DEFINITIONS OF "INFECTIOUS WASTE" AND "RENDERED SAFE"

CONTENTS

DEFINITIONS OF "INFECTIOUS WASTE" AND "RENDERED SAFE"

1.0 INTRODUCTION

In 1997, the following definitions were proposed by a consultancy team to the Environment Agency (EA) in the United Kingdom. The rationale for the definitions is set out at Appendix A.

1.1 "Infectious Waste"

Infectious Waste
"Waste which contains, may reasonably be presumed to contain, pathogens which may cause disease in persons or animals subsequently exposed to them".

1.1.1 Secondary Definitions

- "contains or may reasonably be presumed to contain" must be assessed in relation to the source of the waste. It is possible that wastes could be categorised by source, (for example, from pathology laboratories, isolation wards, general wards), or by the category of organism known or suspected to be present (i.e. ACDP categorisation)

- "pathogens" include microorganisms, protozoa, rickettsia, fungi, bacteria, viruses, parasites and prions.

- "may cause disease" will require assessment with respect to type of infectious agent present (including reference to ACDP categorisation and known infectious properties (including infectious dose levels) to man and animals) and the concentration and quantity of the agents present.

    - "exposed to": exposure can occur at a number of points during waste disposal including:

- segregation, storage and handling of the wastes
- transfer and transportation of the waste
- during treatment or disposal activities
- following treatment or disposal

1.2 "Rendered Safe"

Rendered Safe

"An accepted method or process has been applied which:

i) Reduces the apparent numbers or activity of pathogenic agents so that no additional precautions are needed to protect workers or the public against infection by the waste.

ii) Destroys any wastes within group A(C)

iii) Renders any syringes or needles unusable

and evidence has been provided that the waste has been so treated"

1.2.1 Secondary Definitions

(i) Group A(C) means group A(C) as defined in the HSC document "The Safe Disposal of Clinical Waste" (HSC, 1982).

APPENDIX A

Defining "Infectious" and "Rendered Safe"

A1.0 INTRODUCTION

This appendix sets out background material to the definitions of "Infectious" and "Rendered Safe" proposed in the main report. Section A4.0 sets out a number of extracts from legislation and literature which either provide definitions or discussion material related to definitions. Sections A2.0 and A3.0 set out the underlying thought process leading to the proposed definitions.

Clinical waste is defined at present in the Controlled Waste Regulations 1992 (CWR92):

"Clinical waste" means -

(a) *any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, or syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and*

(b) *any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it;"*

The consultancy brief called for the consultants to propose definitions of "infectious waste" and "rendered safe". A large number of definitions have been examined, and these are reviewed in Sections A4.0.

It can be seen in the above statutory definitions, in (a), that "Rendered Safe" is linked to the term "prove hazardous to any person coming into contact with it ...". It can also be seen with regard to (a) that:

- it relates to a list of specific waste types
- those waste types would not be clinical waste unless they might prove hazardous.

By contrast, (b) above relates to wastes from a broad range of activities, and to "may cause infection".

Thus "Rendered Safe" may relate to a number of hazards, whilst "infectious" is only one hazard. Indeed, COSHH 94 defines a biological agent in terms of "... may cause any infection, allergy, toxicity or otherwise create a hazard to human health". Risk Groups 1-4 are based only on infection, and it is noted that a group 1 organism may not be infectious but may still require control measures due to allergy, toxicity etc.

The consultancy team consider that the definition of "Rendered Safe" is broader and more important than a definition for infectious. In considering the need for a statutory definition, we feel that any prosecution is more likely to relate to whether waste has been rendered safe, rather than whether it was originally infectious.

A2.0 "INFECTIOUS WASTE"

A legalistic approach would suggest that a definition of infectious waste should ideally be along the lines that it is waste which contains more than a specified number of organisms of specified types. However,

- the question of what is infectious is not absolute, and

- most sources counsel against testing for the presence of pathogenic agents in waste. Rather an assessment of the likelihood of their presence should be made based upon the source of the waste and clinical judgement.

A2.1 Hazard and Risk

Defining "infectious waste" is a function of the environment it exists in as well as its microbiological characteristics. This does not mean the microbiological characteristics (e.g. type, concentration, and virulence) are not important. Rather, they are an intricate part of a chain that must have all pieces linked together for disease to occur. Infectious agents are prevalent in the human population, but infection and disease are controlled largely through primary mechanisms of general health promotion such as good nutrition, clothing, shelter, and heat, together with specific protective measures such as immunisations and environmental sanitation.

It is therefore necessary to distinguish between hazard, which is the inherent potential of the waste to cause damage, and risk, which is the chance of circumstances arising in which the waste can actually cause such damage.

