regulations (1992) place a statutory duty of cooperation between employers, eg the Health Service and its contractors, to provide each other with clear communication in Health and Safety matters including any hazards associated with the transfer of material or equipment.

Whilst the advice in this notice relates particularly to microbiological hazards, equipment may also become contaminated with chemicals which may be corrosive, irritant, toxic, cytotoxic or radioactive. The same requirements apply in such instances.

The guidance in this document has been prepared in consultation with representatives of manufacturers and suppliers of medical devices and equipment and the Health and Safety Executive.

Guidance on a safe system of work

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment, either on hospital premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately treated so as to remove or minimise the risk of infection or other hazards; appropriate documentation is required to be provided to indicate the contamination status of the item.

Guidance on safe systems of work in clinical laboratories is provided in Safe Working and the Prevention of Infection in Clinical Laboratories (1991). Model rules for maintenance staff and equipment service engineers in clinical laboratories are provided in *Safe working and the prevention of infection in clinical laboratories, model rules for staff and visitors (1991).* A separate document provides similar information for mortuaries and post-mortem rooms (Health Services Advisory Committee (1991)).

Suppliers have a responsibility to provide information on the compatibility of their particular medical devices or equipment with methods and agents for decontamination. Some guidance on decontamination has been issued in HC(91)33. Such general guidance will require to be interpreted in the light of particular local situations.

All items intended for inspection, service, repair or transportation should be provided with a declaration of contamination status. An example of such a declaration which may be copied and used is provided in this Annex.

If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, suppliers may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs (see also Flowchart 1 and 2).

In particular situations, for example when the condition of an item which is the subject of complaint or investigation may be altered or influenced by a decontamination process, the investigator may wish the item not to be decontaminated. In such situations, the advice of the investigating body should be sought and, if the item is to be dispatched from the hospital premises:

- prior warning should be given to the intended recipient
- the condition of the item should be clearly labelled so that it can be determined prior to opening of the inner packaging
- the packaging should be sufficiently robust to withstand transport
- the packaging should ensure that the content of the inner pack cannot contaminate the outer one.

In addition, agreement of any carrier used to transport a contaminated item may be required.

The above also applies to items which are not subject to investigation but cannot be decontaminated before inspection, service or repair (see also Flowchart 1 and 2).

Further information on methods of packaging is contained in the Classification, Packaging and Labelling of Dangerous Substances Regulations (1984), and the Mailguide (1992).

Advice on reporting to the Department incidents involving a range of products including medical devices and equipment has been issued in HSG(93)13.

Bibliography

1. Health and Safety Commission (1991) Safe working and the prevention of infection in clinical laboratories. HMSO

2. Health Services Advisory Committee (1991) Safe working and the prevention of infection in clinical laboratories - model rules for staff and visitors. HMSO

3. Health Services Advisory Committee (1991) Safe working and the prevention of infection in the mortuary and post-mortem room. HMSO

4. The Health and Safety, at Work, etc, Act (1974)

5. The Control Of Substances Hazardous to Health Regulations, 1988 (SI No 1657)

6. The Management Of Health and Safety, at Work Regulations, 1992 (SI No 2051)

7. Health and Safety Commission (1992) Management of Health and Safety, at Work Regulations, Approved Code of Practice. HMSO

8. 90/679/EEC Council Directive of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work. Official Journal L374; 31.12.90

