THE SCOTTISH OFFICE

National Health Service in Scotland
Management Executive

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NHS
MEL(1994)88

Dear Colleague

CLINICAL WASTE MANAGEMENT

31 August 1994

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For action:
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DMUs

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Summary

1. This circular reminds health bodies of their responsibilities regarding the management of clinical waste and offers guidance on appropriate methods of disposal. Included is a comprehensive statement on extant policy along with policy guidance on emerging technologies relating to alternatives to incineration.

Action

2. Chief Executives and General Managers, as appropriate should:-

a. ensure that their arrangements for the safe disposal of clinical waste comply with relevant legislation and with good practice for the protection of patients, staff, the public and the environment.

b. note that clinical waste incinerators must meet new stringent flue emission standards by 1 October 1995. Contingency plans may be required where appropriate action has not yet been taken.

c. note especially the Health and Safety Commission (HSC) guidance entitled "Safe Disposal of Clinical Waste" (ISBN 0 11 886355 X), priced £4.50 available from HMSO.

d. take full account of the guidelines which form the Appendix to this circular.

e. bring this letter and its Appendix to the attention of nursing home owners, managers of private hospitals, registration and inspection teams for Nursing Homes (including those jointly registered by Local Authorities) and satisfy themselves that such homes have appropriate arrangements for clinical waste management.

f. bring this letter to the attention of all General Practitioners, Dentists and Hospital/Community Pharmacists.

Background

3. The Environmental Protection Act 1990 (EPA) sets out the framework for statutory control on how controlled waste, which includes clinical waste, is to be managed and finally treated, by using a system of licences and authorisations. However, the detailed and final controls lie in the secondary documents issued on a site by site basis by the relevant Local Authority. In particular the EPA places a "duty of care" on those who produce, carry, keep and dispose of waste and failure to comply could result in severe fines and in custodial action for either or both the body corporate, and any one or more of its Officers. The removal of NHS Crown Immunity from 1 April 1991 makes it imperative for relevant NHS senior managers to be well acquainted with the regulatory systems and statutory duties imposed by the EPA.

4. Managers of clinical waste should also take account of costs and be alert to expected cost increases towards the end of 1995 when higher incineration exhaust gas emission standards come into force signalling the introduction of expensive specialist gas cleaning equipment. Some existing NHS incinerators will not be capable of adaptation and other arrangements for safe disposal will be required.

5. Both the Royal Commission on Environmental Pollution and the European Commission (EC) have turned their attention to waste minimisation, and both promote the concepts of re-use, re-cycling and better management. Re-use and re-cycling may provide special difficulties when applied to clinical waste and this should be borne in mind when determining waste segregation policy. In general terms Chief Executives and General Managers should:-

a) take action, wherever possible, to minimise the quantity of waste generated;

b) assess the risks of the components of the clinical waste stream;

c) segregate waste to ensure appropriate disposal according to its relative risk and potential for recovery or recycling;

d) act to secure the continuing commitment of staff to make such arrangements work.

6. Previous NHS Circulars on Clinical Waste Management along with their current status are listed in paragraph 14 of the Appendix to this circular.

Yours sincerely

H R McCALLUM
Head of Estates

APPENDIX

CLINICAL WASTE MANAGEMENT

1. Definition of Clinical Waste

1.1 The precise definition of clinical waste is stated in the Controlled Waste Regulations (1992)(SI588). The Health and Safety Commission's (HSC) document entitled, "Safe Disposal of Clinical Waste", ISBN 0 11 886355-X is also helpful. For the purposes of this Appendix the following is a **summary** of the group definitions.

Group A - All human tissue (whether infected or not), animal tissue, soiled surgical dressings, swabs and other soiled waste from treatment areas.

Group B - Discarded syringe needles, cartridges, broken glass etc generally known as SHARPS.

Group C - Microbiological cultures and potentially infected waste from pathology departments and other clinical research laboratories.

Group D - Certain pharmaceutical products and chemical wastes.