"Infectious" is a hazard. Risk assessment involves wider consideration of the general health issues just discussed, as well as routes by which people could come into contact with the waste. The definitions at A1.0 above refer to contact with the waste, however the consultancy team consider that any other mechanisms for exposure to infection transmitted from the waste (for example, any environmental pathways) should also form part of any risk assessment.

A2.2 Risk Assessment

A risk assessment should be performed on waste streams to evaluate:

- What is the likelihood that the waste contains pathogenic agents? What is the nature of the agent? Is the waste potentially infectious?
- What other hazards are potentially inherent in the waste?
- How might persons be exposed to the hazards of the waste? e.g. healthcare workers, waste collectors, waste treatment operatives, waste hauliers, landfill workers and the public.

- What is the likelihood of infection

- Can management regimes reduce or eliminate risk?

A detailed appraisal of the principles involved in microbiological risk assessment is presented in the Advisory Committee on Dangerous Pathogens (ACDP) document, 'Microbiological Risk Assessment: an interim report', 1996.

A2.3 Exposure Routes

A2.3.1 General

A good illustration of the concept of exposure routes in used in Spaulding's Classification of chemical disinfectants. Selection of an appropriate disinfection level for a patient care item was based upon what the item would be used for:

- entering into sterile body sites (e.g. surgical instruments).

- entering mucous membranes (oral cavity or vaginal vault).

- having contact with intact skin (e.g. blood pressure cuffs).

Possible routes of exposure are:

- Inhalation (Human respiratory diseases are typically spread person to person)
- Ingestion (e.g. Ingestion of contaminated food stuffs)
- Direct contact (Direct contact must also include a portal of entry into the body - cut, abrasion or splash to a mucous membrane - e.g. eye, mouth)
- Percutaneous (Cut/stuck with a contaminated sharp object - needle, lancet, scalpel blade)

In the context of waste and the public, if contact does not occur or is unlikely to occur with the waste, disease transmission is not likely to occur. Essentially, there is

sufficient data to support the proposition that the waste stream poses more of an occupational hazard (primarily percutaneous hazards).

A2.3.2 Clinical Waste

Public

The public would not normally ingest, have direct contact, or have a percutaneous exposure to waste. Fugitive bioaerosol emissions from wastes handling and treatment is a possible exposure route into which research has only recently commenced.

Workers

Workers would not ingest waste and subject to normal hygiene precautions would not ingest microorganisms. Inhalation may not be an issue when only carrying or handling waste, but may be associated with a mechanical process (treatment device). Percutaneous hazards pose a significant risk to workers handling waste. The health of workers is primarily a matter for HSE.

Environmental

According to a position paper prepared for the Society for Hospital Epidemiology of America (SHEA) in 1992 (ref. [1]):

> *"Household waste contains more micro-organisms with pathogenic potential for humans on average than medical waste".* (Details of numbers detected are provided in the reference)

[1] Rutala W and Mayhall G, "The Society for Hospital Epidemiology of America - Position Paper on Medical Waste", Infection Control and Hospital Epidemiology, Vol. 13, No. 1, pp 38 - 48, January 1992

"Whilst most states have prevented sanitary landfill disposal of regulated medical waste, data suggests that untreated medical waste can safely be disposed of in sanitary landfills, provided procedures to prevent worker contact with this waste during disposal are employed".

"Several laboratory and field studies on the survival and transport of pathogenic micro-organisms in solid waste and its leachate found that enteric viruses and bacteria are largely adsorbed and inactivated in landfilled solid waste, are present in leachates at relatively low concentrations, and are unlikely to migrate through soils into groundwater."

A2.4 Definition of Infectious Waste

A2.4.1 General

Review of variety of definitions from legislation and the literature showed a great deal of consistency in approach, with the following common features:

- a simple description
- consideration of potential infectiousness according to source, rather than testing
- a risk assessment approach.

The difficulty in producing a legalistic definition has already been noted at A2.0 above.

A2.4.2 Special Waste Regulations 1996 (SWR 96)

SWR 96 introduce into UK legislation the definition of the hazard "infectious" from the EC Hazardous Waste Directive:

"H9 "Infectious": substances containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms."

This has the drawbacks that:

i) The substance must contain micro-organisms, which implies testing, and

ii) There is no consideration of risk that persons will be exposed to the hazard.

A2.4.3 Proposed Definition

The consultancy team initially proposed the following definition:

Infectious Waste
"Waste which contains or could contain pathogenic agents, which may cause disease in persons or animals subsequently exposed to them".

