

Implementation this month of the *Hazardous Waste Regulations 2004* is not without its fair share of issues or implications for those working in laboratory medicine. Here, Ian Blenkarn takes the longer view and provides guidance on the interpretation of legislation based on wide experience.

# Pathology waste

## Issues, implications and regulations

**The effective management of waste is a major issue in laboratory hygiene and safety. Although waste from microbiology laboratories is of primary concern, all disciplines generate considerable volumes of hazardous waste. The prevention of infection, of physical injury, and of illness through exposure to chemicals that may be present in waste, are of greatest concern. Other key issues include obligations to environmental legislation and to overarching health and safety legislation, to effective laboratory management and successful laboratory accreditation, and inevitably to matters of cost.**

Infectious laboratory waste, generally classified as group C clinical waste, will often be made safe by autoclaving before being removed from the laboratory. Alternatively, it may be packaged into approved yellow clinical waste sacks or rigid bins for transport to an off-site treatment facility, together with clinical waste from other parts of the hospital. Despite the simplicity of categorisation that defines clinical waste into five distinct groups (Table 1), much of the waste placed into yellow clinical waste sacks and bins is not clinical waste and might be disposed of by some other, less expensive route.

Bulk clinical waste from acute hospitals inevitably includes a high proportion – often up to 40% – of items other than clinical waste. These include innocuous packaging material, domestic-type refuse, paper waste etc. Although less likely to contain a large proportion of non-clinical waste items, laboratory waste can contain some non-hazardous materials that might be processed separately. With costs exceeding £450 per tonne for clinical waste disposal, there is a strong incentive for more extensive segregation at source, although the simple logistics of time and space make such an approach cumbersome and impractical.

Moreover, as the implications of failure in segregation that may result in the inadvertent processing of infectious waste with more general waste can be profound, the principles of effective risk management dictate that further segregation shall not be considered.

### Hazardous waste regulations

Implementation this month of the *Hazardous Waste Regulations 2004* (HWR), together with commercial and technological developments in clinical waste management, seeks to rationalise the management of all waste. These changes impact on the management of laboratory waste and should provide a focus for the detailed re-evaluation of current waste management arrangements. HWR defines hazardous waste as that having one or more properties that are hazardous to health or to the environment, as documented in the European Waste Catalogue (EWC).

The impact of these new regulations on laboratory waste management may be profound, and without care in their implementation might be incompatible with safe laboratory practice. The EWC categorises

many laboratory waste products as non-hazardous (Table 2). Indeed, this classification may embrace the vast majority of waste from laboratories. But is this appropriate, especially with regard to the infectious properties of laboratory waste?

The *Hazardous Waste Regulations 2004* have much to commend them. By reference to EWC, they identify waste hazardous to health or to the environment and thereby ensure that care is taken in its disposal. Hazardous waste requires additional care and control in its terminal destruction, and there will be corresponding constraints on the transfer, transport and storage of hazardous waste, necessitating separation from non-hazardous waste, in order to ensure correct processing and avoid cross-contamination or inadvertent and inappropriate co-disposal. Costs for commercial disposal will be high.

Waste subject to special requirements in order to prevent infection (EWC 18 01 03) is defined as hazardous and subject to additional control. In contrast, waste whose collection and disposal is not subject to special requirements in order to prevent

**Table 1.** Categorisation of clinical waste.

<b>Group A</b>	Soiled surgical dressings, swabs and all other contaminated waste from treatment areas; materials other than linen from cases of infectious disease; all human tissue (whether infected or not), animal carcasses and tissues from laboratories, and all related swabs and dressings
<b>Group B</b>	Discarded syringes, needles, cartridges, broken glass and any other sharp instrument
<b>Group C</b>	Laboratory and post-mortem waste other than waste included in group A
<b>Group D</b>	Certain pharmaceutical and chemical waste (that falling within the definition of clinical waste)
<b>Group E</b>	Used disposable bed-pan liners, urine containers, incontinence pads and stoma bags
From: <i>Safe Disposal of Clinical Waste</i> (Health and Safety Executive, 1992).	

infection (EWC 18 01 01, 18 01 02 and 18 01 04) is considered non-hazardous. Logically, there is provision to reclassify this non-hazardous waste in circumstances where an additional infection hazard is recognised and EWC 18 01 03 may apply. This should be based on risk assessment, but is largely subjective.