Group E - Items used to dispose of urine, faeces and other bodily secretions not falling into Group A. These include used disposable bed pans or bed pan liners, incontinence pads, stoma bags and urine containers etc.

2. Legislation and Regulations

2.1 Complementary to the Health and Safety at Work (Etc) Act 1974 (HSWA), the Control of Substances Hazardous to Health Regulations 1988 (COSHH) expands and clarifies the duties of employers regarding hazardous substances at work to which employees and others may be exposed. Clinical waste falls within the scope of these regulations. COSHH especially requires that risk assessments are made for all hazardous substances likely to be encountered as a result of a work activity.

2.2 The categories of clinical waste mentioned in 1.1 will form the foundation of local risk assessments. The actual level of risk will vary both within and between the groups but to ensure that clinical waste does not present an unacceptable risk to staff and others, suitable control measures must be adopted and adhered to, as appropriate, for each group.

2.3 The Environmental Protection Act 1990 has 9 parts and 16 schedules so it is important when quoting the Act to be precise. The "duty of care" aspect is set out in Part II but for "authorisation", Part I must be consulted. The "duty of care" required by the Environmental Protection Act 1990 is of particular importance because it requires those producing waste to take all reasonable means to ensure that the waste is not treated, kept, or disposed of in any way which could cause pollution of the environment or harm to human health. The responsibility cannot be fully delegated to a waste disposal contractor. The Environmental

Protection Act also provides for proceedings against Officers of a corporate body, as well as the body itself, where a contravention of the Act is alleged.

2.4 The Controlled Waste Regulations 1992 which came into force on 1 April 1992, define clinical waste in terms of that which "unless rendered safe may prove hazardous to any person coming into contact with it". Anything could prove hazardous one way or another but because of the importance of segregating wastes which are sufficiently hazardous to require special provisions from those which do not, it is necessary to adopt a practical approach to deciding what waste actually falls under the Regulations. The statutes do not define "contact", "hazardous" or "infectious", and appropriate pragmatic yardsticks need to be adopted.

2.5 The legal and practical requirements of waste management indicate the need to appoint a Senior Manager to act as a Clinical Waste Control Officer. A job description can be found in Appendix 1 of the Health and Safety Commission document, "The Safe Disposal of Clinical Waste", mentioned earlier. Such an appointment does not remove responsibility from other relevant Officers or the corporate body.

2.6 A waste management licence from the Waste Regulation Authority (WRA) ie the District or Island Council, is required under the EPA for nearly all sites on which waste treatment, storage and disposal takes place. In terms of the EPA, it is the organisation responsible for managing a licensable process (ie the licencee) which has to be "fit and proper" and not necessarily the individuals involved; a popular misconception. Financial probity requirements apply to an organisation as a whole; the absence of criminal convictions for environment offences relates to the organisation as a whole and to individuals who are part of the top management eg Directors. Technical competence, as far as the EPA is concerned, has to be found individually or collectively amongst those responsible for day to day management of the licensed facility.

2.7 Compulsory environmental assessments, details of which will vary with the size and design of a disposal plant, are required as part of the planning application process for all new incinerator plant. However, any such plant dealing with clinical waste will be an installation for the disposal of controlled waste for the purposes of the Environment Assessment (Scotland) Regulations 1988 and these installations are covered by Schedule 2, so it depends on the particular circumstances of each case as to whether an assessment is required. It is suggested that for all NHS sites where clinical waste arisings are treated, an environmental impact study be carried out.

2.8 Mandatory assessments, such as for planning proposals to support applications for various consents, or technical investigations in accordance with regulatory requirements, are open to the public. Environmental impact or compliance audits are treated, at present, as being of interest only to management and EC Directive 90/313/EEC and Statutory Instrument 3240 on "Freedom of Access to Information on the Environment" do not yet apply to such environmental audits, they are voluntary. However, where appropriate, information should be made public.

It should be noted that currently there are proposals for an EC eco-auditing system which includes certain information to be made available to the public, so it may be worthwhile conducting early environmental assessments of any planned disposal plant. Where the disposal is to be carried out by the private sector the Contractor should be encouraged in this direction.