However, this simple definition begs further definitions of the terms used in it, and the consultants favoured a hierarchical approach to the definition, with the terms defined in secondary and tertiary definitions if necessary.

The team considered replacing the term "pathogenic agent" with "biological agent" from COSHH 94, but this goes beyond infection (as noted in Section A1.0). As the dictionary definition of "pathogen" is "any agent that can cause disease", it seems unnecessary to speak of "pathogenic agents".

The team reconsidered the words "or could contain", and felt that these words essentially create a definition with no definitive end point (everything in nature "could" contain a pathogenic agent in the broadest sense).

Using, as an alternative, the words "may reasonably be presumed to contain" requires an objective (while not quantitative) analysis of the waste stream in question - where did it come from, what is the appearance (e.g. shredded versus intact inside of a yellow bag, large quantities of blood and/or body fluids).

The consultants therefore arrived at the recommended definition in the main text, namely:

Recommended Definition

> "Waste which contains, or may reasonably be presumed to contain, pathogens which may cause disease in persons or animals subsequently exposed to them".

A2.4.4 A Statutory Definition

This report has already explained that a definition which requires testing is not practicable. The decision as to whether a waste may be infectious must therefore be based upon one or both of:

- a clinical judgement.
- the source of the waste.

The first of these is too imprecise for a waste holder or regulator to make a decision with certainty that they will, respectively, avoid prosecution or secure a conviction.

The latter can offer more certainty, but means treating waste as infectious whether it is or not.

It may also be difficult for a regulator faced with potentially illegally deposited waste to establish what its original source was.

Nevertheless, a source-based definition would offer the opportunity to introduce HSC Categories A-E, as has been advocated by a number of consultees.

Potentially infectious waste would be waste in groups A, B, C but not D. E is more difficult, as such waste is not always potentially infectious. At present, unless all group E wastes are included, the best option appears to be to refer to Group E wastes from clinically diagnosed cases of Group 2, 3 or 4 micro-organisms.

A statutory definition of "Potentially Infectious Waste" could then be:

Potentially Infectious Waste

Group A

a. Soiled surgical dressings, swabs and all other contaminated waste from treatment areas;

b. Materials other than linen from cases of infectious disease;

c. All human tissue (whether infected or not), animal carcasses and tissues from laboratories, and all related swabs and dressings.

Group B

Discarded syringes, needles, cartridges, broken glass and any other sharp instruments.

Group C

Laboratory and post-mortem room waste other than waste included in Group A.

Group E

Used disposable bed-pan liners, urine containers, incontinence pads and stoma bags from the care of cases of clinically diagnosed illnesses involving Biological Agents in Risk Groups 2, 3 or 4.

It may then be desirable to review Groups A - E, for example to include "sanitary items" in Group E.

As already stated in Section A1.0 the consultancy team consider that the definition of "Rendered Safe" is broader and more important than a definition for infectious. In considering the need for a statutory definition, we feel that any prosecution is more likely

to relate to whether waste has been rendered safe, rather than whether it was originally infectious.

A2.4.5 Secondary Definitions

- "contains or may reasonably be presumed to contain" must be assessed in relation to the source of the waste. It is possible that wastes could be categorised by source, (for example, from pathology laboratories, isolation wards, general wards), or by the category of organism known or suspected to be present (i.e. ACDP categorisation) (not needed if statutory definition adopted).

- "pathogens" include micro-organisms, protozoa, rickettsia, fungi, bacteria, viruses, parasites and prions.

- "may cause disease" will require assessment with respect to type of infectious agent present (including reference to ACDP categorisation and known infectious properties (including infectious dose levels) to man and animals) and the concentration and quantity of the agents present.

- "exposed to": exposure can occur at a number of points during waste disposal including:

    - segregation, storage and handling of the wastes
    - transfer and transportation of the waste
    - during treatment or disposal activities
    - following treatment or disposal

A3.0 RENDERED SAFE

A3.1 Introduction

It is clear from the CWR 92 definition of clinical waste at A1.0 that all hazards, not just the risk of infection, must be removed to render waste safe.

These hazards might be:

- microbiological, which includes a wider range of considerations than simply "infectious"
- pharmacological (e.g. HSC Group D wastes)
- physical (e.g. sharps)

In addition there are perceived hazards: clinical waste may be recognised, and there may be no indication as to whether it has been satisfactorily treated. Some human tissue wastes are also subject to ethical considerations: it is not considered ethical to landfill them (for example) whether they are hazardous or not - such wastes require respectful and sensitive handling.

At present, it is possible that such human tissue wastes may not be caught by either leg of the (a) and (b) CWR 92 definition of clinical waste.

