TITLE: SERIOUS ADVERSE EVENTS/SENTINEL EVENTS and MEDICAL DEVICE REPORTING AND MANAGEMENT

POLICY:

New York-Presbyterian Hospital is committed to enhancing quality and patient safety through rigorous analyses of serious adverse events/sentinel events ("SAE/SE"). Critical elements of this commitment include timely identification, reporting, and evaluation of unanticipated adverse patient outcomes, identification of risk reduction and improvement strategies and implementation of corrective actions as indicated.

The regulatory agencies to which the Hospital must report certain SAE/SEs include, but are not limited to:

- The New York State Department of Health (NYSDOH) into its New York Patient Occurrence Reporting and Tracking System (NYPORTS) program;
- The New York State Department of Health – Wadsworth Center Blood and Tissue Resource Program, related to any blood or tissue serious events;
  The New York State Justice Center (JC), for the Protection of People with Special Needs;
- The New York State Office of Mental Hygiene (NYSOMH);
- The New York City Department of Health – Bureau of Environmental Radiation Protection (BERP)
- The Centers for Medicare and Medicaid Services ("CMS");
- The Joint Commission (TJC) through its surveillance program;
- The Organ Procurement and Transplantation Network (OPTN), and the End-stage Renal Disease (ESRD) Network for any transplant related serious event.
- The U.S. Food and Drug Administration (FDA)

PURPOSE:

The purpose of this policy is to define SAE/SEs that require root cause analyses, describe the mechanism for reporting SAE/SEs, and to set forth the process for conducting root cause analyses in accordance with regulatory (NYC, NYS and Federal) requirements.

APPLICABILITY:

All hospital, medical and professional staff

Serious Adverse/Sentinel Event Required reporting:

According to the DOH, much of what is reportable reflects adverse events that are known to occur with certain frequency and in no way implies that an error has been made or particular blame is to be assigned. Towards that end, there are certain NYPORTS that are reportable to DOH for the purposes of tracking and trending. There are other NYPORTS which in addition to being part of the NYPORTS database require a thorough investigation and in some cases require the Hospital to conduct a Root Cause Analysis (RCA). Notification to DOH is done within 24 hours of awareness by Patient Services Administration.

Therefore each of the occurrences must be reported immediately by staff to:

- Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM or the Administrator-On-Call

and

- entered into the Hospital's on-line medical event reporting system in accordance with the hospital's procedure

Definitions:

Serious Adverse Event / Sentinel Event:

A serious adverse event / sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, i.e. a near miss

Root Cause Analysis:

Root cause analysis is a thorough process for identifying the contributory factors that underlie variation in performance, and result in a SAE/SE or near miss. A root cause analysis focuses primarily on systems and processes, not on individual performance. It identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines that no such improvement opportunities exist.

The root cause analysis and action plan must be completed in a timely manner in accordance with various regulatory requirements. The time frame for completion required by: NYSDOH-NYPORTS is 30 days from submission of the event into the system and for the Joint Commission is within 45 business days of the event or of becoming aware of the event. Any exceptions must be vetted through Patient Services Administration. Approval from the specific agency would need to be sought. An RCA is not only performed for situations that are required by regulatory entities but may also be done as mandated by the GEM Committee (see below).

Global Event Management Committee

The Global Event Management ("GEM") Committee is a component of the Hospital's quality and patient safety program. It is a multidisciplinary group that is scheduled to meet twice weekly to review reported possible SAE/SEs. The GEM Committee is responsible for determining whether a SAE/SE is reportable to an

outside regulatory agency, and whether or not a root cause analysis ("RCA") is required. Members of the GEM Committee participate in RCAs.

