



Health and Safety Executive		Operational Circular	
		OC 285/9	
Review Date	07/09/2013	Open Government Status	Fully Open
Version No & Date	1: 07/09/2003	Author Unit/Section	Medical Sciences Unit, COSAS

Target Audience:

FOD staff dealing with agriculture, food and services
SMIs, MI's, OHI's in EMAS

SAFE HANDLING OF CYTOTOXIC DRUGS

This OC aims to make inspectors aware of new HSE guidance about the hazards associated with cytotoxic drugs and precautions to be taken when handling them. The guidance has been published in the form of an [information sheet](#) (IS) MISC 615 and is available on HSE's website.

BACKGROUND

1 Cytotoxic drugs, sometimes known as antineoplastic or anticancer drugs, are extensively used in the treatment of cancer. This is because they possess the ability to inhibit the growth of tumours by disrupting cell division and killing actively growing cells. However, their action is not specific to tumour cells and normal cells may also be affected, which can result in side effects of treatment. Some of these drugs have other medical applications, for example as immunosuppressive agents in transplantation and in the treatment of diseases with an immunological basis such as certain forms of arthritis.

2 In general, cytotoxic drugs are substances hazardous to health as defined in COSHH 2002. Some are considered carcinogenic and are therefore subject to Appendix 1 of the COSHH ACOP which provides additional guidance on the control of carcinogenic substances. They are prescribed medicines. Their safety, quality and efficacy are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA, formerly the Medicines Control Agency). Further details on the role of the MHRA and possible areas of overlap with the work of FOD can be found in [SIM 7/2000/18](#) (currently undergoing revision).

3 The drugs may be used in a range of settings. These include hospitals, specialist oncology units, hospices, care homes, charitable organisations, domestic homes and veterinary clinics. Employers and employees need to be aware of the risks involved in using cytotoxic drugs and the precautions to take when handling them. In support of this, inspectors can refer the IS to relevant persons outside HSE, which include pharmacists, pharmacy technicians, medical and nursing staff, veterinary practitioners and others involved in handling these drugs and related waste. The guidance is not specifically aimed at manufacturers of cytotoxic drugs.

4 The IS has been developed to provide a focus on the relevant regulatory framework, including risk assessment, and prevention/control of exposure. It does not cover the detailed technical aspects of how to prepare and administer cytotoxic drugs. However, if this information is needed, some useful references are listed at the end of the

IS. They include the MARC (Management and Awareness of the Risks of Cytotoxics) guidelines, which can be found on the internet and are the subject of [SIM 7/2001/25](#).

ACTION BY INSPECTORS

5 Where inspectors encounter cytotoxic drugs they should refer to the guidance provided in the IS. Particular attention should be given to ensuring:

- a suitable and sufficient COSHH assessment has been carried out (IS para 13);
- suitable measures are in place to control exposure (IS paras 15-32);
- there is good supervision and monitoring of equipment used to control exposure (IS paras 33-39);
- health records for staff handling cytotoxic drugs are kept where appropriate (IS paras 40-44);
- protocols are available for dealing with spillages and safely disposing of waste (IS paras 45-51);
- all persons handling cytotoxic drugs have been given sufficient information, instruction and training (IS para 52).

QUERIES

6 Any queries from FOD related to the new guidance or possible enforcement action, should be directed to the Services Sector for health care or the Agriculture and Food Sector for veterinary practice.

Date first issued: 07 September 2003
(FOD/220/1039/03)

J:/Editors/Intranet/operational/ocs/200-299/285/9.doc