Sharps (EWC 18 01 01) will be of particular concern and a prudent approach will err on the side of caution (EWC 18 01 03). Non-hazardous waste largely escapes more stringent control of disposal, which had previously been applied in a blanket fashion to the management of all clinical waste. This permits correspondingly lower disposal costs.

The construction of HWR cannot be criticised directly but it does introduce a strong cost incentive to the down-regulation of waste classification, which may be a dangerous path. Without care and consideration in the implementation of HWR, standards of laboratory waste disposal may decline, particularly in circumstances where waste is not processed in-house, and laboratories rely on more general hospital-wide disposal arrangements that are largely outside the control of laboratory personnel.

The EWC classifications are clear and largely unambiguous, although application to the busy clinical laboratory will be fraught with difficulty if additional segregation of waste is proposed, based on an assumed risk of infection. Although the legislation may be largely robust, the risk of infection associated

with waste will always be troublesome in interpretation. Guidance is available from the Environment Agency (*Interpretation of the definition and classification of hazardous waste technical guidance*, WM2) and includes schemata for the classification of infection risk of waste.

In this guide ([www.environment-agency.gov.uk/business/444217/590750/590821/502174/496498/](http://www.environment-agency.gov.uk/business/444217/590750/590821/502174/496498/)), it is made clear that classification of waste should be based upon clinical judgement and formal risk assessment. The schemata may be oversimplified. For example, it is proposed that waste from orthopaedic wards might be classified largely as non-hazardous because those patients are unlikely to be suffering any infectious disease. Although provision is made for wastes from patients known to suffer from, for example, hepatitis B or C or human immunodeficiency virus (HIV) infection, no provision is made for those with undiagnosed or unrecognised and latent infection.

Can we identify such individuals? Their carers may be unaware, as may the individuals themselves. A codicil to such schemata, that anticipates additional clinical judgement applied to the classification of waste, is surely without merit and serves only to highlight a lack of understanding in the formulation of such guides, and to the realities of work in clinical laboratories. To propose a scheme for the segregation of clinical wastes based on fundamentally

oversimplified assumptions of the risk of infection is to negate totally the CDC Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections.

With the implementation of HWR, universality in the protection of patients, healthcare workers and others becomes conditional. This legislation, and the categorisation of waste that it requires, is most clearly inappropriate when considering the protection of healthcare workers, and of others, from acquired infection. In the laboratory, as elsewhere in hospitals,<sup>1</sup> the only safe approach is to categorise all clinical waste as hazardous under the definitions of HWR.

### Managing waste

Maintaining a blanket approach to the classification of laboratory waste as potentially hazardous, due to the risk of infection, is the only safe and satisfactory approach and will satisfy any reasonable risk assessment. To ensure that laboratories manage their waste effectively, a laboratory waste manager should be appointed, together with separate representatives for each laboratory discipline.

Waste managers should ensure that all staff are aware of disposal arrangements for all waste, and ensure that protocols are working properly. They should undertake regular audit of disposal practices, to include a full audit trail that records information about the fate of all waste removed from the laboratory. Working in close liaison with safety officers and laboratory managers, and with the site facilities and waste managers, the laboratory waste manager must also develop contingency plans to be implemented in the event of failure of routine disposal services (eg the breakdown of an autoclave or unexpected termination of contract disposal services).

