

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390117	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED: 06/09/2017
NAME OF PROVIDER OR SUPPLIER: UPMC BEDFORD		STREET ADDRESS, CITY, STATE, ZIP CODE: 10455 LINCOLN HIGHWAY EVERETT, PA 15537		
STATE LICENSE NUMBER: 650501				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
A 0000	INITIAL COMMENT	A 0000		
A 0115	This report is the result of an unannounced onsite complaint investigation (JOH17C031J) conducted on May 23, 2017, and completed on June 9, 2017, at UPMC Bedford Memorial. It was determined the facility was not in compliance with the requirements of 42 CFR, Title 42, Part 482-Conditions of Participation for Hospitals.	A 0115		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE:

(X6) DATE:

Any deficiency statement ending with an asterisk (*) denotes a deficiency which may be excused from correction providing it is determined that other safeguards provide sufficient protection to the patients. The findings stated above are disclosable whether or not a plan of correction is provided. The findings are disclosable within 14 days after such information is made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

This form is a printed electronic version of the CMS 2567L. It contains all the information found on the standard document in much the same form. This electronic form once printed and signed by the facility administrator and appropriately posted will satisfy the CMS requirement to post survey information found on the CMS 2567L.

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A 0115	Continued from page 1 482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This REQUIREMENT is not met as evidenced by:	A 0115	To ensure that UPMC Bedford protects the personal privacy, dignity and respect of each patient in the future, the facility has completed the following steps: (1) The Director of Nursing sent a memo to all clinical staff members on 1/20/17 highlighting the need to adhere to current health system policies: HS-FM 0214: Photographing, Filming and Recording within UPMC Facilities; HSRI-1305: Initial Incident/Event Reporting (IIER); and HS-HD-PR-01, Patient's notice and Bill of rights and responsibilities. All clinical staff members reviewed this memo and the three attached policies, and indicated that review with read/sign accountability forms, which were returned to the HR Manager by 2/1/17. Additionally, all staff members in the surgical services department attended a mandatory in-service on privacy and confidentiality, presented by a health system attorney on January 27, 2017. Attendance is evidenced by a signed class roster.	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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A 0115	Continued from page 2	A 0115	<p>Following investigation of the reported event, all involved staff members were disciplined per existing human resources policies for the institution. Evidence of this discipline was placed into each individual's human resource file. The existing camera in the operating room was examined after this event and found to work correctly. Staff were educated by the clinical coordinator of the operating room regarding correct operation of the camera on January 26, 2017. Attendance at this training is evidenced by a signed roster. An additional camera has also been ordered by the director of surgical services and will be received by August 1st to ensure availability for patient needs/documentation. A change in surgical services leadership was made with the appointment of a new Surgical Services Nursing director on April 19th, 2017. The Medical-Executive Committee was notified of this event on January 10, 2017 by the Vice President of</p>	

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A 0115	Continued from page 3	A 0115	<p>Medical Affairs. Investigation was then started. One of the attending physicians in the case was summarily suspended on January 13, 2017 by the CEO.</p> <p>A special Medical-Executive Committee meeting was held January 19th, 2017. At that meeting, the suspension of the physician was lifted, effective January 21, 2017.</p> <p>The third physician, not involved in the direct care of the patient, but present in the operating room was summarily suspended by the CEO on January 19, 2017.</p> <p>A special Medical-Executive Committee meeting was held on January 26, 2017. At that meeting, the suspension of the third physician not involved in the direct care of the patient, but present in the operating room was lifted effective January 26, 2017. Additionally, the Medical-Executive Committee determined to begin a formal investigation. A sub-committee of two physicians from the Medical-Executive Committee and the Director of Nursing were</p>	