2.9 Where incineration of clinical waste is involved such plant is subject to compliance with the very stringent framework set out in the EPA. Authorisations to undertake incineration processes for plants with throughput greater than, or equal to, one tonne/per hour are provided by HMIPI; for plants of less than one tonne/per hour, Local Authorities issue authorisations for air pollution control. These set emission limits, combustion controls and monitoring requirements. All emissions must be free from visible smoke, fumes, droplets and offensive odours and all emissions require regular monitoring to demonstrate compliance. Where an incinerator is controlled under the Local Authority air pollution control regimes of Part I of the EPA, discharges to water are still regulated but not in an integrated manner. If the discharge is to sewer, the Sewerage (Scotland) Act 1968 applies.

2.10 The EPA also comprehensively revises legislation on the handling and transport of controlled wastes including clinical wastes. In particular it placed a particular "duty of care" on those who produce, carry, keep and dispose of waste, all of which is subject to criminal law. Handling practices should comply with the HSWA and, where appropriate, be agreed with the Health and Safety Officer, the Control of Infection Officer and the Infection Control Committee of the Hospital or Trust. Comprehensive guidance on the handling and transport of clinical waste including the use of protective clothing is given in the HSC's "Safe Disposal of Clinical Waste". It states that appointed staff should wear the appropriate protective clothing (including face masks), heavy duty gloves, sturdy shoes or industrial boots, an industrial apron or leg protectors. All healthcare staff including those in primary care who are at risk of infection, should be offered hepatitis B vaccinations. More specific advice is given in "Waste Management: The Duty of Care: A Code of Practice", available from HMSO, priced £5.

2.11 Some types of waste in the Group D category may be "special waste" as currently defined by the Control of Pollution (Special Waste) Regulations 1980. Special wastes comprise substances and materials listed in the 1980 Regulations which are dangerous to life or are flammable, and prescription medicines. Listed substances include acids, alkalis, heavy metal compounds, laboratory chemicals, pharmaceutical and veterinary compounds. The 1980 Regulations require that those who produce, transfer or dispose of special waste must operate a consignment note system involving the proper description of the proposed consignments, pre-notification to WRAs and the maintenance of records. Detailed guidance on the operation of the system is given in Scottish Office Circular SDD 5/1981. It should be noted that the 1980 Regulations are in the process of revision for conformity with the EC Directives on Hazardous Waste (91/689/EEC). Controlled drugs are also subject to special waste regulations and, in addition, their destruction must be witnessed in

accordance with the requirements of the Misuse of Drugs Regulations 1985, by an Authorised Person.

3. Waste Minimisation

3.1 In September 1989 the EC proposed a community strategy for waste management, to the Council of Ministers and Parliament. In March 1990 the Council of Environment Ministers expressed approval, and made a resolution on the strategy. The strategy considered that some waste streams should be dealt with individually one of which was healthcare waste. A project group was established to pursue the proposal and that Group has defined healthcare waste as "a solid or liquid waste arising from health care". This has not been particularly helpful so far.

3.2 In general, to minimise waste, the Group proposed the ladder principle ie the preference in descending order of favour as:-

a. prevention
b. re-use
c. re-cycling (defined as "using waste as a raw material")
d. combustion with energy recovery
e. incineration
f. landfill

3.3 Chief Executives and General Managers may wish to adopt this profile in determining this clinical waste segregation policy. Further news from the group is awaited.

Re-use of Medical Devices

3.4 Many medical devices are available in either re-usable or single-use product ranges. The eventual choice will be based on a number of factors such as:-

a. cost,

b. the purchaser's ability to reprocess devices appropriately and safely,

c. the ultimate disposal cost of the product after use.

3.5 The design of medical devices intended for reprocessing should take into account the compatibility of the product with any cleaning and, where necessary, any sterilisation process, and any testing which must be applied to ensure the product remains fit for its intended use.

