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The United States (U.S.) Centers for Disease Control (CDC) published a report on August 21, 1987, that emphasized the need for all health care workers to routinely use appropriate barrier precautions when contact with blood or other body fluids of any patient is anticipated.

HEALTH CARE WORKERS TO USE PROTECTIVE BARRIERS

On December 6, 1991, the U.S. Occupational Safety and Health Administration (OSHA) enacted regulations requiring the use of work practice controls and protective clothing, including gloves, to minimize worker exposure to blood-borne pathogens.

Importation of medical gloves rose dramatically from 1986, when less than 1 billion gloves were imported, to 1995 when that number increased to about 15.4 billion. It is anticipated that gloves will be used increasingly to help prevent the transmission of Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other blood-borne pathogens.

The CDC report recommends that health care workers wear medical gloves when:

- touching blood and other body fluids, mucous membranes, or non-intact skin of all patients;
- handling items or surfaces soiled with blood or other body fluids; and
- performing venipuncture and other vascular access procedures.

Because of the emphasis in the CDC recommendations upon gloves as a barrier to HIV, as well as HBV and other blood-and-fluid borne infectious agents, and the need for greater assurance against transmission between patients and health care workers, the Food and Drug Administration

(FDA) believes that gloves worn by health care workers must provide an effective barrier to the transmission of infectious agents. Obviously, this effective barrier can be provided only if medical gloves meet appropriate standards and prevailing guidelines. The FDA, the Agency that regulates medical gloves, has determined that glove defects, such as pinholes, which may not be readily detectable by the users of gloves, can significantly compromise the effectiveness of the barrier and result in patients or health care workers being unnecessarily exposed to infectious agents.

In order to increase the level of public health protection, FDA has taken several actions:

- produced guidance, such as this manual, to aid manufacturers in meeting FDA requirements and improving the quality of medical gloves;
- increased the regulatory controls placed on patient examination gloves to bring them in line with the existing controls for surgical gloves;
- implemented a more effective test method for detecting pinholes and revised the FDA enforcement action levels to correspond with the new test method;
- increased the sampling and testing of gloves;
- sent a letter to manufacturers advising them of allergenic problems with latex devices;
- conducted an International Latex Conference, Baltimore, Maryland, USA, Nov. 5-7, 1992 and conducted seminars on FDA requirements in most glove-producing countries;
- encouraged and supported the American Society for Testing and Materials (ASTM) in modifying existing and developing additional standards for medical gloves;
- encouraged manufacturers to develop gloves with low levels of chemical residues and water-soluble proteins; and
- is now allowing a protein claim in labeling.

The added regulatory controls include premarket notification [or 510(k)] and good manufacturing practices (GMP). The 510(k) submission and clearance process, as well as other regulatory controls, allows FDA to better monitor the introduction of medical gloves into the U.S. market. In addition, meeting GMP requirements will assist in assuring that manufacturers provide an acceptable quality level for medical gloves, thus improving their safety and effectiveness.

Information on the regulatory requirements for patient examination gloves, surgeon's gloves, and some non-medical gloves is contained in this manual. Increased knowledge of your regulatory obligations will result in increased compliance if your company is willing to earnestly apply that knowledge.