CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050093	A. BUILDING _____ B. WING _____	01/13/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Saint Agnes Medical Center	1303 E Herndon Ave, Fresno, CA 93720-3309 FRESNO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00261250 - Substantiated Representing the Department of Public Health: Surveyor ID # 22968, HFES The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Health and Safety code Section 1279.1(c): "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made." The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects		1.Immediate discussion regarding this issue was done with the surgical teams in all locations, to determine the frequency of practice of abdominal "packing" with blue towels. A request that white x-ray detectable towels be ordered and shipped over night. A. Responsibility: Interim Director of Surgical Services, Medical Director of Peri-operative Services and Surgical Services Administration. 2. Incident was reviewed by Risk Management, and the Patient Safety Officer and forwarded to the Chief Medical Officer, the Medical Director of Peri-operative Services and Hospital Administration. POC ACCEPTABLE YES X NO ☐ Reviewed By: _____ Name Fax _____ Original X Facility Notified Name: Karen Newton Date: originals accepted 5/8/12 Time: _____ Notified By: _____ Name	03/02/2011 03/02/2011

Event ID:BN0211 8/10/2012 3:10:55PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Nancy Hollingsworth | TITLE: CEO | (X6) DATE: 4-11-12

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	Continued From page 1 intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. Deficiency Constitutes Immediate Jeopardy Title 22 Surgical Service General Requirements 70223(b)(2) (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Based on staff interview, clinical record and administrative document review, the hospital failed to implement Surgical Services Policy and Procedure: Counts of Instruments, Sharps, Sponges when the surgery for Patient 1 on [redacted]10 did not reflect the use and count for one surgical Operating Room (OR) towel. The failure to not follow hospital surgical policies and procedures resulted in Patient 1 suffering a small bowel obstruction, additional hospitalization, subsequent additional surgery with the OR towel identified as a retained foreign object and preventable pain, injury and harm. Findings:		3. Incident was reported to California Department of Public Health 4.The incident was discussed daily in surgery report with a review of what a "count" must look like. All staff was reminded that any deviation from count policy must be reported immediately to Surgical Services Administration. Current policy review and revision started. A. Responsibility: Interim Director of Surgical Services, Medical Director of Peri-operative Services, Surgery Clinical Instructor. 5. Speciality towels displayed and discussed in the morning surgery report with staff. Staff reminded that under NO circumstances will non x-ray detectable items be placed in any incision or body orifice. Supply Coordinator worked with each surgical location, including OB, to determine a location for a minimal supply of towels on each location. A. Responsibility: Interim Director of Surgical Services, Medical Director of Peri-operative Services, Surgery Supplies Coordinator and Surgical Services Administration.	03/04/2011 03/04/2011 03/07/2011

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Nancy Hellmuth	CEO	4-11-12

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	Continued From page 2 The clinical record for Patient 1 was reviewed for hospitalizations and surgeries. Patient 1 was admitted on [redacted]10 through the Emergency Department (ED) and treated by MD 1. The Discharge Summary (dictated by MD 1) documented the hospital admission date as [redacted]10 and the discharge date as [redacted]10. The narrative summary indicated Patient 1 "... presented to the emergency room with a three day history of abdominal pain ... and was noted to have generalized tenderness...The patient clinically had a perforated sigmoid diverticulitis (the wall of the lower intestines breaks and causes serious illness) and was admitted to the hospital for further management...The patient was taken to surgery on the day of admission, when a perforated sigmoid diverticulitis (serious infection of the intestines) was excised (taken out) and Hartmann procedure (the end part of the lower intestines is taken out and the rectum is closed. The end part of the intestines is brought out to the skin) and a pouch was performed..." The Operative Report (dictated by MD 1) for [redacted]10 surgery indicated the pre-operative diagnosis as possible perforated bowel with a pelvic abscess and small bowel obstruction (serious infection of the intestines); the post-operative (after surgery) diagnosis as sigmoid diverticulitis (inflammation of the lower intestines), pelvic abscess (infection) and small bowel obstruction (blocked intestines) for basically adhesions (scar tissue) to the pelvic abscess; the operative procedures as exploratory laparotomy (surgery to the abdomen to discover the problem), drainage of		6. Radiopaque towels were added to the facility's electronic ordering system, and given an item number to facilitate reordering. The items are ordered in packs of four sterile towels, 17 x 27 " in size. The item was also added to the "Physician Preference" cards, as a prompt for the circulator nurse to make sure the radiopaque towels would be available for surgeons as part of their normal surgical supplies. A. Responsibility: Interim Director of Surgical Services, Medical Director of Peri-operative Services, Surgery Supplies Coordinator, Distribution System Administrator, Surgical Team Leaders and Services Administration. 7. The "Counts of Instruments, Sharps, Sponges" policy(C-8) was revised to read; All items that could conceivably be lost in a patient during surgery will be counted. This includes but is not limited to: A. the radiopaque disposable OR towel A. Responsibility: Interim Director of Surgical Services,Medical Director of Peri-operative Services, Clinical Practice Council/Instructor and Chief Nursing Officer.	03/09/2011 03/18/2011