It seems appropriate to consider "hazardous" in this sense as analogous with causing harm as defined in the Environmental Protection Act 1990, which includes "offence to any of (mans) senses".

A3.2 Microbiological

A widely accepted protocol for the assessment of microbial inactivation is set out in [the licensing guidance document], and is referred to in the recommended definition at Sections A3.4/A3.5.

A3.3 Physical/Ethical

There is a general acceptance that clinical waste should be rendered "unrecognisable", "unusable" or "destroyed". The problem lies in defining these terms.

In the USA, the term "Destroyed Regulated Medical Waste" (RMW) "*means RMW that has been ruined, torn apart, or mutilated through processes such as thermal treatment,*

melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognisable as RMW. It does not mean compaction". New York State guidance goes on that "*generally, "unrecognisable" means destroyed with the intent to render the RMW material unusable and not recognisable as RMW (e.g., 100 percent of sharps must be rendered unrecognisable as intact sharps devices)*"

However, "unrecognisable" is in the eye of the beholder. The public may not recognise shredded waste; a regulator might - but the regulator should not be offended by shredded clinical waste.

The public should not have access to properly regulated waste facilities, neither should waste leave such facilities, for example, to be washed up on beaches as has happened in the past. Clinical waste is only likely to be exposed in the case of a transport accident.

Therefore evidence of treatment might take a physical form, such as shredding or bags which react to processing (e.g. autoclave tape), or documentation of some kind, or both. In the U.S. State of New York, a Treatment Certificate has to be completed, shown at Annex 1. [Not included with electronic version

A3.4 Recommended Definition

In the light of the above, the following definition is proposed:

Rendered Safe

"An accepted method or process has been applied which:

i) Reduces the apparent numbers or activity of pathogenic agents so that no additional precautions are needed to protect workers or the public against infection by the waste.

ii) Destroys any wastes within group A(C)

iii) Renders any syringes or needles unusable

and evidence has been provided that the waste has been so treated"

A3.5 Secondary Definitions

(i) Evidence of treatment may comprise documentation or the physical form of the waste, or both.

A4.0 EXTRACTS FROM LEGISLATION AND LITERATURE

The following extracts of relevant definitions, or discussions related to definitions, are presented as background to Sections A1.0 - A3.0.

A4.1 UK Legislation and Governmental

i. *"H9 "Infectious": substances containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms."* (Special Waste Regulations 1996, Schedule 2, Part II).

ii. *"Infectious - (wastes) containing micro-organisms or their toxins which cause disease in man or other living organisms"* (Carriage Classification under CDG-CPL).

iii. *"Infectious substances containing micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms".* (CP Regulations, 1996/1972).

iv. *"Biological agent" means any micro-organism, cell culture, or human endoparasite, including any which have been genetically modified, which may cause any infection, allergy, toxicity or otherwise create a hazard to human health;* (Control of Substances Hazardous to Health Regulations 1994 (COSHH 94).

v. *"Micro-organism" means a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material;* (Control of Substances Hazardous to Health Regulations 1994 (COSHH 94).

vi. *Definitions and classification (regulation 2 and Schedule 9, paragraphs 1 and 3)*

4. *The definition of "biological agent" includes the general class of microorganisms, and also cell cultures and human endoparasites, provided that they have one or more of the harmful properties specified in the definition. Most biological agents are microorganisms, among which are bacteria, viruses, fungi, microscopic parasites (such as malarial parasites, amoebae and trypanosomes) and the microscopic infectious forms of larger parasites (e.g. the microscopic ova and infectious larval forms of helminths pathogenic to humans). Naked DNA is not a biological agent.*

5. *Biological agents are classified into four hazard groups according to their ability to cause infection, the severity of the disease that may result, the risk that infection will spread to the community, and the availability of vaccines and effective treatment. These infection criteria are the only ones used for classification purposes, even though an infectious biological agent may have toxic, allergenic or other harmful properties, and some biological agents are not infectious at all. A non-infectious biological agent falls into Group 1; substantial control measures may still be needed for it, depending on the other harmful properties it has.*

6. *Any biological agent which appears in a classification list approved by the Health and Safety Commission (referred to as an 'approved classification') falls into the hazard groups specified there. However, where a strain is attenuated or has lost virulence as a result of genetic modification it may in effect by reclassified by the employer, using the criteria in Schedule 9, paragraph 3, for the purpose of selecting containment measures under Schedule 9, paragraphs 7 and 8. In other words, it may be treated as though it were a differing agent from the parent that appears in an approved classification. Conversely, an agent modified in such a way that it becomes more hazardous may need to be regarded as though it appeared in a higher hazard group than the parent.*