9. Royal Mail, Mailguide: a comprehensive guide to mail services, October 1992

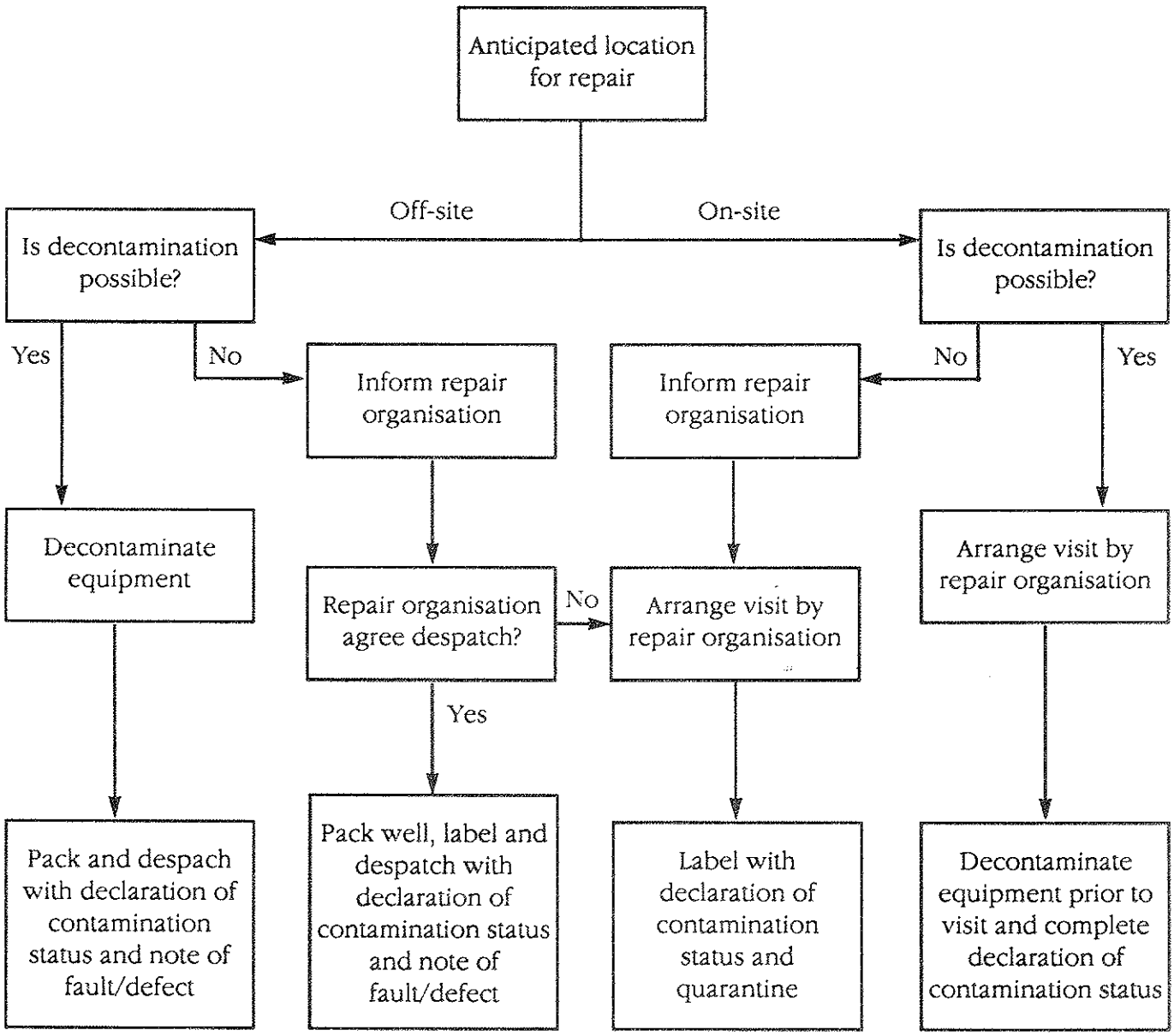
10. HC(91)33 Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or Human Immunodeficiency Virus

11. HSG(93)13 Reporting adverse incidents and reactions and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant, and medicinal products