3.6 There is continuing debate about the reprocessing of single-use devices. Almost all of these are supplied pre-sterilised and the nature of the materials used in their construction is such that steam sterilisation cannot be used for re-sterilisation. The alternative would be the use of ethylene oxide but that is both toxic and flammable, and introduces potential hazards for staff and the environment even when carried out to BS specifications. Moreover, if the manufacturer has designed and marketed the product for single use, re-use could be followed by legal action should harm

result. Under Part 1 of the Consumer Protection Act 1987 staff may be deemed liable if instruments labelled 'single use' by the manufacturer are then re-used and cause suffering or injury.

3.7 Although, perhaps, not strictly in the category of medical device reuse it is worth reiterating that deceased patient's heart pacemakers must be removed before cremation and returned to Cardiology Departments or other Departments, as locally agreed.

Packaging

3.8 The packaging of medical devices and medicinal products is integral to them as it preserves the quality and performance between production and use. Additionally, there is a growing need for more accurate and precise instructions to be issued with devices and medicinal products. The potential for minimisation of packaging for these products is thus limited. While medical device packaging may be suitable for general recycling, the arrangements necessary for accurate segregation on busy wards, in theatres etc, may effectively preclude this. While the conclusions of the EC Waste Project Group have yet to be finally endorsed by the Community and enacted into UK legislation, they indicate a clear and sound direction of thinking towards waste minimisation.

3.9 From the EPA stand point, consideration should always be given to using less potentially polluting materials over those that are more so, eg polyethylene rather than polyvinyl chloride. Thus, even where the scope for reducing packaging is limited, the material the packaging is made from might be "optimised". It is worth noting that the EC is also pressing for packaging recycling/recovery and a Directive is imminent. Manufacturers should be encouraged by NHS purchasers to design products capable of being recycled, (especially packaging), where economic and practicable.

4. Segregation

4.1 Segregation policy is a key element of clinical waste management and has a major influence on the options for the treatment and disposal of waste. Senior managers should review their policies and practices on the segregation of clinical waste in the light of the legislative changes and the high cost of disposal.

4.2 Classification of all ward waste as clinical waste leads to a very substantial increase in the quantity to be disposed of as clinical waste and, therefore, higher disposal costs. Given the environmental impact of the disposal of clinical waste, it is desirable to minimise its volume.

4.3 It should be noted that the "duty of care" provisions of the EPA do not impose penalties on managers and/or a corporate body if segregation procedures are ineffective. However, there is potentially a serious penalty if wastes are improperly described or disposed of eg: if clinical waste is found in a load of canteen waste left for a Local Authority waste collection service.

4.4 Other issues which might be considered by management include:

Risks:

- incorrect segregation
- safety of employees and other waste handlers
- health (potential contamination and spread of infection)
- penalties (legal and contractual)

Costs:

- of segregation (training, different procedures and equipment for clinical and non-clinical waste, Certificates of Competence required by the EPA for certain staff);

- of non-segregation (increased quantity of waste to be disposed of as clinical waste).

4.5 Full consultation is essential before decisions are taken on segregation policy, in particular with the Control of Infection Officer, Infection Control Committee and Health and Safety Representatives. Where the final treatment process is to be a disinfection heat treatment process and not incineration, precise segregation of particular groups of clinical waste is essential and further guidance is now available from The Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow, G20 9NB, Telephone: 041-946-7120; Fax: 041-946-4359.

4.6 Clinical waste must not be packaged in coffins and incinerated in crematoria used for the ceremonial disposal of human corpses. A human corpse does not fall under the definition of clinical waste.

5. Disposal of foetuses and foetal tissue following termination of pregnancy

5.1 The guidelines provided in SOHHD/DGM (1992)4 dated 10 January 1992 on the sensitive disposal of foetuses should still be followed. Maceration and sluicing methods for disposal of foetuses is not appropriate and all such tissue must be disposed of by incineration.

6. Method of Final Disposal

Incineration

6.1 Incineration can be used to treat all clinical waste.

Group E clinical waste, which can be sent directly to landfill should, if the waste arises from an NHS Hospital or healthcare premise, be treated before landfill. It may be incinerated, or disinfected as described in paragraph 7 herein.