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A 0115	Continued from page 4	A 0115	<p>appointed to conduct this investigation and submit the report to the Medical Executive Committee for action per section 7.2-4 of the Medical staff bylaws.</p> <p>A special Medical-Executive Committee meeting was held on February 14, 2017. At this meeting, one of the physicians previously selected to serve on the formal investigation committee was recused due to a potential conflict of interest with one of the physicians being reviewed. A member of the board was selected to replace the physician on the committee. The formal investigation committee was reformed, and was comprised of one physician from the Medical-Executive Committee, one individual from the Facility Board of Directors and the Director of Nursing.</p> <p>A special Medical-Executive Committee meeting was held on April 4, 2017. The formal investigation committee presented their findings and written report to the full Medical-Executive</p>	

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A 0115	Continued from page 5	A 0115	Committee. After that presentation, the Medical-Executive Committee determined the following actions would be taken: One of the attending physicians involved in the case was provided a letter of guidance on April 12th, 2017, from the Medical-Executive Committee. The attending physician's staff appointment and clinical privileges were suspended by the Medical-Executive Committee for 7 days. Additionally, this physician had to complete six CME hours related to HIPAA, patient privacy and medical ethics. This physician was suspended June 24, 2017 through July 1, 2017. CME hours were completed on April 26th, 2017. The third physician, not involved in the care of the patient, but present in the room had the medical staff appointment and clinical privileges suspended for 28 days, pending completion of 18 CME category 1 credits related to HIPAA, privacy and ethics. Failure to complete those credits would result in a six-week suspension. The physician	

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A 0115	<p>Continued from page 7</p> <p>Based on a review of the patient's medical record (MR), facility documents, and interview with facility staff (EMP), it was determined that UPMC Bedford failed to protect the personal privacy, dignity and respect of the patient, 482.13(c)(1), by failing to provide care in a safe setting, 482.13(c)(2), and by failing to protect a patient's confidentiality, 482.13(d), by permitting people not directly involved in the patient's care to be present in the Operating Room, and to take photographs of the patient using their personal devices, for one of one patient (MR1).</p> <p>Findings Include:</p> <p>UPMC Policy and Procedure Manual, Index: HS-HD-PR-01 Index Title: Patient Rights/Organizational Ethics. Subject: Patients Notice and Bill of Rights and Responsibilities. Date: December 4, 2015. "I. Policy: It is the policy of the UPMC to promote the interest and well-being of patients served ... f. informed by your physician and making decision if you will give or withhold your</p>	A 0115		

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A 0115	Continued from page 8 informed consent before your physician starts and procedure or treatment with you, unless it is an emergency ... Privacy, Respect, Dignity and Comfort. You have a right to: 1. Personal privacy, including: a, during personal hygiene activities, treatments or examinations; b. sharing your personal information only with your consent unless otherwise permitted or required by law ... 3. Give or withhold consent for the facility to produce or use recordings, films or other images of you for purposes other than your care. Staff and environment you have a right to: 1. Receive respectful care given by competent personnel in a setting that: a. is safe and promotes your dignity, positive self-image and comfort ... c. is free from all forms of abuse, exploitation or harassment or neglect ... Personal Health Information. 1. You have the right to appropriate management of your personal health information as set forth in our Notice of Privacy Practices ... Quality, Support, Advocacy. You have the right to ... 2. Quality care and high professional standards that continually are maintained and reviewed. 3.	A 0115		

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A 0115	Continued from page 9 Have the facility implement good management techniques that consider the effective use of your time and avoid your personal discomfort ... "UPMC Policy and Procedure Manual, Index: HS-HR0736 ... Human Resources. Subject: Confidential Information, date: February 29, 2016, ... revealed, "I. Policy: It is the policy of UPMC to protect confidential information from disclosure to any person or entity without a legitimate business or medical need to access the information. Confidential Information must only be accessed by and disclosed to individuals with appropriate authorization and a legitimate business need to have access to the information. ... II. Scope/Purpose: The purpose of this policy is to ensure that all Confidential Information is only accessed and disclosed on a need to know basis. ... 'Need to Know' means that the recipient of the information must have access to the information to fulfill his or her job duties. It is the responsibility of all staff members of UPMC to safeguard Confidential Information against inappropriate disclosure, loss, tampering, or use by	A 0115		