12. The Classification, Packaging and Labelling of Dangerous Substances Regulations, 1984 (SI No 1244)

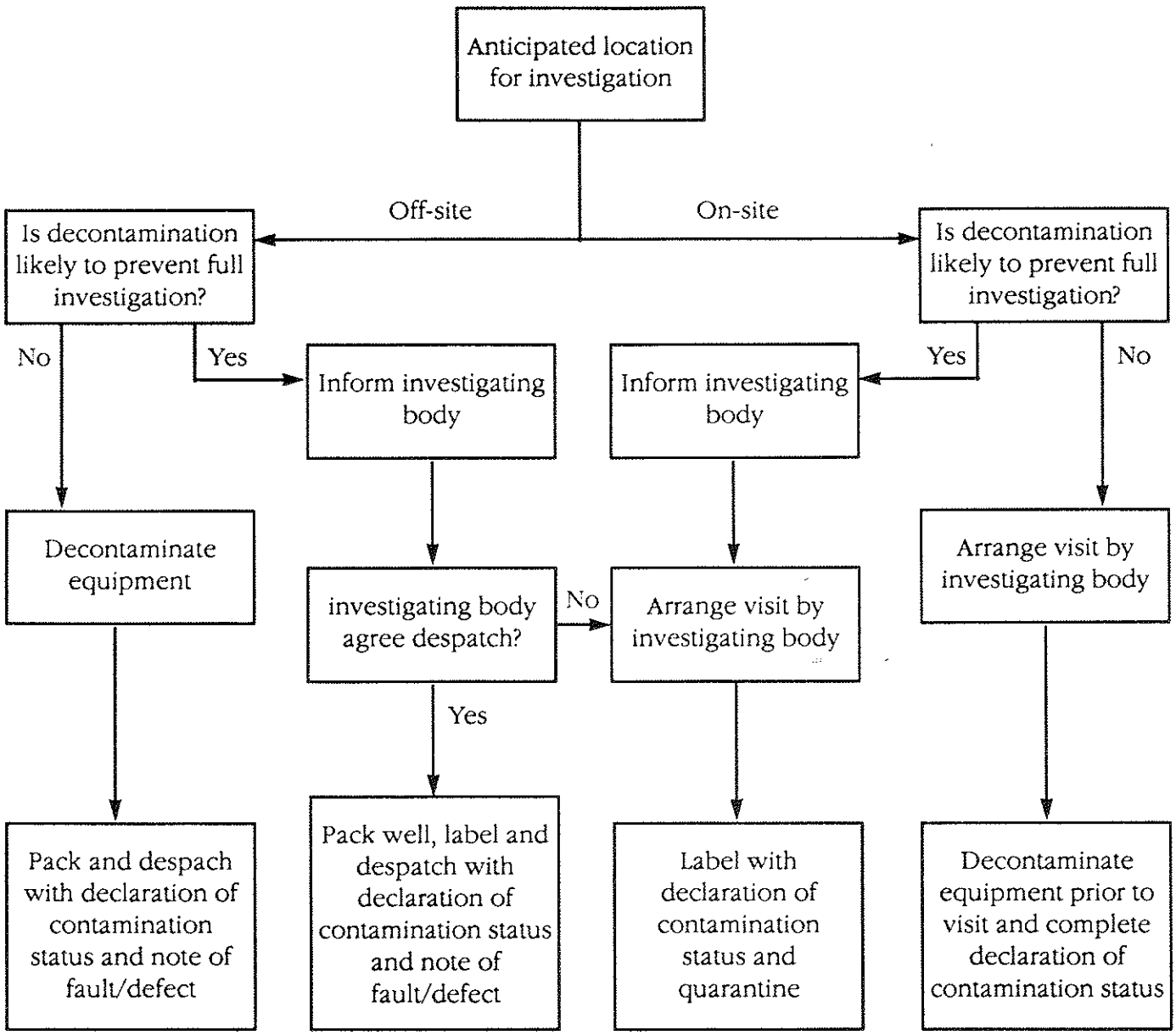
Flowchart 1

Decontamination of equipment for repair, service or inspection



Flowchart 2

Decontamination of equipment that is the subject of complaint or investigation



DECLARATION OF CONTAMINATION STATUS

Prior to the Inspection Servicing, Repair or Return of Medical and Laboratory Equipment

TO:

Make and Description of Equiprnent:

Model/Serial/Batch No:

Authority's Ref or Order No:

Recipient's Service or Returns Authorisation Reference or Contact Name:

Tick box A if applicable. Otherwise complete all parts of B, providing further information as requested or appropriate.

A. ☐ This equipment/item has not been used in any invasive procedure or been in contact with blood, other body fluids, respired gases, or pathological samples. It has been cleaned in preparation for inspection, servicing, repair or transportation.

B.

1. Has this equipment/item been exposed internally or externally to hazardous materials as indicated below?
Provide further details here

YES/NO	Blood, body fluids, respired gases, pathological samples
YES/NO	Other biohazards:
YES/NO	Chemicals or substances ha;~ardous to health:
YES/NO	Other hazards:

2. Has this equipmenUitem been cleaned and decontaminated?
YES/NO Indicate the methods and materials used:

If the equipment/item could not be decontaminated please indicate why:

Such equipment must not be returned/presented without the prior agreement of the recipient whose reference or contact name must be given above.

3. Has the equipment/item been suitably prepared to ensure safe handling/transportation?
YES/NO

I declare that I have taken all reasonable steps to ensure the accuracy of the above information, in accordance with HSG(93)26.

Authorised signature

Unit

Name (printed)

Dept

Position)

Tel no

Date