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	Continued From page 3 the pelvic abscess, lysis (separation) of the small bowel from the pelvic abscess and sigmoid colectomy (taking out of a part of the large intestines), proximal colostomy and Hartmann procedure. The operative report by MD 1 further documented "... The patient tolerated the procedure well, went to the recovery room in stable condition..." The Intraoperative Record for the [redacted]/10 surgery was reviewed and indicated on page 4 (of 7) that the Wound Closure and Final counts were correct and verified by the scrub nurse and circulating nurse for each of the counts. [redacted] months after surgery on [redacted]/11, Patient 1 presented to the hospital ED complaining of nausea, vomiting and abdominal pain. Patient 1 was admitted with a diagnosis of rule out small bowel obstruction. She was hospitalized for 5 days and discharged on [redacted]/11. No surgery was performed. Treatment during this hospitalization was limited to intravenous (within the blood vessels) fluids and medications. MD 1 dictated in the Discharge Summary "... (Patient 1) became very comfortable ... eating a regular diet and having normal colostomy function. She will be followed by her primary care physician." Patient 1 was seen in the hospital ED (Emergency Department) on [redacted]/11 for symptoms of nausea, vomiting, abdominal pain and possible small bowel obstruction. Patient 1 was admitted to the Medical-Surgical floor of the hospital on [redacted]/11 and was treated by MD 2. MD 2 performed surgery		8. The same policy "Counts of Instruments, Sharps, Sponges" policy (C-12) was further revised to incorporate Trinity Health Care safety initiative, a national safety project for the prevention of retained surgical items, "NoThing Left Behind" and the "Sponge Accounting System" (SAS). This program is designed to give clinicians and surgeons a visual accounting of where the sponges are that are used for surgery and also to enhance communication between all personnel involved in a surgery. The goal of this program is for every Trinity Hospital to have ZERO retained sponges once the program has started. A. Responsibility: Chief Medical Officer Trinity Health, Trinity Peri-operative Steering Committee, Peri-operative Operations/Technical Team, Peri-operative Collaborative, Interim Director of Surgical Services, Medical Director of Peri-operative Services, Clinical Practice Council/Instructor and Chief Nursing Officer.	01/21/2012

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Nancy Hellmgarth	CEO	4-11-12

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	Continued From page 4 on Patient 1 on [redacted]11 to treat the small bowel obstruction 4 months later from the original surgery. The hospital Discharge Summary (dictated by MD 2) indicated the following: "The patient (Patient 1) was admitted and given bowel rest and intravenous fluids. Her intestinal obstruction did not resolve with no operative management and CT scan (specialized three dimensional x-ray) showed a mass in the left abdomen that appeared to be present on the CT scan that was done during her last hospital admission in [redacted](2011). She was explored and found to have a high-grade mechanical small bowel obstruction associated with severe peritoneal adhesions. She underwent small bowel resection and anastomosis, and the surgical specimen was noted to have a surgical towel at the point of obstruction". The principal diagnosis was documented as "small bowel obstruction" with other diagnoses listed included "complications of foreign (body)..." The Operative Report dictated by MD 2 indicated the following: Date of service was [redacted]11. The Pre-operative diagnosis was listed as "small bowel obstruction". The post-operative diagnosis was listed as "small bowel obstruction secondary to foreign body." The operative procedure was listed as "small bowel resection and anastomosis" (part of the upper intestines is taken out and the two ends are put back together). The Description of Procedure indicated "...We observed that there was distal (toward the bottom) collapsed small bowel and proximal (toward the head) dilated (bloated) small bowel. The point of obstruction was in the left		9. The Medical Director of Perioperative Services sent a letter to all the physician members of the Department of Surgery and OB/Gyn. The letter was regarding a clarification of the policy an procedure regarding objects placed intracorporeally during the course of an operation. The policy is, and will be going forward, that only objects which are counted and radiopaque can be placed intracorporeally Responsibility: The Chief Medical Officer and Medical Director of Peri-operative Services. 10. Surgical staff were interviewed by the Patient Safety Officer regarding the event and circumstances leading up to the event in preparation of a Root Cause Analysis. 11. A Root Cause Analysis was conducted and included surgeons, OR nursing staff OR Clinical educator, Hospital Administration, Medical Director and Interim Director of Peri-operative Services. An Action Plan was developed with five action items. Responsibility: Chief Executive Officer, Patient Safety Officer, Director of Risk Management, Interim Director of Peri-operative Services	03/14/2011 03/16/2011 03/21/2011

