The Protectus Medical Safety Syringe and the Federal Mandate

Protectus Medical Devices, Inc., from inception, set forth a firm list of criteria that ***any*** safety syringe development program should consider and address in a final design and, on this basis, designed the Protectus Safety Syringe. This list of "Criteria for Acceptance" addresses the elements specifically intended by the definition of "**Engineering Controls**" stated by The Occupational Safety and Health Administration (OSHA):

- *"An **engineering control** is the use of available technology and devices to isolate or remove hazards from the worker."*

- *"Examples of **engineering controls** include, but are not limited to, puncture-resistant sharps containers, splash guards, mechanical pipetting, and **self-sheathing needles**[1]."*

- *"**Engineering Controls** shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness*[2,3]."

The Protectus Safety Syringe primary design and function patent (U.S. Patent 5,086,086) and its newly granted counterpart (U.S. Patent 7,799,002) specify that a fixed barrier (sheath) shall automatically cover the needle if intentional control of the device is lost at any time during its use, thus making the device **self-sheathing.**

The OSHA "Guideline" was entered into the Federal Register as a mandate in 1991[3]. In a subsequent Federal Register in 2001, OSHA specifically restates this mandate (see Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Injuries; Final Rule 66:5317-5325). The Final Rule amended the "**Engineering Controls**" definition to*:*

- *"**Engineering Controls** means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace*[5]."

The revisions also clarify the important need for employers to select safer needle devices <u>as they become available</u> and to involve employees in identifying and choosing the devices. Specifically, the revised OSHA Bloodborne Pathogens Standard obligates employers to consider safer needle devices when they conduct their annual review of their exposure control plan. These rules/regulations are the exact language used to write both federal and state legislation. To date, nearly all fifty states have also passed such legislation.

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[1] Compliance Assistance Guideline for February 27, 1990 OSHA Instruction CPL 2-2.44B Enforcement Procedures for Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus
[2] Federal Register/Vol. 56 No. 235/ Friday, December 6, 1991/Rules and Regulations
[3] OSHA 29 CFR Part 1910.1030 Bloodborne Pathogens
[4] Ibid.
[5] Ibid.