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A 0115	Continued from page 10 unauthorized persons. This policy applies to all persons who have access to Confidential Information, including but not limited to UPMC domestic staff-members, students, volunteers, employed physicians and contract workers. ... in no case should Confidential Information be conveyed to individuals outside the organization, including family or associates, or to other UPMC staff members, who do not need the information to perform their job duties ... 2. Each staff member, student, volunteer, contract worker and physician shall exercise caution and discretion in discussing any matters concerning a patient's name, diagnosis and treatment or the patient's other Protected Health Information." UPMC Policy and Procedure Manual, Index: HS-EC1900 ... Title: Ethics & Compliance. Subject: Code of Conduct. Date: June 3, 2016. "I. Policy: UPMC has a Code of Conduct (Code) policy that governs the actions of individuals employed by or associated with UPMC and its affiliates. The Code's written guidelines which are	A 0115		

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A 0115	Continued from page 11 based on UPMC's mission, vision, values, and ethics, outline how people must conduct themselves when providing any service on behalf of UPMC ... II. Purpose: UPMC endorses the Code because: A. At the core of our business, we are focused on providing compassionate high quality, cost-effective services in a safe, efficient and effective manner. B. We demonstrate honesty, fairness, respect and dignity to everyone within a safe and healthy work environment ... H. We value the patient-caregiver relationship by demonstrating our accountability for patient safety ad by safeguarding patient trust, particularly for our most vulnerable patients... Examples of unacceptable behaviors include but not limited to: ... g. Breaching confidentiality of patient, ... h. Behaviors and/or actions that could or do compromise patient safety, including those that are malicious, careless or risky ... l. Misusing electronic media, including electronic mail, text messaging, instant messaging, Internet/web technology, etc. ... or by viewing, sending, or receiving pornography, obscene jokes, or sexually harassing content"	A 0115		

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A 0115	Continued from page 12 UPMC Policy and Procedure Manual ... Policy: HS-FM0214 ... Index Title: Facilities & Safety ... Subject: Photographing, Filming and Recording or making Recordings within UPMC Facilities ... Date: August 5, 2016. " ... II. Policy/Scope ... B. No Photographing, Filming, or Recording by UPMC employees, staff or contractors should occur within a UPMC facility unless it is appropriate and necessary for a business, education or patient care purpose ... E. Where photographing, Filming or Recording also involves a patient, as specific separate authorization (which includes the circumstances of the use of Photographing, Filming or Recording) must be signed by the patient or the patient's designated representative prior to Photographing, Filming or Recording the patient, except: ... III. Definitions: A. 'Photographing' refers to the taking of an image using a digital camera (including camera phones and other devices that are capable of capturing a photographic image) or film camera. B. 'Filming' refers to the taking of a motion image using a video camera (including camera	A 0115		

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A 0115	Continued from page 13 phones ... IV. Procedure A. UPMC employees, staff and contractors should only use photography, film, and recording that has been provided or specifically approved by UPMC for such purposes. Provided that a personal smartphones may be used when: a. There is a business requirement for use of the personal device; b. The device is securely managed with UPMC's mobile device management solution; c. Images can only be capture [sic] through an application supplied through mobile device management solution (APPS@WORK); and d. Requirement set forth in the Mobile Device Network and Exchange Access Standard (ISD-EMM003) are met. ... 2. When photographs, Films, or Recordings are to be used for other internal purposes (for example, inclusion in the caregiver's private teaching files), written patient authorization is required. The authorization form must ... include a statement providing sufficient details to allow the patient to fully understand the intended use, as well as whether the images or use would result in the patient's face or other identifying	A 0115		