The standing members of the GEM Committee include the following:

Vice President, Patient Services Administration
Vice President/MD, Quality and Patient Safety
Vice President, Risk Management and Associate General Counsel or designee
Associate Chief Quality Officers/MD (6)
Associate Chief Medical Officer
Corporate Director, Patient Services Regulatory Affairs
Directors Patient Services Administration (3)
Director Patient Services / Quality-Behavioral Health, NYP/WD
Director, Patient Safety & Significant Events
Associate General Counsel (3)
Directors of Nursing, NYP/CU, WC, MSCH, TAH, WD, LM
Director of Nursing – Quality (Corporate)
Director of Nursing – Quality (3)
Manager, Significant Events Reporting (3)
Manager, Quality/Behavioral Health, NYP/CU, MSCH, TAH
Manager, Patient Services Regulatory Affairs
Ad Hoc Representatives from departments as indicated

PROCEDURE:

1. Identification of SAEs/SEs:

a. New York State Department Of Health and The Joint Commission

Listing of SAE Categories:

Attachment "A" lists the occurrences that must be reported immediately to Patient Services Administration or the Administrator-On- Call and entered into the Hospital's on-line medical event reporting system in accordance with the procedures discussed in Section 2.

Note: Level 1 events (NYPORTS) require a Root Cause Analysis. Note, the list of SAE/SEs requiring root cause analyses is not all-inclusive. If an occurrence does not fit one of the descriptions, but is a serious event, or near miss, it may still be reported to DOH and undergo root cause analysis; such determination shall be made by the Global Event Management ("GEM") Committee.

b. The Justice Center (JC) and NYS Office of Mental Health (OMH) reporting:

Attachment B lists the incidents determined by the New York State Office of Mental Health (OMH) to be reportable as follows:

1. **"Reportable Incidents"** are required to be reported to the Justice Center and/or OMH. These include Allegations of Abuse, and Significant Incidents. Significant incident means a reportable incident, other than an incident of abuse or neglect, that because of its severity or the sensitivity of the situation may result in, or has the reasonably foreseeable potential to result in, harm to the health, safety or welfare of a patient.

2. **"Reviewable Incidents"** Reviewable incident means adverse events that do not result in injury to patients that requires medical intervention or treatment beyond first aid, or which do not occur on program premises or under the actual or intended supervision of staff, but which must be internally reviewed by providers.

3. Death of a patient enrolled in an OMH or OASAS program must be reported to the Death Reporting line (855-373-2124). An OMH NIMRS form must be completed within 5 business days of this call. For OASAS programs, a required form must be completed and submitted. If there is any reason to suspect that the death was due to neglect or abuse, a separate report must be made to the Vulnerable Persons Central Register (VPCR) (855-373-2122).

4. Each of the occurrences must be reported immediately to Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM or the Administrator-On-Call and entered into the Hospital's on-line medical event reporting system in accordance with the procedures discussed in Section 2.

c. Transplant Service:

As applied to transplant programs, examples of adverse events include, but are not limited to:

- Death of a living donor, within 2 years following organ donation
- Serious medical complications or death as a result of living donation of an organ
- Aborted living donor organ recovery after administration of general anesthesia
- A living liver donor is listed on the liver wait list within 2 years after organ donation
- A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation
- A living donor organ is recovered but not transplanted
- A living donor organ is recovered and transplanted into someone other than the intended recipient
- Unintentional transplantation of organs of mismatched blood types
- Transplantation of organs to unintended recipients
- Unintended transmission of infectious disease and or malignancy to a recipient

Each transplant program administrator is responsible for notification of any serious adverse event to Patient Services Administration or the Administrator-On-Call and entered into the Hospital's on-line medical event reporting system within 24 hours of awareness of the event.

External reporting of events to United Network for Organ Sharing (UNOS), Organ Procurement and Transplantation Network (OPTN), End-stage Renal Disease Network (ESRD), the DOH and other regulatory agencies as indicated will be jointly determined by Transplant Service leadership, and the Global Events Management (GEM) Committee. The need to conduct a root cause analysis will be determined in accordance with regulation and or by the GEM Committee. If the event occurred within the context of an approved clinical research study or involves an investigational medication or device, the appropriate Institutional Review Board (IRB) is notified by the Attending Physician and/or the protocol's Primary Investigator.

d. The U.S. Food and Drug Administration

In accordance with FDA regulations (see Attachment C), the Hospital complies with medical device reporting requirements.

(1) Reports of death: The Hospital will submit a report to the FDA as soon as practicable but no more than 10 work days after the day that it becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a Hospital patient. The Hospital will also submit the report to the device manufacturer, if known. The Hospital must submit the information required by, and in the form required by, applicable FDA regulations.

