

Michigan Department of Licensing & Regulatory Affairs (LARA)
Bureau of Health Care Services
Health Facilities Division
Health Facilities Engineering Section



Interpretive Bulletin: #11-2003	
Subject	Rule Reference
Biological Safety Cabinets (Hoods) Used for Cytotoxic Drug Preparation	1998 Minimum Design Standards for Health Care Facilities in Michigan Section 7.17.F4 & MDCIS Publication "Recommendations for Safe Handling and Disposal of Cytotoxic Drugs"
	Date
	March 5, 2003

Interpretive Bulletins are released by the Health Facilities Engineering Section to clarify sections of the 1998 Michigan Design Standards for Health Care Facilities in Michigan and when research, experience, or technology illustrates present regulations do not adequately address the specific instances or circumstances in the health care environment.

Section 7.17.F4 of the 1998 Minimum Design Standards for Health Care Facilities in Michigan-1998 and MDCIS, Division of Health Facilities & Services publication "Recommendations for Safe Handling and Disposal of Cytotoxic Drugs" require that Cytotoxic Chemotherapy Agents be prepared in a Class II Type B2 biological safety cabinet with 100% of the air exhausted to the outside. These documents were written based upon the best available information at the time. However, the current Occupational Safety & Health Administration Technical Manual, on Controlling Occupational Exposure to Hazardous Drugs allows the use of any Class II, Type B (includes sub-types "B1", "B2" & "B3") or Class III Biological Safety Cabinets in the preparation of cytotoxic drugs. Therefore, to be consistent with other regulatory authorities we will accept a Class II, type B, or Class III Biological Safety Cabinet in the preparation of cytotoxic agents in a licensed healthcare facility.

Note: Class II, Type "B" and Class III biological safety cabinets are the most protective since, by definition, these hoods vent to the outside and do not recirculate air (back into the room). In all cases the approved biological safety cabinet must be installed in accordance with the manufacturer's specifications and may require special features such as pressure monitors, alarms and fan interlocked with the building exhaust so as to shut down the hood in the event of a fan failure.