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A 0115	<p>Continued from page 14</p> <p>features being visible. ... C. Photography, Film and Recording equipment should be provided by UPMC (personal equipment should not be used). ... "</p> <p>1. Review of MR1 History and Physical, dated December 23, 2016, revealed, "... Urology. ... Hospital Course: Briefly, ... The Emergency Room physician described [genital injury] ... Clinical Discharge Summary ... Admission Date/Time: 12/23/16 9:36 AM ... Reason For Visit: Genital Injury ... Attending: [EMP6] ... Surgeon: [EMP6] ... Surgery: Removal Foreign Body ... "</p> <p>2. An interview was conducted with EMP1 on May 23, 2017, at approximately 9:15 AM. "In January a hospital employee came forward to complain about photographs that were circulating around the hospital, of a patient under anesthesia while in the OR. The patient had a genital injury and OR staff had apparently taken photos and video of the patient using their personal cell phones, and were showing the photos to other hospital staff. We started an investigation into this. EMP6 wanted a</p>	A 0115		

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A 0115	Continued from page 15 photo taken to use for future medical lectures. We have a camera in the OR for that purpose, but it was reportedly broken and so personal phones were used. Initially, we thought there was only one picture taken but later we learned of others. We also had the camera checked out, it is working, it is just too complicated to use." 3. An interview was conducted with EMP5 on May 23, 2017, at approximately 2:20 PM. "... There were more people in the OR than usual ... I was attending to the patient and at one point when I looked up there were so many people it looked like a cheerleader type pyramid. EMP6 asked one of the staff to take a photo. Because they had gloves on and were sterile I took the picture. I don't take my phone into the OR, so I went to my drawer and got my phone. I only took a photo of the operative area, and a second one after the procedure was completed. The OR camera was dysfunctional, not working. The surgeon requested a picture, I didn't over-analyze. I can take a picture without compromising the patient's identity. I did witness	A 0115		

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A 0115	Continued from page 16 other staff taking pictures. ... The surgeon said, 'That's enough, we have to get going.' ... I did not harm the patient, no delay to take pictures. The patient went to Recovery timely." 4. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM. "... I do take pictures of genitourinary anomalies for educational purposes. The OR camera was not working so I had my assistant take the picture. ... I have many pictures of genitourinary anomalies for teaching and documentation purposes. I was very busy taking care of patients that day, can't read words verbatim on the consent, but I know the consent covers it. I did not ask the patient for permission to photograph their genital area prior to the start of the procedure. Generally, we don't tell that to the patient. I don't recall inviting others into the OR to watch. We are a small hospital, it is commonplace for everyone in the facility to know what cases are coming in. It was a medical curiosity. I respected the patient, I did say, 'Stop, this is a HIPAA violation.' I could not hold anyone	A 0115		

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A 0115	Continued from page 17 back, in the spirit of a medical anomaly I told them they could come in once the patient was asleep. EMP20 came up from the office but did not assist in the case. Whenever I'm doing a case, I get interrupted for calls, there are people coming in and out of the OR all the time." Cross Reference: 482.22(c) Medical Staff Bylaws 482.42 Infection Control 482. 51 Surgical Services	A 0115		

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A 0115	Continued from page 18	A 0115			
A 0353		A 0353			

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A 0353	Continued from page 19 482.22(c) MEDICAL STAFF BYLAWS The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: This REQUIREMENT is not met as evidenced by:	A 0353	The Director of Surgical Services will formulate a policy that addresses appropriate traffic control within the operating room by July 5, 2017. The policy will be submitted to the Surgery/Anesthesia Department for approval via electronic mail, with responses due by July 10th, 2017. Approval is anticipated at that time, and the policy will be effective from the date of that approval. The staff in the surgical services area will be educated regarding this new policy by the Director of Surgical Services via memo, with a read/sign accountability sheet completed by 90% of the staff members by August 1, 2017. Any staff member on leave at this time will be required to review the information on their return to the facility. The policy will be sent out electronically with read receipt to all members of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11, 2017. The policy entitled HS-FM 0214: Photographing, Filming and Recording within UPMC Facilities will be sent electronically with read	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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A 0353	Continued from page 20	A 0353	<p>receipt to all members of the medical staff by the Vice President of Medical Affairs by July 11, 2017. Following investigation of the reported event, all involved staff members were disciplined per existing human resources policies for the institution. Evidence of this discipline was placed into each individual's human resource file. The existing camera in the operating room was examined after this event and found to work correctly. Staff were educated by the clinical coordinator of the operating room regarding correct operation of the camera on January 26, 2017. Attendance at this training is evidenced by a signed roster. An additional camera has also been ordered by the director of surgical services and will be received by August 1st to ensure availability for patient needs/documentation.</p> <p>A change in surgical services leadership was made with the appointment of a new Surgical Services Nursing director on April</p>	