(2) Reports of serious injury: The Hospital will submit a report to the manufacturer of the device no later than 10 work days after the day that it becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, the Hospital must submit the report to the FDA containing the information required by, and in the form required by, applicable FDA regulations.

2. **Internal reporting of SAE/SE:**

Whenever any member of the Hospital's medical or nursing staff or any other Hospital employee becomes aware of any event or occurrence which may be a SAE/SE, that person should immediately:

i. Notify Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM as indicated below for each campus:

AND

ii. Enter the event into the Hospital's on-line medical event reporting system

NYP/Columbia University Medical Center and Morgan Stanley Children's Hospital

- Patient Services Administration at 305-5904, Monday – Friday, 9 AM – 5 PM (excluding holidays);
- All other times contact the Administrator-on-Call through the page operator.

NYP/Allen Hospital

- Patient Services Administration at 932-4321, Monday – Friday, 9 AM – 5 PM (excluding holidays);
- All other times contact the Administrator-on-Call through the page operator.

NYP/Weill Cornell Medical Center

- Patient Services Administration at 746-4293, Monday – Friday, 9 AM – 5 PM (excluding holidays);
- All other times contact the Administrator-on-Call through the page operator.

NYP/Westchester Division

- Patient Services Administration at 914-997-5920, Monday – Friday, 9 AM – 5 PM (excluding holidays);
- All other times contact the Doctor-on-Call at 914-682-9100.

NYP/Lower Manhattan

- Patient Services Administration at 212 312-5034, Monday – Friday, 9 AM – 5 PM (excluding holidays);
- All other times contact the On-Call Administrator Nursing Supervisor.

3. **Notification and Initial Hospital Investigation:**

Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM will conduct an initial investigation of the event and will promptly report the potential

SAE/SE to the Gem Committee and as appropriate, to the senior administration of the Hospital. Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM in consultation with the GEM Committee will determine whether the event requires an RCA and reportability to regulatory agencies, including but not limited to, NYS DOH, Justice Center, New York State Office of Mental Hygiene, and CMS. All notifications regarding an SAE are made by Patient Services Administration at NYP/CU/WC/TAH/MSCH/WD and LM.

4. **Designation of Team to Assess Variation in Performance:**

The GEM Committee will review the event and identify team(s), services and/or clinical departments appropriate to conduct quality reviews and participate in a root cause analysis. Additional members of the team may be designated as the root cause analysis progresses.

The root cause analysis team is responsible for reviewing the SAE/SE for root cause(s) as well as assisting departments in formulating, as needed, a plan(s) of action and mechanism(s) to monitor and measure the effectiveness of such action plan(s). This shall be done in consultation with the departmental Quality Chair, Clinical Service Chief and/or

Administrator. Quality and Patient Safety will assist in the process of conducting the review and will be responsible for the final preparation of the root cause analysis in the appropriate format.

5. **Internal Reporting:**

SAE/SE's and corresponding root cause analyses including findings and recommendations will be reported through the Hospital's Quality and Patient Safety Program. Root cause analysis findings and recommendations will be approved by the GEM Committee. A summary report will also be presented to the Executive Committees of the Medical Board Quality and Performance Committee and Board of Trustees Quality and Performance Improvement Committee's regular meetings. The full written report of the root cause analysis will be provided to the Medical Board/QPI Committee, BOT/QPI Committee, and senior leadership as requested.

6. **Implementing and Monitoring of RCA – Action Plans:**

The Clinical Service Chief(s) and/or Administrator(s) of the involved department(s) is responsible for the following: implementing any recommendations identified by the root cause analysis, including without limitation, educating staff within their departments as to all system changes and improvements, monitoring of compliance with and effectiveness of the plan as well as reporting the results of that monitoring through the Quality and Performance/Patient Safety Program across all campuses performing like procedures/processes.

The Quality and Patient Safety Department shall review the status of all plans of action for completeness. A summary report will be presented to the GEM Committee periodically and the Board of Trustee Quality and Performance Improvement Committee at least on an annual basis and as requested.