6.2 The design, construction and operation of clinical waste incinerators should:

a. sterilise the waste including the destruction of any pathogens;

b. destroy cytotoxic and other drugs (the primary and secondary chamber operating temperature requirements laid down by statute are partially to satisfy this purpose);

c. render "sharps" safe to handle, transport and landfill;

d. reduce by a very substantial measure the volume of residue to be recovered and landfilled.

e. include pollution prevention devices necessary to allow the incinerator to be authorised.

6.3 Incinerators generally use gas as the primary combustion fuel. This currently has the advantage of a relatively low price and a high fuel-to-energy primary conversion ratio.

6.4 The operation of heat recovery is an essential economic element in large and small schemes where installations must operate for the greater part of the day, all or most days of the week.

7. Alternatives to Incineration

7.1 The HSC document "Safe Disposal of Clinical Waste" states at paragraph 10 that all wastes in Groups A and B must be incinerated. However, provided there is full compliance with environmental waste disposal requirements and the relevant health and safety guidelines are met, other technologies may treat certain elements of Group A and B waste.

7.2 The market presently offers a variety of alternatives to incineration for some groups of clinical waste most of which are designed to reduce the risk of infection in handling and transport and/or render the waste non-hazardous for disposal to landfill or to municipal incinerators. Many of the alternative treatments are new techniques being tried overseas but some trials have been undertaken in Scotland. Such methods normally achieve a degree of disinfection (not sterilization) and are only suitable for certain clinical wastes. The more hazardous clinical wastes will still require incineration.

7.3 Guidance on the groups of clinical waste which may be disinfected instead of incinerated is available from The Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow, G20 9NB, Telephone: 041-946-7120; Fax: 041-946-4359.

7.4 The introduction of disinfection plant to the waste disposal stream requires a very strictly and rigorously enforced segregation policy. A disinfection process must be capable of rendering the waste unidentifiable and the process must be capable of recorded validation, supported by microbiological testing.

These alternative heat treatment systems of course may provide the opportunity for the waste to be recycled as raw material.

7.5 Healthcare premises laboratory and other similar units waste must be sterilised before removal from the laboratory.

7.6 Microwaving, autoclaving and other heat treatment systems are already in use in the USA, Germany and France although reservations have been expressed in Germany about microwaving. Some plants use mechanical macerators to grind the waste to small "amorphous" pieces, or involve shredding, to prepare it for heat treatment and subsequent landfill or municipal incineration. The method is not suitable for treating human tissue or cytotoxic drugs and there are some doubts about the control of the spread of microbial agents from the maceration process. Before using, for example, a microwave systems the guidance published by, The Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow, G20 9NB, telephone: 041-946-7120; Fax: 041-946-4359, should be carefully noted.

7.7 Other methods of disposal such as plasma treatment, X-Rays, exposure to radioactivity, chemical disinfection, treatment by gas sterilisation, pyrolysis/gasification are not immediately available commercially in the UK to handle the quantities of waste generated by the NHS. Further advice on these methodologies is available from Ian McLuckie, NHS ME, Room 370, St Andrew's House, Edinburgh, EH1 3DG. Telephone: 031 244 2080. Fax 031 244 2323.

8. Radioactive Waste

8.1 Accumulation and disposal of radioactive waste is regulated by the Radioactive Substances Act 1993 and requires an Authorisation issued by HMIPI. Arrangements and disposal should accord with the requirements of NHS MEL (1993)79, dated 9 June 1993 "Health Service Use of Ionising and Non-Ionising Radiation", and satisfy the relevant Radiation Protection Adviser. The relevant extant statute is "The Radioactive Substances Act 1993".

9. Mercury

9.1 Mercury is subject to specific control through secondary legislation resulting from the EC Dangerous Substances Directive and should not normally be discharged to sewer except with the consent of the sewerage undertaker. Mercury bearing waste is mainly from dentistry and equipment such as thermometers but it also should be noted that some pharmaceuticals may contain inorganic or organic mercurials and must be dealt with as "special waste".