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A 0353	Continued from page 21	A 0353	<p>19th, 2017.</p> <p>The Medical-Executive Committee was notified of this event on January 10, 2017 by the Vice President of Medical Affairs. Investigation was then started. One of the attending physicians in the case was summarily suspended on January 13, 2017 by the CEO.</p> <p>A special Medical-Executive Committee meeting was held January 19th, 2017. At that meeting, the suspension of the physician was lifted, effective January 21, 2017.</p> <p>The third physician, not involved in the direct care of the patient, but present in the operating room was summarily suspended by the CEO on January 19, 2017.</p> <p>A special Medical-Executive Committee meeting was held on January 26, 2017. At that meeting, the suspension of the third physician not involved in the direct care of the patient, but present in the operating room was lifted effective January 26, 2017. Additionally, the Medical-Executive Committee determined to begin a formal</p>	

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A 0353	Continued from page 22	A 0353	<p>investigation. A sub-committee of two physicians from the Medical-Executive Committee and the Director of Nursing were appointed to conduct this investigation and submit the report to the Medical Executive Committee for action per section 7.2-4 of the Medical staff bylaws.</p> <p>A special Medical-Executive Committee meeting was held on February 14, 2017. At this meeting, one of the physicians previously selected to serve on the formal investigation committee was recused due to a potential conflict of interest with one of the physicians being reviewed. A member of the board was selected to replace the physician on the committee. The formal investigation committee was reformed, and was comprised of one physician from the Medical-Executive Committee, one individual from the Facility Board of Directors and the Director of Nursing.</p> <p>A special Medical-Executive Committee meeting was held on</p>	

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A 0353	Continued from page 23	A 0353	<p>April 4, 2017. The formal investigation committee presented their findings and written report to the full Medical-Executive Committee. After that presentation, the Medical-Executive Committee determined the following actions would be taken: One of the attending physicians involved in the case was provided a letter of guidance on April 12th, 2017, from the Medical-Executive Committee. The attending physician's staff appointment and clinical privileges were suspended by the Medical-Executive Committee for 7 days. Additionally, this physician had to complete six CME hours related to HIPAA, patient privacy and medical ethics. This physician was suspended June 24, 2017 through July 1, 2017. CME hours were completed on April 26th, 2017. The third physician, not involved in the care of the patient, but present in the room had medical staff appointment and clinical privileges suspended for 28 days, pending completion of 18 CME category 1</p>	

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A 0353	Continued from page 24	A 0353	credits related to HIPAA, privacy and ethics. Failure to complete those credits would result in a six-week suspension. The physician completed the required CME credits on May 21st, 2017. The physician was suspended from April 26th, 2017 through May 25, 2017. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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A 0353	Continued from page 25 Based on a review of the MR1, facility documents, and interview with facility staff it was determined that UPMC Bedford failed to ensure that members of the Medical Staff follow their adopted Medical Staff Bylaws by failing to restrict the number of staff in the OR to those directly involved in the patient's care, and by permitting staff to take photographs of a patient on their personal devices, and by sharing these photos with additional hospital staff and other persons. (MR1) Findings Include: UPMC Bedford, Medical Staff Bylaws adopted by the Board October 24, 2016, revealed, "... Article III. Membership: 3.2 Qualifications. 3.2-4 Basic Qualifications. An individual meets the basic qualifications for medical staff membership only if he: a. Exercises his clinical privileges and prerogatives in a manner that will result in quality patient care, as demonstrated by evidence of ... competence, good judgment, and ... ; b. Adheres to the ethics of his	A 0353		