7. **Maintenance of Documentation:**

A copy of the final root cause analysis and supporting documentation will be maintained in each campus specific Patient Services Administration office, NYP/CU/WC/TAH/MSCH/WD and LM and the Quality and Patient Safety department.

8. **Confidentiality:**

Oral or written communications, reports, memoranda, recommendations, or information created by or for, any person, body, department, or committee regarding quality reviews and RCA's of a SAE/SE are privileged and shall be kept strictly confidential. Such information should be clearly identified as Q.A. Data Protected by P.H.L. The information is to be used to improve patient care processes or systems at New York-Presbyterian Hospital. Questions concerning the use or release of information concerning SAE/SE's should be directed to the Office of Legal Affairs/Risk Management.

RESPONSIBILITY:

Patient Services Administration
Quality and Patient Safety
Office of Legal Affairs/Risk Management

REFERENCES:

- The Joint Commission – Accreditation Manual – Sentinel Events – January & June 2015
- NYSDOH NYPORTS / DOH Wadsworth – Sentinel Events – July 2013
- Justice Center & NYS OMH – NIMRS Incident Types and Severity Ratings June 2013
- UNOS – Transplant Regulations
- FDA – Medical Device Reporting 21 CFR 803

POLICY DATES:

Revised: October 1999
Revised: May 2002 (Previously Policy #S105)
Revised: August 2005; March 2006; October 2008; October 2009; November 2010; April 2011; April 2012; November 2012; December 2012
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Revised: February 2014; May 2015**,** July 2015, **December 2015**

APPROVAL:

Medical Board: November 2008, November 2010, May 2011; May 2012; February 2013, April 2014, August 2015; February 2016

[Note: Policy I125 *Incident Reporting to The New York State Department of Health (NYSDOH)* has been merged with the current Policy S120 *Serious Adverse Events/Sentinel Events*]

Attachment A – NYP Reviewable Events – NYS-DOH and TJC:

Serious Adverse / Sentinel Events	**Applies to:**	
Event Category ***Root Cause Analysis (RCA) Required**	**NYS DOH**	**The Joint Commission**
Abduction of a patient of any age*	X	X
Death or serious injury, patient or staff, associated with a burn*	X	
Death, near death or serious injury, patient, associated with a fall*	X	
Death or serious injury, maternal, associated with labor and delivery. Includes events that occur within 42 days post-delivery *	X	X
Death or serious injury, neonate, associated with labor and delivery*	X	
Death, full-term infant (unanticipated)*	X	X
Death or serious injury, patient, associated with a medication error: wrong patient, drug, dose, time, rate, preparation, route of administration or omissions*	X	
Death, patient, unexpected – intra-operative or immediately post-operative/post procedure (ASA Class 1 or 1E patient)*	X	
Death or serious injury, patient or staff, resulting from a physical assault*	X	
Death or serious injury, patient, associated with patient elopement*	X	
Death or serious injury, patient associated with the use or function of a device (includes user error)*	X	
Death or serious injury, patient, associated with unsafe administration of blood products (Reported to DOH – Wadsworth Center Blood Resources Program)*	X	
Death or serious injury resulting from the irretrievable biologic specimen*	X	
Death or serious injury associated from failure to follow up or communicate lab, pathology, or radiological test results*	X	
Death or serious injury of patient or staff associated with the introduction of a metallic object into the MRI area*	X	
Death or serious injury in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards*	X	

Serious Adverse / Sentinel Events	**Applies to:**	
Event Category ***Root Cause Analysis (RCA) Required**	**NYS DOH**	**The Joint Commission**
Death or serious injury associated with the use of physical restraints or bedrails while being for in a healthcare setting*	X	
Disaster, **external,** outside the control of the hospital that effects facility operation	X	
Disaster, **internal**, e.g. Hospital fire or other internal disaster, disrupting patient care or causing harm to patients or staff	X	
Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person ("individuals who do not have "decision-making capacity" e.g. includes newborns, minors, adults with Alzheimer's Disease)*	X	X
Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care*		X
Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)*	X	X
Misadministration of radiation or radioactive material (prolonged fluoroscopy with cumulative dose >1,500 rad to a single filed or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose)	X	X
Poisoning occurring within the hospital	X	
Rape, assault (leading to death, permanent harm or severe temporary harm), or homicide of any **patient or staff member** receiving care, treatment, and services while on site at the hospital*	X	X
Rape, assault (leading to death, permanent harm or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital*		X
Sever maternal morbidity is care that is unexpected and not directly related to the condition of the patient on admission, and that results in admission to the intensive care unit(ICU) and/or transfusion of 4 or more units of packed blood cells(PRBC)*,		X
Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)		X