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	Continued From page 5 mid abdomen where there was an area of small bowel with severe dilatation associated with collapsed distal small bowel. We lysed fairly severe peritoneal (inside wall of the abdomen) adhesions (scar tissue) and then it appeared that the best way to restore intestinal continuity was to do small bowel resection and anastomosis...On the back table, I opened the small bowel to see what was obstructing it and saw that it contained a foreign body: a surgical towel. We sent the small bowel and the foreign body in formalin (preservative liquid) to the Department of Pathology as a specimen..." The Pathology Report was completed on [redacted]11 and contained the following: The tissue removed was listed as "... 1. Incisional pus, sent for microbiology study; 2. Obstructed small bowel with foreign body. .." Page 4 of the report contained the following as an addendum: "This addendum is to document additional information from (MD 2). Per (MD 2), this blue towel came with the specimen is truly foreign body removed from the patient's (Patient 1's) abdomen..." On 1/5/12 at 2:15 p.m., during an interview, Director of Accreditation (Dir Acc) acknowledged that the hospital internal investigation confirmed the OR towel found in Patient 1 during the [redacted]11 surgery was placed during the surgery on [redacted]10. Dir Acc confirmed the standard of practice and expectation of the hospital was to perform counts of surgical items prior to the closure of an open surgical site. Dir Acc explained that that the OR towel was usually not a routine part of the count and would have had to be especially requested from the		12. Action item #1: Improve communication w/staff and OR leadership by sharing information related to reported incidents, SRE's and staff perceptions at daily huddles and monthly staff meetings. Include:)Incident report summary trends 2) AHRQ Culture of Safety Survey Results 3) Emphasis on ALL staff to reporting issues (licensed & non-licensed) 4) Reporting all concerns (practice and behavior) 13. Measures of Effectiveness for Action Item #1: A. OR/CVOR staff meeting had an extensive discussion regarding the importance of incident reporting for both positive and negative situations. When an incident report must be completed and the importance of patient safety. B. Video, Safety as a System, by Bryan Sexton and Culture of Safety results specific to surgical services were shared with all staff. C. Ongoing monitoring of incident reports on a daily basis for patient issues is done and reported back to Surgical Services in a monthly report	03/21/2011 03/25/2011 03/25/2011 03/2008

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	Continued From page 6 physician to scrub nurse in order for the OR towel to be counted. in this case the OR towel was not considered part of the count and was missed, because the intraoperative record documented counts as correct. On 1/5/12 at 4 p.m., during a concurrent interview, RN 2 and Scrub Tech 1 stated they both were relief staff for the surgery of Patient 1 on [redacted]10. Neither could say whether or not an OR towel was requested by the physician for use in the surgery. The Scrub Tech stated her relief began while the MD 1 was closing the abdominal surgical site. RN 2 and Scrub Tech 1 confirmed that if the OR towel was requested for use in the surgical site then there would be a manual mark on the white board of the OR room. The white board was described as a writing board to document the surgical site items that were required to be counted and correct prior to the closure of the surgical site. RN 2 and Scrub Tech 1 confirmed that the OR towel was an item not routinely used in surgical sites. In addition, because of the OR towel not being radio opaque, the importance of communicating the use of the OR towel between the surgeon and scrub tech was important in order to count the item at the end of surgery. Both acknowledged that this was not done during this surgery. On 1/13/12 at 8 a.m., during an interview, MD 2 stated he was the primary surgeon for Patient 1 during the [redacted]11 surgery. MD 2 stated he became involved because MD 1 was not available. MD 2 confirmed his findings of the surgery on Patient 1; namely, that he found an area of the small		14. Action Item #2: Revise the Count policy to include: use and count of radio opaque towels 15. Measures of Effectiveness for Action Item #2: A. Count policy revision for Counts of Instruments,Sharps,Sponges" policy(C-12 was completed and signed. -Literary References included: 1. AORN Standards, Recommended Practices & Guidelines 2. Alexander's Care of the Patient in Surgery Thirteenth Edition 2007 3.Risk Factors for retained foreign bodies after surgery. Canadian Journal of Surgery, 47(1), 57-59 B. Staff education was completed at staff meeting and a copy of the revised policy was emailed to all OR staff. C. The revision was also published in the Surgical Services New to Use, Volume 1 Issue4.	03/18/2011 03/25/2011 04/15/2011