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A 0353	Continued from page 26 profession; c. Works cooperatively with others so as not to adversely affect quality care; ... 3.3 Responsibilities: ... 3.3-2 Basic Responsibilities. The basic responsibilities of the medical staff membership are that the member is to: a. Endeavor to exercise his clinical privileges and prerogatives and discharge his responsibilities only in a manner that will result in quality of care; b. Abide by the ethics of his profession and ethics statement signed pursuant to subsection 3.3-3; c. Cooperate with others so as not to adversely affect quality of care; d. Comply with these bylaws, the medical staff rules and regulations, Article XIV Miscellaneous Provisions 14.1 Rules and Regulations The medical staff shall initiate and adopt such rules and regulations and manuals, as required by applicable law or these bylaws, or as it may otherwise deem necessary for the proper conduct of its works, and shall periodically review and revise its rules and regulations and manuals to comply with appropriate medical staff practice. ... Applicants and practitioners shall be governed by such rules and	A 0353		

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A 0353	Continued from page 27 regulations and manuals as are properly initiated and adopted." UPMC Bedford Memorial, Department of Surgery Rules and Regulations, approved by the Medical Executive Committee, June 14, 2016. "... Pre-Operative Requirements ... 5. Operative consents shall be completed and signed prior to the patient going to the Operating Room ... Informed consent: 1. Informed surgical consent shall be obtained from the patient, and should include the practitioner's signature and the procedure to be performed, as well as who will be performing the procedure. The informed consent shall be obtained from the patient, by the responsible practitioner. It is the responsibility of that practitioner to explain to the patient, the procedure, the risk of the procedure, alternatives to the procedure and the risk of not having the procedure done. It is the responsibility of the practitioner performing the procedure to obtain the informed consent. ... Observer's in the Operating Room ... 2. Medical students, surgical tech students, nursing students, physician assistants, CRNP	A 0353		

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A 0353	Continued from page 28 Practitioners, and mid-wives are assigned a physician or staff mentor who is responsible to oversee their activity in the OR. ... " 1) UPMC Bedford Memorial, Medical Executive Committee Meeting minutes dated January 26, 2017, revealed reports of an occurrence on December 23, 2016, where several staff members, including physicians took video and photographs of a patient during a surgical procedure, that had no clinical justification and shared those videos and photographs to others uninvolved with the patient's care. An interview was conducted with EMP3 on May 23, 2017, at approximately 9:30 AM. "it was a couple days before Christmas, I received a picture text on my phone from Anesthesia, made a comment and moved on. We do pass on interesting stuff ... " An interview was conducted with EMP4 on May 23, 2017, at approximately 1:50 PM. "... There	A 0353		

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A 0353	Continued from page 29 was a suspected infraction. ... We have never had a circus like this before. Now they know. They knew, but now they really know!" A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM. "... I do take pictures of genitourinary anomalies for educational purposes. The OR camera was not working so I had my assistant take the picture. ... I was very busy taking care of patients that day, can't read words verbatim on the consent, but I know the consent covers it. I did not ask the patient for permission to photograph their genital area prior to the start of the procedure. Generally, we don't tell that to the patient. ... I could not hold anyone back, in the spirit of a medical anomaly I told them they could come in once the patient was asleep. ..." A telephone conference call was conducted with EMP11 on May 31, 2017, at 9:00 AM. "I was doing a tendon repair, when someone, I don't remember who, one of the OR staff, came into the room and said that there was a patient in the ER	A 0353		

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A 0353	Continued from page 30 with a genital injury. I thought, how does this happen? I was curious, I couldn't imagine how the patient did it. I finished my case and ran into EMP6 in Recovery and said, 'What the hell, how does this happen?' I don't know who was or wasn't in the room, but there was quite a crowd. I had nothing else scheduled for the rest of the day so I stayed and watched. I did not have a purpose to be in there. It was sheer curiosity. I did take pictures and shared them with my spouse." 2) A review of the facility's internal investigation revealed the following statments made by employees who were in the Operating Room on December 23, 2016: EMP19 remembered looking in the window of the Operating Room door and saw EMP5 and someone else in front of EMP19. EMP14 stated that the patient was the focal point of all the chaos and that there was a "ton" of people in the room. EMP14 told EMP12 to clear the area and that EMP19 came in with a poster that said, "No pics." EMP14 heard that pictures were sent to	A 0353		