Serious Adverse / Sentinel Events	**Applies to:**	
Event Category ***Root Cause Analysis (RCA) Required**	**NYS DOH**	**The Joint Commission**
Sexual abuse / Sexual assault on a patient or staff member within hospital/on grounds*	X	
Strike by hospital staff	X	
Suicide of any patient, all attempted suicides, or self-harm that results in serious injury while being cared for in a healthcare setting*	X	
Surgical or other non-surgical invasive procedure / treatment on the wrong patient, body part or site not consistent with documented procedural/surgical plan for patient: wrong site/level/side/digit, or wrong procedure*	X	X
Termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel	X	
Unintended retention of a foreign body*	X	X

Attachment B – NYP Reviewable and/or Reportable Events– New York State Office of Mental Hygiene(OMH) and/or the Justice Center (JC):

NIMRS Serious / Sentinel Adverse Event Category ***Root Cause Analysis (RCA) Required**
Adverse drug reaction, severe*
Allegation of staff abuse or neglect (physical, psychological, sexual, medication, or neglect)*
Assault or physical attack using force or violence by a person other than a custodian which client is either victim or aggressor which results in injury/harm
Child missing from staff supervision (outpatient program)*
Choking event
Contraband, possession of
Crimes (Homicide attempt, homicide by client, narcotics sale or possession, robbery, possession of a deadly weapon)*
Crimes, other
Death of a client (natural causes, homicide, suicide, accidental, lack of appropriate treatment, restraint or seclusion related, unexplained) inpatient and/or outpatient within 30 days of discharge*
Deliberate inappropriate use of restraints*
Falls with Harm or Risk level 2 or 3
Fights physical altercations between 2 or more patients in which there is no clear aggressor/victim with Harm or Risk level 2 or 3
Fire Setting
Inappropriate sexual behavior, children and adolescents
Injury, accidental/unknown origin
Medication Error in prescribing, dispensing, or administering a drug
Missing patient (inpatient)
Missing subject of AOT Court Order* Mistreatment: Unauthorized Restraints or Seclusion Intentional improper Administration of Medication

NIMRS Serious / Sentinel Adverse Event Category ***Root Cause Analysis (RCA) Required**
Misappropriation of patient resources
Obstruction of reports of reportable incidents
Self-abuse not intended to result in death that results in serious injury or harm
Sexual assault (rape or non-consensual sodomy, other)*
Sexual contact or activity, child*
Sexual contact, adult (non-consensual or consensual)
Suicide Attempt*
Verbal aggression by patients
Other Incident (not listed above, which has or may have an adverse effect on the life, health or welfare of the client)

Attachment C – NYP Reviewable and/or Reportable Events– The U.S. Food and Drug Administration (FDA):
Hospital's FDA Medical Device Reporting (MDR) Requirements as per 21 CFR 803, Subpart C—User Facility Reporting Requirements

(a)§803.30: The Hospital must submit reports of death to the manufacturer or to the FDA, or both, as specified below:

(1)Report of deaths must be submitted to the FDA as soon as practicable but no more than 10 work days after the day of aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a patient's death. The hospital must also submit a **Report of death** to the device manufacturer, if known. **Reports submitted** must include the information required by §803.32. Reports sent to the Agency must be submitted in accordance with the requirements of §803.12(b).

(2)Reports of serious injury must be submitted to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient. If the manufacturer is not known, the report must be submitted to the FDA. **Reports submitted** must include the information required by §803.32. Reports sent to the Agency must be submitted in accordance with the requirements of §803.12 (b).

