DEVICE OR MEDICAL/SURGICAL SUPPLY

The following document outlines the subject matter of interest and the resultant information to be collected for the Device or Medical/Surgical Supply event type. The Common Formats contains core and supplemental datasets for Event Reporting – Hospital Version 2.0a. Core data elements are required for event reporting at the local level, by providers, to PSOs and the PSOPPC for national aggregation and analysis. **All line items, or data elements, that are bolded and *italicized* are required for submission to the PSOPPC.** Supplemental data elements may be collected at the local level for additional analysis, and may be reported to PSOs but will not be accepted by the PSOPPC for national aggregation and analysis.

1.0 Definition of Event

1.1 ***A device or supply event or unsafe condition involves a defect, failure, or incorrect use of a device.***

1.1.1 ***Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue) (e.g., joint replacement, implantable pacemaker)***

1.1.2 ***Medical equipment (e.g., walker, hearing aid)***

1.1.3 ***Medical/surgical supply, including disposable product (e.g., incontinence supply)***

1.2 ***Processes of Care***

Device defect or failure, or use error

1.2.1 ***Device defect or failure***

1.2.2 ***Use error***

1.2.3 ***Combination or interaction of device defect or failure and use error***

1.3 Patient Outcomes

The event definition for the “Device or Medical/Surgical Supply” category encompasses incidents, near misses, and unsafe conditions and does not require that a patient outcome be identified.

2.0 Scope of Reporting

Patient safety concerns for the “Device or Medical/Surgical Supply” category include incidents, near misses, and unsafe conditions that occur in a hospital.

3.0 Risk Assessments and Preventive Actions

None specified.

4.0 Circumstances of Event

4.1 ***Descriptive Information***

4.1.1 ***Reuse of a device intended for single use (including use of a reprocessed single-use device)***

4.1.2 ***For implantable device***

4.1.2.1 ***Event prior to time of implantation (e.g., near miss)***

4.1.2.2 ***Event at time of implantation***

4.1.2.2.1 ***Event resulted in removal***

4.1.2.2.2 ***Not removed***

4.1.2.3 ***Event following implantation***

4.1.3 ***Event or unsafe condition also involved a medication or other substance***

4.1.4 ***Device identifiers***

4.1.4.1 ***Unique Device Identifier (UDI)***

4.1.4.2 Name of device, product, software, or medical/surgical supply

4.1.4.3 Name of manufacturer

4.1.4.4 Model number

4.1.4.5 Software version

4.1.4.6 Firmware version

4.1.4.7 Serial number

4.1.4.8 Lot or batch number

4.1.4.9 Other unique product identifier

4.1.4.9.1 Type

4.1.4.9.2 Identifier

4.1.4.10 Expiration date

4.1.4.11 Asset tag

4.2 Risk Factors

None specified.

4.3 Contributing Factors

None specified.