10. Disposal of Human Tissue

10.1 The disposal of amputated limbs and other large tissues require special attention. Any risk that the general public could come into contact with recognisable human tissue is completely unacceptable. Such human tissue must be incinerated unless there are particular requests for burial on religious grounds. Only clinical waste incinerators are suitable for human tissue, municipal waste incinerators normally do not have suitable handling facilities nor are the burn conditions adequate. Such tissue must be dealt with promptly and guidance on storage temperatures and handling is available from The Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow, G20 9NB, Telephone: 041-946-7120; Fax: 041-946-4359.

11. Clinical Waste in the Community

11.1 Clinical waste is generated in the home and other non NHS healthcare establishments although the quantities are small. Such waste and that from Veterinary Practices etc has to be properly managed and advice on these aspects is given in HSC's "Safe Disposal of Clinical Waste". Local policies for handling the increasing clinical waste generated through general practice and home visits should be continually reviewed in conjunction with Health Boards.

12. Local Procedures and Training

12.1 The purpose of training of staff is to minimise the risk both to patients, staff and the public and to meet the statutory obligations enshrined in the "duty of care" and health and safety legislation. It is important not only for staff working in hospitals, the community and primary care setting to receive appropriate training but also those working outwith the hospital environment where clinical waste is managed. Safety training should be accompanied by written safety instructions. In addition a comprehensive waste management policy should be developed. Guidance on policy and training is given in the Health and Safety Commission's document "Safe Disposal of Clinical Waste" and it is recommended that a member of Senior Management is designated a 'Clinical Waste Control Officer' whose function it is to oversee all training. A sample job description is provided in Appendix 2 of the Health and Safety Commission's document.

12.2 The "Code of Practice for the Safe Use and Disposal of Sharps (1990)" and the "Code of Practice for Sterilization of Instruments and Control of Cross Infection (1989)" produced by the British Medical Association may also be particularly useful in the context of local procedures and training.

12.3 Local policies should address the questions associated with organisation, disposal procedures, segregation procedures, packaging, labelling, transport, protective equipment, spillages, disinfection of spillages, treatment and final disposal. Local procedures must be kept up-to-date and be posted at appropriate work sites. Suitable monitoring and audit procedures must also be established in order to ensure compliance with the policy and to reveal deficiencies. Regular reassessment of the risks posed by clinical waste is advised.

12.4 The Waste Management Industry Training and Advisory Board (WAMITAB) has been established to develop training in the waste management industry and is the industry lead body. It has developed accreditation schemes leading to qualifications for operational managers engaged in waste management. This will enable managers to demonstrate their technical competence for the purposes of determining who is fit and proper person to hold a waste management licence.

12.5 Waste Management Paper No 4, "Licensing of Waste Facilities" by the DoE, gives comprehensive advice on the requirements for

technical competence and the awarding of certificates of technical competence by WAMITAB.

13. **Liaison with Agencies**

The respective roles of several regulatory bodies ie District and Island Councils, River Purification Boards, Water and Sewerage Departments of Regional Councils, The Health and Safety Executive and HM Industrial Pollution Inspectorate which are responsible for the enforcement of statutory provisions regulating the handling and disposal of waste should be clearly understood and arrangements made for close liaison.

14. **Previous NHS Circulars on Clinical Waste Management**

a) DGM(1989)52: Emission from Hospital Chimneys. The guidance in this DGM is superseded by this Management Executive letter.

b) DGM(1990)43: Hospital Clinical Waste Incineration: Research Project. The guidance in this DGM is superseded by this Management Executive letter.

c) DGM(1991)31: Clinical Waste Disposal: Removal of Crown Immunity and Introduction of the Environmental Protection Act. The guidance in this DGM is superseded by this Management Executive letter.

d) DGM(1992)4: Sensitive Disposal of Foetus and Foetal Tissue following termination of Pregnancy. This guidance is extant.

e) MEL(1993)21: Policy on Disposal of Clinical Waste, Safe Handling and Disposal. This guidance is extant.

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