



**Royal
Pharmaceutical
Society**
of Great Britain

**THE HAZARDOUS WASTE (ENGLAND AND WALES)
REGULATIONS 2005**

**Interim Guidance for the NHS Hospital Sector for England and
Wales and Information for Scotland**

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Interim Guidance for the NHS Hospital Sector for England and Wales and Information for Scotland

***This Interim Guidance is intended to cover only Pharmaceutical Hazardous Waste
and not for example Refrigerators, Freezers and VDU's***

Background:

Special Waste Regulations 1996

Following implementation of the 1996 Special Waste Regulations, the NHS Pharmaceutical Quality Assurance Committee issued 'Guidelines on the Handling and Disposal of Pharmacy Wastes' in September 2002. Due to forthcoming changes to Waste legislation that becomes effective on 16th July 2005 the Committee asked the original group to update the Guidelines. The group has expanded to include representation from RPSGB, PSNC, Care Home representatives and expert advice from the Environment Agency.

This interim guidance has been prepared following meetings of the group and help and participation from all group members.

The legislation derives largely from European Directives. The storage, carriage, processing and supply of waste are all subject to stringent controls designed to minimise the negative effects of waste on the environment. As the impact of inappropriate handling of waste could have considerable effect on the environment, the penalties for breach are severe. Fines of up to £20,000 or terms of imprisonment of up to six months per offence are possible. This is a criminal offence not a civil offence.

Duty of Care

Under the **Environmental Protection (Duty of Care) Regulations 1991**, those of us who produce, carry, keep, treat or dispose of Controlled Waste must ensure the safe handling and disposal. This duty continues throughout the waste chain and all intermediaries until final disposal. If any part of the disposal chain fails, the initial producer can be held to have failed in their duty of care.

Licensing of the Storage of Waste

The storage of waste on the premises of production by the producer does not normally require a waste management licence. This means that a Pharmacy department does not require a licence to store its own unwanted date expired stock, unwanted stock returned from wards/departments or other waste produced in its practice pending disposal. The holding of waste from other sources requires a licence or registered exemption under the **Waste Management Regulations 1994**. (e.g. satellite hospitals in another trust). A Waste Management Licence (WML) will have to be obtained by the Trust as the legal entity and all departments on the Trust site including

Pharmacy will be covered by this licence. If however there is a separation of sites by a public highway then a licence needs to be obtained for those sites.

Destruction of Controlled Drugs

Controlled drugs have been disposed of as 'Special Waste' only after the controlled drug has been rendered irretrievable (e.g. by denaturing). In the past various methods have been used to denature controlled drugs, including grinding together with other waste medicines, and/or dissolving in soapy water or bleach, or adsorbing onto cat litter. All these methods constitute waste treatment and in theory require a Waste Treatment Licence. This is currently under review with the Environment Agency and is not expected to be regulated as a licensable waste treatment.

'De-Blistering'

As many medicines are now supplied in blister packs, this primary packaging, outer cardboard cartons and associated patient information leaflets occupy large volumes of space when sent for destruction. Pharmacists may have attempted to reduce the amount of 'Special Waste' by removing blister packaging from the cardboard carton, and in some cases by de-blistering the individual tablets or capsules. This activity could also fall within the definition of waste treatment, which as stated above, is a licensable activity. The Environment Agency has confirmed that the removal of a blister strip from other inert packaging, so that the blister strip can be placed in the waste container and the outer packaging can be recycled, would not be regulated as a licensable waste treatment.

'Sharps'

Sharps are generated in two main areas, an aseptic preparation unit attached to the Pharmacy and at ward/department level. In order to reduce the number of sharps containers required it is proposed that two sharps containers only will be used.

1. Cytotoxic and Cytostatic sharps box.
This is for syringes and needles and broken ampoules contaminated with this group of medicines in preparing for and or used for direct patient administration (see appendix) and will be consigned as hazardous waste for incineration.
2. Other Medicines sharps box.
This is for syringes and needles and broken ampoules contaminated with medicines (NOT Cytotoxic or Cytostatic) in preparing for and or used for direct patient administration (see appendix) and will be disposed of by incineration.

Segregation of Medicines

The 'Special Waste Regulations, 1996' placed legal obligations on the waste contractor with respect to mixing of waste, but not on the waste producer. It did not require segregation into solids, liquid and aerosols etc. but this may have been a requirement of the waste contractor.

Hazardous Waste

From 16th July 2005 the '**Special Waste Regulations 1996**' will be replaced by the Statutory Instrument 2005 No. 894 '**The Hazardous Waste (England and Wales) Regulations 2005**'. At this time the majority of prescription only medicines will no longer be classed as hazardous, and will not be required to be consigned for disposal. The last consignment date under the Special Waste Regulations will be 13th July 2005 as 72 hours notification is required. Following the coming into force date the only medicinal products that are automatically deemed to be hazardous are cytotoxic and cytostatic medicines.