(b)Reports submitted must include all information required in this subpart C that is **"reasonably known"** to the Hospital. The FDA considers **"reasonably known"** information to include information found in documents possessed by the hospital and any information that becomes available as a result of reasonable follow up within our facility/hospital. The hospital is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably know by the hospital.

FDA Medical Device Reporting (MDR) Requirements as per §803.32 regarding what information must be submit in the hospital's individual adverse event reports:

Reports must include information reasonably known to the hospital, as described in §803.30(b). These types of information correspond generally to the elements of Form FDA 3500A. See below

a) Patient information (Form FDA 3500A, Block A). Must submit the following:
(1) Patient name or other identifier;
(2) Patient age at the time of event, or date of birth;
(3) Patient gender; and
(4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). The Hospital must submit the following:
(1) Identification of adverse event or product problem;
(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An

outcome is considered a serious injury if it is:
(i) A life-threatening injury or illness;
(ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
(iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
(3) Date of event;
(4) Date of this report;
(**5)** Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
(6) Description of relevant tests, including dates and laboratory data; and
(7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form FDA 3500A, Block D). The Hospital must submit the following:
(1) Brand name**;**
(2) Product Code, if known, and Common Device Name;
(3) Manufacturer name, city, and state;
(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;
(5) Operator of the device (health professional, lay user/patient, other); **(6)**Date of device implantation (month, day, year), if applicable;
(7) Date of device explantation (month, day, year), if applicable;
(8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)
(9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;
(10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and
(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form FDA 3500A, Block E). The hospital reporter must submit the following:
(1) Name, address, and telephone number of the reporter who initially provided information to the hospital, or to the manufacturer or distributor;
(2) Whether the initial reporter is a health professional;
(3) Occupation; and
(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) User facility information (Form FDA 3500A, Block F). The hospital reporter must submit the following:
(1) An indication that this is a user facility report (by marking the user facility box on the form);
(2) Our user facility number;
(3) Our Hospitals address;
(4) Our Hospitals contact person;
(5) Our contact person's telephone number;
(6) Date the hospital's reporter became aware of the event (month, day, year);

(7) Type of report (initial or followup); if it is a followup, our reporter must include the report number of the initial report;
(8) Date of the report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to the "MedWatch Medical Device Reporting Code Instructions");
(11) Whether a report was sent to FDA and the date it was sent (month, day, year);
(12) Location where the event occurred;
(13) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer's name and address, if available.

Hospital's FDA Medical Device Reporting (MDR) Requirements regarding what must be included in the facility's/hospital's required annual report as per §803.33.

(a) An annual report must be submitted by the hospital on Form FDA 3419 each year **by January 1**. The form can be obtained from the following sources:
(**1) On the Internet at**:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080796.pdf
or
(2) From the: Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993-0002,
by email: DICE@fda.hhs.gov, **FAX:** 301-847-8149, or **telephone:** 800-638-2041

(b) The hospital's annual report **must be clearly identify** as such. The hospital's annual report must be **submitted to**: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Our annual report must include:
(1) Our hospital's **CMS provider number** used for medical device reports, or the number assigned by the FDA for reporting purposes in accordance with §803.3; **(2)** Reporting year;
(3) The hospital's name and complete address;
(4) Total number of reports attached or summarized;
(5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890-2011-0001 through 1000);
(6) Name, position title, and complete address of the individual designated as our Hospital's contact person responsible for FDA reporting and identify whether that person is a new contact for the hospital; and
(7) Information for each reportable event that occurred during the annual reporting period including:
(i) Report number;
(ii) Name and address of the device manufacturer;
(iii) Device brand name and common name;
(iv) Product model, catalog, serial, and lot number and unique device identifier (UDI) that appears on the device label or on the device package;
(v) A brief description of the event reported to the manufacturer and/or the FDA; and
(vi) Where the report was submitted, i.e., to the manufacturer, importer, or FDA.

(c) In lieu of submitting the information in paragraph (b)(7) of this section, our facility/hospital may submit a copy of each medical device report that was submitted to the manufacturers and/or to the FDA during the reporting period.

(d) If our facility/hospital did not submit any medical device reports to manufacturers or the FDA during the time period, the facility/hospital does not need to submit an annual report.