Local sterilisation of infective laboratory waste is a preferred option, eliminating risk of infection and providing the opportunity for cost saving in subsequent disposal. A modern well-maintained autoclave of sufficient capacity is required. Regular thermal mapping of the load chamber must demonstrate that all parts of the load achieve sterilising temperature and that this temperature is maintained throughout the chosen holding time at temperature (HTAT).

The composition of waste will vary greatly. The packaging of waste in its primary containers, and thus the density and porosity of the load, must be accommodated during the autoclave cycle, usually by increasing HTAT by at least 50% in order to ensure safe processing of waste at all times. The geometry and density of chamber loading may be critical. The containers used – usually metal or polypropylene bins – to package waste for the autoclave, and the use of autoclave bags, may greatly affect the rate of heat penetration to the load, and particular care is needed to ensure satisfactory steam

**Table 2.** European Waste Catalogue 2002, categorisation of clinical waste.

18	Wastes from Human and Animal Health Care and/or Related Research (except kitchen and restaurant waste not arising from immediate healthcare)	
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans	
18 01 01	sharps (except 18 01 03)	
18 01 02	body parts and organs including blood bags and blood preserves (except 18 01 03)	
18 01 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection	A
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (eg dressings, plaster casts, linen, disposable clothing, diapers)	
18 01 06*	chemicals consisting of or containing dangerous substances	M
18 01 07	chemicals other than those mentioned in 18 01 06	
18 01 08*	cytotoxic and cytostatic medicines	A
18 01 09	medicines other than those mentioned in 18 01 08	
18 01 10*	amalgam waste from dental care	A
Any waste whose six-digit code is marked with an asterisk (*) is a hazardous waste. Classification may be <b>absolute</b> (A), defining waste as hazardous regardless of the concentration of any 'dangerous substance' within it, or a <b>mirror entry</b> (M) covering waste with the potential to be hazardous or non-hazardous, depending on composition and the concentration of 'dangerous substances' within it. The hazard potential is determined by reference to published threshold limits or, for infection hazards, on risk assessment.		

**Table 3.** STAATT sterility assurance levels for waste disposal technologies.

Level I	Inactivation of vegetative bacteria, fungi and lipophilic viruses at $\geq 10^6$ reduction
Level II	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at $\geq 10^6$ reduction
Level III	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at $\geq 10^6$ reduction; and inactivation of <i>Bacillus stearothermophilus</i> or <i>B. subtilis</i> spores at $\geq 10^4$ reduction
Level IV	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, mycobacteria and <i>B. stearothermophilus</i> spores at $\geq 10^6$ reduction

penetration. Repeat thermal mapping and adjustment of the autoclave operating profile, as necessary, must confirm variation in any of these factors.

Supplementary biological testing of autoclave efficacy, using *Bacillus stearothermophilus* spore preparations, provides confirmation of proof of process. Day-to-day control of performance is achieved using a timed record of temperature and pressure profiles in the autoclave chamber, in the load itself, and in the autoclave drain. Recording must be fully automated and available as a permanent record. Time, temperature, and pressure gauges must be formally and independently calibrated.

### Into the autoclave

Autoclaves must be properly maintained and regularly serviced, and the laboratory waste manager should devise protocols that accommodate periodic down-time. Older autoclaves may need to be upgraded or replaced to achieve necessary performance standards. It is particularly important to ensure a high-quality working area that provides secure storage.

Autoclaves must be located away from critical areas, as fugitive release to the atmosphere of microorganisms originating from the load is not uncommon, although this can be prevented by the use of appropriate air filters or the modification of autoclave design.<sup>2</sup> Robust waste management protocols must be part of the laboratory

operational plan, and these must be regularly reviewed. Adequate training and supervision of staff is essential.