Cytotoxic and Cytostatic medicines are defined as any medicinal product that has one or more of the following hazardous properties: Toxic (H6), Carcinogenic (H7), Mutagenic (H11) or Toxic for Reproduction (H10).

(Note; Toxic for Reproduction should not be confused with Contraindicated for Use in Pregnancy, the former is based on specific chemical risk phrases).

At the time of preparation of this interim guidance, no definitive list of such products has been prepared. The Environment Agency will receive guidance from this group. The National Institute for Occupational Safety and Health (NIOSH) in the USA produced a list of human medicines known to have these properties. Appendix A.

Defined by NIOSH as:

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

Until an accurate list is issued authoritatively, Pharmacists are advised to use this list as a starting point, in identifying medicines that are hazardous.

Every person who produces or stores hazardous waste must notify their premises to the Environment Agency. This would normally be done by the Trust Waste management department. Notification can be made on the internet (<http://www.environment-agency.gov.uk/subjects/waste/1019330/1029396/>), on disk, by e-mail, by post or by telephone, and the cost of notification varies with method used.

Cytotoxic and Cytostatic waste medicines must be consigned in the same way that Special Waste was consigned, but with a new consignment note. These do not have to be purchased but are available for download from the internet (http://www.environment-agency.gov.uk/commondata/acrobat/hwcnscs01v051_1105438.pdf). The consignment note requires the wastes to be listed, together with the six digit EWC code. Examples of the codes for wastes arising from treatment of humans include:

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.
18 01 04	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)
18 01 06*	Chemicals consisting of or containing dangerous substances
18 01 07	Chemicals other than those mentioned in 18 01 06
18 01 08*	Cytotoxic and Cytostatic medicines
18 01 09	Medicines other than those mentioned in 18 01 08

Those six digit codes which there is a star (*) are classified as hazardous waste. All other products are classified as 'waste'. Although both hazardous waste and non hazardous waste will be collected at the same time by the waste disposal contractor, and they may (or may not) be incinerated at the same facility, they must nevertheless be segregated at the pharmacy, and only hazardous waste will be subject to hazardous waste consignment notes.

Therefore, a waste bin consigned for disposal which contains only cytotoxic products would be coded 18 01 08. The other waste container in a pharmacy will generally be coded 18 01 09 (unless any other types of waste are included).

The description should also include an estimate of the quantity in kilograms (which is the total weight of waste in the container including packaging etc), the chemical/biological components of the waste (for example 'cytotoxic medicines'), and the physical form (e.g. solid, liquid. Aerosol, mixed), the EWC hazard codes. It is also necessary to list each hazardous medicine, which may require a continuation sheet to accompany the consignment note.

This information is critical to the safe destruction of the waste. The container type and size is also specified.

The waste disposal contractor may assist with the completion of the consignment note – BUT - the consignor (i.e. the Pharmacist) remains responsible for the accuracy and completeness of the consignment note.

The **Hazardous Waste Regulations 2005** prohibit the mixing of different types of hazardous waste, and the mixing of hazardous waste with non-hazardous waste. This means that Pharmacies will require at least two containers, one for 'cytotoxic and cytostatic' waste and one for 'Non cytotoxic and cytostatic' waste.

Not only would the Pharmacy commit an offence if 'cytotoxic and cytostatic' medicines are placed in the 'non hazardous' waste container, but an offence would also be committed if 'non-hazardous' waste is placed in the 'cytotoxic and cytostatic' waste container.

'Non Cytotoxic and Non Cytostatic' Waste

Non- Hazardous Waste

A list of waste medicines that do not have hazardous waste properties will be produced that will be suitable for disposal into the foul sewer or for disposal onto landfill sites or other methods of treatment. Such waste should not be harmful to the flora or fauna of the environment and should also pass the 'Western Mail' test if found on landfill sites. Such medicines will include most date expired I/V fluids of for example Glucose and Sodium Chloride that have not had additions or been partly used by a patient, the bags can then go to landfill disposal. Patient part used IV fluids may present a risk of infection and should not be disposed of this way.

From 2007 liquids will not be allowed to be disposed of on landfill sites.

The Remaining Group of Waste Medicines

This will be the largest group and will be all those medicines not included in the 'Cytotoxic and Cytostatic' and the 'Non-hazardous' wastes. We will need to propose a term to the Environment Agency to identify this group.