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	Continued From page 7 intestines that was obstructed and in order to treat this obstruction he resected a portion of the small intestines. This resected portion was later opened to reveal an OR towel. MD 2 confirmed that the presence of the OR towel in the abdomen directly lead to the small bowel obstruction. MD 2 also commented on the standard of practice of using an OR towel outside of its intended use. (The OR towel is routinely used to dry hands, wipe utensils and surgical instruments and to cover and protect the top of the scrub nurse table know as a Mayo table). MD 2 commented that he routinely used OR towels during abdominal surgeries and that there was "nothing like an OR towel" to help visualize the surgical field. MD 2 also acknowledged the importance that when he does use the OR towel that a critical part is requesting the use from the scrub tech so that the item could be part of the count at the end of surgery. On 1/13/12 at 9 a.m., during a concurrent interview, the CMO (Chief Medical Officer) and MD 3 (Medical Director of Surgical Services) commented on the expectation of surgeons and the importance of counts to be correct and the importance of following policies and procedures. The CMO and MD 3 acknowledged they were unaware, prior to the [redacted]11 surgery, that surgeons were using OR towels outside of their intended use and utilizing OR towels to help visualize the surgical field. The CMO and MD 3 also agreed, that if an OR towel was to be used in the surgical field, then the expectation was that the surgeon would request from the scrub tech the use of the OR towel. This necessary communication, explained CMO and MD		16. Action Item #3: Send a letter to all surgeons outlining revision to counting procedure and follow up with outliers per "Counts of Instruments Sharps,Sponges" policy(C-12) 17. Measure of Effectiveness for Action Item #3: A. Letter was created,sent and signed by the Interim Director and Medical Director of Peri-operative Services. 18. Action Item #4: Evaluate types of cases that require add'l staff- new staffing model. 19. Measure of Effectiveness for Action Item #4: A. The Interim Director of Surgical Services started an overtime log to evaluate how staff is being used to justify more staff. Interim Director was looking at a more effective staffing model. In all cases a minimum staffing model will include a circulating nurse and scrub nurse/tech. Daily 1:00 PM meeting occur with the OR Practice Coordinators and Manager to review the surgery schedule for the following day. (cont)	03/14/2011 03/14,2011 03/28/2011

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	Continued From page 8 3, was important to account for all items in the surgical field in order to protect the patient. Both agreed that this was not done in the case of Patient 1. On 1/13/12 at 10 a.m., during an interview, MD 1 confirmed he was the surgeon for Patient 1 on [redacted]10. MD 1 confirmed his involvement with Patient 1 began in the hospital ED where he diagnosed an emergent small bowel obstruction and immediately took Patient 1 to the Operating Room. MD 1 confirmed his routine use of OR towel in the surgical field and that he always requests the OR towel from the scrub tech/nurse prior to placing in the surgical field. MD 1 did not comment on how the OR towel was missed during that surgery. MD 1 explained that he routinely sweeps the abdominal cavity prior to closing and did not know how he missed it. He also did not remember if the white board accounted for the OR towel and whether or not the OR towel was part of the count at the end of that surgery. On 1/13/12 at 12 p.m., during an interview, RN 1 confirmed her role in both surgeries of Patient 1; as the scrub nurse/assistant to the surgeon for [redacted]10 and as the circulating nurse for the [redacted]11 surgery. RN 1 stated she "was devastated" about the OR towel being retained in Patient 1. RN 1 stated that MD 1 did not request the use of the OR towel at any time during the surgery. RN 1 explained the accepted procedure was to request the OR towel, hand the OR towel to the surgeon and then verbalize the OR towel to the circulating nurse to write on the white board for later counting.		(cont) At that time there is discussion around staffing, acuity of cases and consideration for the need for additional staff for lengthy, complex cases. Any additional staffing will be determined on a case by case basis.. 20. Action item #5: Send case to Peer Review 21. Measure of Effectiveness for Action Item #5: A. The initial incident report was referred by Risk Management Department to Medical Staff for PEER review. 22. Surgical Services has developed an ongoing"Surgical/Procedural Observation Checklist which randomly selects surgical cases throughout the month for direct observation. The checklist can be revised to observe different component of a surgical procedure and/or various locations. Some elements that are being observed are: Time outs, patient identifiers and correct count	03/02/2011 09/2010