Autoclave treatment residues are particularly unpleasant. In most cases, the liquid fraction can be discarded to drain, while the solid residues are processed commercially as non-hazardous waste, usually by co-disposal with municipal waste. Savings up to £300 per tonne might be anticipated, although this is unlikely to make significant impact on the capital and running costs of an autoclave, even in the largest laboratory complex. However, including also the risk management implications of laboratory (clinical) waste management and the cost implications of poor performance in this area, which may include prosecution under environmental and health and safety legislation, and loss of accreditation status, in-house processing of waste becomes much more attractive.

### Health and safety

Prosecution has become a real threat. To complicate matters, there appears to be a potential conflict between HWR and health and safety. This is of major concern and will impact directly on healthcare waste management. Health and safety legislation has been used to bring successful prosecution of NHS Trusts in breach of section 3, sub-section 1, of the *Health and Safety at Work Act, 1974*. This places on employers "a duty... to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety". Prosecution has followed storage of clinical waste in areas of hospitals accessible to the public. No mitigation was entertained on the basis of the infectious nature of the waste, or lack of it. Thus, under health and safety legislation, clinical waste is deemed a potential hazard to health. We should not disagree.

Trusts must exercise an appropriate duty of care to ensure waste is properly managed, in such a way as to ensure the safety of its employees and others. It is questionable if this duty will be satisfactorily discharged if some waste is managed to a lesser standard, based on arbitrary and ill-defined HWR categorisation that is itself fundamentally flawed through our inability to apply meaningful and precise definitions of infection risk for clinical waste.

We might conscientiously exclude laboratory waste from this argument, and accept that it should be classified as hazardous under HWR. However, if this waste is processed remotely, with clinical waste from other areas of the hospital, the fate of laboratory waste moves outside the control of the laboratory and may enter an incorrect (non-hazardous) waste stream.

What will happen if an employee, contractor or member of the public suffers a sharps-related or other illness from exposure to clinical waste defined as 'non-hazardous'

in the context of HWR? The infection risk, although possibly small, cannot be dismissed and relevant health and safety legislation may apply. Furthermore, additional civil liability may greatly magnify the costs.

The architects of HWR may not have foreseen the difficulties these fine distinctions in waste classification may force upon hospitals, and the unfortunate cost incentives that it creates. More seriously, it seems likely that they have failed to foresee the risks to individuals from lax interpretation of the definitions and thereby of inadequate waste classification. This paradox may require that we apply to wastes that might be categorised as non-hazardous similarly stringent controls in collection and disposal to comply with the demands of health and safety legislation. Having adopted the dual classification of EWC, if infection results from exposure to clinical waste "not having special requirements in order to prevent infection" the courts may well assume a breach in duty of care. Consequential liability may be costly, as, by definition, the mandatory risk assessment that enabled classification of that waste as non-hazardous was itself defective.

### Alternative technologies

If waste is made safe by autoclaving, it can be processed subsequently, at correspondingly lower cost, as non-hazardous waste. Treated and untreated waste must remain separate at all times. Where autoclave capacity is limited and only a fraction of the total infectious waste from laboratories is autoclaved, some elect to consign autoclave residues to a single waste stream, together with the untreated fraction and process both fractions as potentially hazardous clinical waste. If sterile, this autoclaved waste presents no further risk of infection and can be disposed of at lower cost, with savings of up to £300 per tonne. Although popular, this 'double whammy' is inappropriately costly and without merit, but it is an arrangement frequently used to compensate for deficiencies in the proper segregation of treated from untreated waste that should be eliminated through effective waste management procedures.

It is particularly appropriate to question the fate of wastes leaving the laboratory. Many hospitals maintain third-party clinical waste disposal contracts that do not specify implicitly the procedures to be used for terminal destruction of waste. It may be incinerated at high temperature or autoclaved in a commercially operated facility, or processed using one of the newer 'alternative technologies' such as 2450 MHz microwave treatment or a dry heat hot oil auger unit operating at temperatures around 110 °C.