All of this group will be required to be disposed of by high temperature incineration and **The Hazardous Waste Regulations 2005** do not require a consignment note. However there is still a **Duty of Care** and best practice would be to have a waste transfer note system with the waste contractor to ensure that the waste goes for high temperature incineration. Such a procedure could be incorporated into the tender document for the contract requirements with potential waste contractors.

Best Practice – Colour Coding

The following colour coding is being proposed for best practice:

- **Yellow** – Infectious Waste; Minimum treatment/disposal required is incineration in a suitably licensed or permitted facility.
- **Orange** – Infectious Waste; Minimum treatment/disposal required is to be 'rendered safe' in a suitably licensed or permitted facility.
- **Purple** – Cytotoxic/Cytostatic Waste; Minimum treatment/disposal required is incineration in a suitably licensed or permitted facility.
- **Tiger Stripe** (Yellow/Black) – Offensive Waste; Minimum treatment/disposal required is landfill in a suitably licensed or permitted site. This waste should not be compacted in un-licensed/permited facilities.
- **Black** – Domestic Waste – Minimum treatment/disposal required is landfill in suitably licensed or permitted site.

Medicines will be disposed of as follows:

1. Cytotoxic/Cytostatic Waste Medicines – **Purple; Incineration**
2. Other Pharmaceutical Waste Medicines - **Yellow; Incineration**
3. Non-Hazardous Waste Medicines – **Tiger Stripe; Suggested Only**

A recommendation for best practice is that Pharmacy upon receipt of drugs should use a purple coloured sticker to identify those drugs classed as 'cytotoxic and cytostatic' as in Appendix A. This should also be the practice when these drugs are sent to the wards or departments.

Working Group

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Kay Witham (Secretary)	NHS QA Cmmt for England
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Alison Rees	Care Commission Representative
Robert Hallworth	Primary Care Representative
Baldip Dhariwal	RPSGB, Practice Pharmacist

Appendix A

List of 'hazardous' medicines (Caution – this is a list from an American paper, so the nomenclature used may not be familiar) Note: Any other medicine which has the properties H6, H7, H10 or H11 is also hazardous

<p>Aldesleukin</p> <p>Alemtuzumab Alitretinoin Altretamine Amsacrine Anastrozole Arsenic trioxide Asparaginase Azacitidine Azathioprine Bacillus Calmette-Guerin Vaccine Bexarotene Bicalutamide Bleomycin Busulfan Capecitabine Carboplatin Carmustine Cetorelix acetate Chlorambucil Chloramphenicol Choriogonadotropin alfa Cidofovir Cisplatin Cladribine Colchicine Cyclophosphamide Cytarabine Ciclosporin Dacarbazine Dactinomycin Daunorubicin HCl Denileukin Dienestrol Diethylstilbestrol Dinoprostone Docetaxel Doxorubicin Dutasteride Epirubicin Ergometrine/methylergometrine Estradiol Estramustine phosphate sodium Estrogen-progestin combinations Estrogens, conjugated Estrogens, esterified Estrone Estropipate Etoposide</p>	<p>Exemestane Finasteride Floxuridine Fludarabine Fluorouracil Fluoxymesterone Flutamide Fulvestrant Ganciclovir Ganirelix acetate Gemcitabine Gemtuzumab ozogamicin Choriogonadotropin alfa Goserelin Hydroxycarbamide Ibritumomab tiuxetan Idarubicin Ifosfamide Imatinib mesilate Interferon alfa-2a Interferon alfa-2b Interferon alfa-n1 Interferon alfa-n3 Irinotecan HCl Leflunomide Letrozole Leuprorelin acetate Lomustine</p> <p>Chlormethine hydrochloride</p> <p>Megestrol Melphalan</p> <p>Menotropins</p> <p>Mercaptopurine Methotrexate Methyltestosterone Mifepristone Mitomycin Mitotane Mitoxantrone HCl Mycophenolate mofetil Nafarelin Nilutamide Oxaliplatin Oxytocin Paclitaxel Pegaspargase Pentamidine isethionate Pentostatin Perphosphamide</p>
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Pipobroman	Thalidomide
Piritrexim isethionate	Tioguanine
Plicamycin	Thiotepa
Podofilox	Topotecan
Podophyllum resin	Toremifene citrate
Prednimustine	Tositumomab
Procarbazine	Tretinoin
Progesterone	Trifluridine
Progestins	Trimetrexate glucuronate
Raloxifene	Triptorelin
Raltitrexed	Uramustine
Ribavirin	Valganciclovir
Streptozocin	Valrubicin
Tacrolimus	Vidarabine
Tamoxifen	Vinblastine sulfate
Temozolomide	Vincristine sulfate
Teniposide	Vindesine
Testolactone	Vinorelbine tartrate
Testosterone	Zidovudine