

# STANDARD PRACTICES TO ENSURE SAFE CYTOTOXIC DRUG RECONSTITUTION IN HOSPITAL PHARMACIES: AN INTERNATIONAL REVIEW

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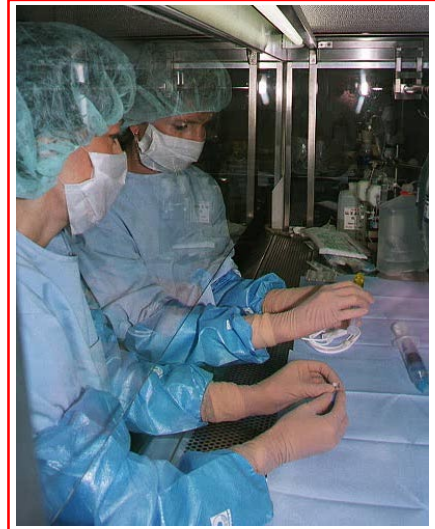
## Background

Cytotoxic Reconstitution Services (CRS) have been developed in hospital pharmacies throughout the world. Their aim has been to reduce the number of persons handling antineoplastic agents, thus diminishing the risks for themselves, the nursing staff and the patients. Recent evidence has suggested that pharmacy staff could be exposed to significant amounts of cytotoxic materials despite normal safety measures<sup>1-5</sup>. The goal of this review was to catalogue the standard practices, guidelines and regulations issued by hospital pharmacy associations, governmental health and safety authorities and medical agencies, concerning the types of safety cabinets recommended in each country and to determine if there was concordance.

## Methods

Nine countries were included in the study: Australia, Canada, France, Germany, New Zealand, Sweden, Switzerland, United Kingdom and the USA. The documents obtained from official sources, either by traditional methods or through internet, concerned four types of safety cabinet:

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|--|---|
| 1) Class 2, Vertical laminar flow cabinets (VLFC). | 3) Rigid negative pressure isolators (RNPI).                  |
| 2) Rigid positive pressure isolators (RPPI).       | 4) Gassed "flexible film" positive pressure isolators (GPPI). |



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## Results

Australia was the first country to have developed Standard Practices for cytotoxic drug reconstitution. VLFC are also allowed.  
*SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments. Australian Journal of Hospital Pharmacy 1999; (2) 29*  
[www.shpa.org.au](http://www.shpa.org.au)

Discussions are underway in the USA concerning the possible use of RNPI and GPPI.  
*AFSCME Health and Safety Fact Sheet. 2001. www.afscme.org/health/faq-cyto.htm*  
*OSHA Technical Manual. 2001. www.osha-slc.gov*

VLFC are the standard in small reconstitution units in France, whereas GPPI are the rule for large scale regional units.  
*Procédures Operatoires Standard. Société Française de Pharmacie Oncologique. March 1998. www.sfpo.com*

New Zealand decided to apply the same Standard Practices as the Society of Hospital Pharmacists of Australia (SHPA).  
*Guidelines for the Safe Handling of Cytotoxic Drugs. Department of Labour. New Zealand. 1997.*

The Canadian Standard Practices are equivalent to those of the USA  
*Guidelines for the Handling of and Disposal of Hazardous Pharmaceuticals. Canadian Society of Hospital Pharmacists 1997. www.cshp.ca*

The consensus in the United Kingdom is for RNPI due to staff protection reasons. VLFC and RPPI are used, but a greater risk of exposure to cytotoxics in the case of accidents is "possible" especially with VLFC<sup>5</sup>.  
*Cytotoxic Drug Preparations and Facilities. 2002. www.marcguidelines.com*

The majority of Swedish hospitals use VLFC but some are converting to RNPI.  
*General Recommendations on the Implementation of the Provisions on Cytostatics and Other Drugs with Enduring Toxic Effects. Swedish National Board of Occupational Safety and Health. 9th December 1999. Published in March 2000.*

Isolators have not been recommended by QuapoS (German Quality Standards). Ergonomic problems have been brought up because of possible ULD (Upper Limb Disease).  
*Quality Standards for the Oncology Pharmacy Service. QuapoS 2000 3rd Edition. Onkopress. D-Oldenburg.*

Only VLFC are directly mentioned in the Swiss guidelines. Isolators of any type can be used if they comply with GMP and the laws governing the security and health of the operators.  
*Directives for Cytotoxic Preparation. 2001 Swiss Society of Public Health, Administration and Hospital Pharmacists. www.gsasa.ch*

## Conclusions

It can be seen that each country has its own Standard Practices and for the moment a consensus has not been reached. Moreover, "the negative pressure isolator controversy" is the subject of intense debate between, on the one hand, the Health and Security Authorities and the Medical Agencies on the other. What should be protected first : the product or the operators? Other solutions include GPPI, but this is a very expensive option, and the possibility of "outsourcing" to the pharmaceutical industry. Discussions should be continued on a global basis to establish world-wide standards for oncology pharmacy services, with the objective to protect both the product and the staff.

✓ A tick in the box indicates the first choice (see individual remarks under each country). During this review, it was found that the environmental air requirements for the production room varied considerably from country to country.

## References

- 1) Antineoplastic hazards. [www.uth.tmc.edu/schools/sph](http://www.uth.tmc.edu/schools/sph)
- 2) Galatowitsch.S. CleanRooms, 13 (10) October 1999.
- 3) Galatowitsch.S. CleanRooms, 13 (11) November 1999.
- 4) Pharm J. 9th January 1999 ; (262) : 56.
- 5) Kiffmeyer TK et al. Pharm J. 9th March 2002; (268) : 331 - 337