The US State and Territorial Association on Alternate Treatment Technologies (STAATT), on behalf of the US Environmental Protection Agency, has proposed four sterility assurance levels to define the levels of microbial inactivation applicable to the disposal of clinical waste. Level-III inactivation is the

required minimum standard of performance for all clinical waste treatment processes. As the alternative technologies provide a sterility assurance level (Table 3) of only  $10^4$ , compared with a minimum sterility assurance level of  $10^6$  for high-temperature incineration or autoclaving, these treatments may be unsuitable for processing potentially infective laboratory waste.<sup>3</sup> Laboratory staff must assure themselves that untreated waste removed from the laboratory is processed using a robust and appropriate technology.

With the implementation of HWR, some hospitals may seek additional cost savings through additional segregation at source into hazardous (infective) and non-hazardous waste components (Table 2). Although identified as a wholly inappropriate and unworkable system for most hospitals, a two-tier system for waste processing may prevail due to financial pressures. Supported by the well-established standards for the prevention of infection in pathology laboratories, any reasonable risk assessment will conclude that laboratory waste (ie patient samples and sample residues, microbiological cultures etc) and the more general detritus of laboratory analysis, does carry a considerable risk of infection. These wastes must be categorised as hazardous and processed accordingly.

A duty of care exists to ensure that off-site processing of wastes is appropriate and laboratory waste managers must assure themselves that untreated waste removed from the laboratory is processed using a suitable destructive technique that provides a sterility assurance level of  $10^6$ . Once more, close liaison with hospital facilities managers or others responsible for site-wide waste disposal arrangements becomes essential.

### Universal responsibility

Several studies have shown that the working environment of a clinical microbiology laboratory is often extensively and heavily contaminated with pathogenic organisms originating from the work in progress. Despite apparently good standards of laboratory performance and hygiene, antibiotic-resistant species may be encountered widely on working surfaces, doors and handles, telephones, computer terminals, and on the floor. Methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci have been identified, together with other less newsworthy pathogens.<sup>4</sup>

None of these should escape the microbiology laboratory. High standards of hygiene and cleanliness must be maintained at all times, and the laboratory cleaners instructed to clear all detritus swept from the floor, and all used cleaning materials, to an appropriate receptacle for disposal as potentially infectious laboratory waste. Storage and treatment areas for laboratory waste must be kept clean at all times, and should be designed and constructed to facilitate effective decontamination in the event of spillage.

Effective waste management is a key part of good laboratory practice. Although infectious waste from microbiology laboratories is a prime concern, other disciplines do not escape this responsibility. Neither 'fashionable' nor 'sexy', laboratory waste management is too often relegated in importance and receives only cursory attention. In reality, however, this is a key component in laboratory safety and good laboratory management. There is universal responsibility for the safe disposal of

laboratory waste, for the safety of ourselves and of others, for the environment, and to a broad array of legislation. This might usefully be enshrined in more explicit Clinical Pathology Accreditation (UK) Ltd standards, in core and in-service biomedical scientist training, and in Health Protection Agency registration standards, to raise awareness and establish uniformly high standards of performance. ■

### REFERENCES

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J Ian Blenkarn CSci FIBMS is an independent consultant specialising in healthcare microbiology (blenkarn@ianblenkarn.com, www.ianblenkarn.com) and previously a member of the Department of Infectious Diseases, Imperial College, London.

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- Staphylococci in animals: prevalence, identification and antimicrobial susceptibility, with an emphasis on methicillin-resistant *Staphylococcus aureus*
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- Altered lipid parameters in patients infected with *Entamoeba histolytica*, *Entamoeba dispar* and *Giardia lamblia*
- Embryopathy in experimental diabetic gestation: assessment of oxidative stress and antioxidant defence
- Blood film review by biomedical scientists
- Hepatitis C antibodies in asymptomatic first-time blood donors in The Gambia: prevalence and risk factors
- Antibody response to *Toxoplasma gondii* in saliva samples from human immunodeficiency virus-infected patients