

Comments Received on the Serious Reportable Events in Healthcare-2011 Update Draft Report

Dec 23 2010 3:26PM	Nancy Levine	CDC			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	<p>- under “additional specifications” – “Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.” Suggest rewording as “Includes, but is not limited to surgical equipment, ventilators, catheters, drains, intravenous tubing and other specialized tubes, infusion pumps, medication vials, syringes, and fingerstick lancing devices.’</p> <p>- under “implementation guidance” – Add second bullet to read “instances in which harm results as a consequence of reuse of single use medications (i.e., single dose vials) or equipment that is intended for use only on individual patients (e.g., syringes)”</p>	Additional Specifications modified to address non-medication related comments. Other SREs, 2A and 4A, address medication-related events.
Dec 3 2010 12:40PM	Kevin Kavanagh	Health Watch USA			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	<p>First what a device is needs to be defined. Is it a complex mechanical item or a simple tube such as an NG (Nasogastric) or ET (Endotracheal) Tube. It depends who defines it FDA vs Webster.</p> <p>Second, the example for subcategory B (misuse), just repeats the first subcategory A (Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.).</p> <p>Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended. As in the previous event, failure to properly clean and maintain a device or misuse of a device that exposes a</p>	<p>Definition of device added to glossary. Suggested addition significantly expands the event and will be considered at next update.</p> <p>Addressed in previous comment.</p>