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Nancy Hollingsworth | TITLE: CEO | (X6) DATE: 4-11-12

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050093	A. BUILDING _____ B. WING _____	01/13/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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	Continued From page 9 Asked as to how the OR towel got in the surgical site, RN 1 stated that the Mayo stand with the OR towels were accessible to the surgeon. The following Surgical Services Policy & Procedure was reviewed. Counts of Instrument, Sharps, Sponges Dated May 2008. The purpose of the document was listed as "To provide guidelines to prevent leaving any unintended foreign material or object in a patient after a surgical procedure." The outcome was listed as "All instruments, sharps, and sponges are accounted for before, during, and after each surgical invasive procedure for the safety of the patient. " The following was listed under "Policy .....6. All items that could conceivably be lost in a patient during surgery will be counted. This includes, but is not limited to: ..." The hospital failed to implement their surgical count procedure for the surgery of Patient 1 on [redacted]10. This failure directly led to a surgical OR towel being retained in the patient for four months. The retained foreign object directly led to an additional hospitalization on [redacted]11. The retained foreign object directly led to surgery on [redacted]11 because of small bowel obstruction. The hospital failures resulted in preventable pain, suffering, injury and harm. The failure to implement the hospital policy and procedure for surgical counts directly led to the licensee's noncompliance with one or more requirements of licensure and caused, or is likely to cause, serious injury or death to the patient. The above facility failures may result in an		23. A second audit tool was developed for the Sponge Accounting System in OR and Procedural Rooms. Ten audits per month is the expectation. Staff from each procedural area were specifically trained in this system and address any incident of non-compliance with "Just in Time" education. 24. Semi-annual reports of the Sponge Accounting System are sent to Trinity to track and trend compliance. 25. The Medical Executive Committee and/or the Medical Affairs Committee will take disciplinary action consistent with the Bylaws of the Medical Staff, to address surgeons identified to be using non radiopaque towel for any intracorporeally procedure and this will be reported to the Board of trustees. A. Responsibility: Chairman of the Board of Trustees, President of the Medical Staff, Chief Medical Officer and Chief Executive officer. 26. Incident reports are continuously monitored and reviewed every business day by the Risk Management Department. Incident reports are referred to Surgical Services as appropriate and monthly reports are sent to Surgery Administration to share with all staff. Responsibility: Director of Risk Management, Risk Management Coordinator, Interim Director of Peri-operative Services and Surgical Services Administration.	11/ 2011 01/2012

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Nancy Hollingsworth	CEO	4-11-12

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050093	A. BUILDING _____ B. WING _____	01/13/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Saint Agnes Medical Center	**1303 E Herndon Ave, Fresno, CA 93720-3309 FRESNO COUNTY**

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	Continued From page 10 Administrative Penalty. This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).		27. Incident reports for surgical services are reported quarterly to the Data Analysis Committee and then forwarded to the Board of Trustees Responsibility: Director of Risk Management Risk Management Coordinator 28. Incident reports are submitted under but not limited to the following "Incident Types" OR-Incorrect Instrument Count OR-Incorrect Needle Count OR-Incorrect Sponge Count Policy/Procedure Not Followed Near Miss Injury-Inpatient Injury-Outpatient Physician Disruptive Behavior Infection Control Practices	06/2008 03/2008

Event ID:BN0211 8/10/2012 3:10:55PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Nancy Goldsmith	CEO	4-11-12

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