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A 0353	Continued from page 31 a surgical tech at a Pittsburgh facility. EMP15 stated EMP20 and EMP6 took pictures and multiple people lined up at the door to take pictures. EMP21 recalled that EMP6 said wait until the patient is asleep before taking pictures. EMP21 took their phone out and took a picture, kept it until the Tuesday after Christmas and asked EMP22 to send the picture to Medical Records. EMP21 admitted showing the picture to their spouse, however, did recall EMP6 saying that the pictures are to go nowhere. EMP16 stated that EMP6 said once the patient was asleep anyone can come in, and that EMP11 had their phone out before the case was done. EMP18 stated they were working in another OR with EMP11 when they heard about this case coming in and were excited to see it. EMP16 and EMP11 were beside EMP18 and that it was okay to take pictures as long as they were not distributed. EMP18 stated EMP20 used EMP6 phone to take the pictures and that EMP8 "shooed"	A 0353		

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A 0353	Continued from page 32 them out of the OR. EMP8 stated that after the patient was asleep, they went to get supplies and told the others to leave because they did not have enough eye protection for everyone due to the sparks flying from the tools that were being used. Cross Reference: 482.13 Patient Rights	A 0353		
A 0747		A 0747		

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A 0747	Continued from page 33 482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This REQUIREMENT is not met as evidenced by:	A 0747	To ensure compliance with the facility's Infection Control Plan, the Infection Control Coordinator will round in the operating room/surgical services biweekly and as needed, beginning the week of July 24th, 2017 utilizing a checklist to observe for compliance with infection control standards and appropriate environmental controls. The Infection Control Coordinator will report findings and discuss any observed deviations at the Quality/Risk Management meeting monthly for three months, beginning with the August 17th meeting. Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. The Director of Surgical Services will formulate a policy that addresses appropriate traffic control within the operating room by July 5, 2017. The policy will be submitted to the Surgery/Anesthesia Department for approval via electronic mail, with responses due by July 10th, 2017. Approval is anticipated at that time,	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390117	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED: 06/09/2017
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A 0747	Continued from page 34	A 0747	and the policy will be effective from the date of that approval. The staff in the surgical services area will be educated regarding this new policy by the Director of Surgical Services via memo, with a read/sign accountability sheet completed by 90% of the staff members by August 1, 2017. Any staff member on leave will be required to review the information upon their return to the facility. The policy will be sent electronically with read receipt to all members of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11, 2017. The Director of Operations will in-service Environmental Staff members and members of the surgical services staff who work in surgical services regarding policy HS-FM0238-PRO Operating Room Cleaning Procedure. Education will be completed by August 1, 2017, as evidenced by read/sign accountability sheets. EVS staff and/or OR staff will begin to document cleaning completed between each case and terminal	

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A 0747	Continued from page 35	A 0747	<p>cleaning for each room, beginning August 1, 2017. The Director of Operations will report compliance with this documentation at the Quality/Risk Committee meeting monthly for three months, beginning with the August 17th, 2017 meeting. Thereafter the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis.</p> <p>The Director of Surgical Services reviewed the policy HS-OR0010 Dress Code in the OR with the surgical services staff at the Unit meeting on June 20th. The policy was discussed at the Medical-Executive Meeting on June 20, 2017 by the Vice President of Medical Affairs. The policy will be sent electronically to all member of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11th, 2017.</p> <p>Observations for compliance with the system dress code policy HS-OR0010 Dress Code in the OR, along with observations for compliance with the OR traffic policy</p>	

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A 0747	Continued from page 36	A 0747	(ensuring only appropriate individuals are in the operating rooms) will be completed monthly by the Director of Surgical Services or designee. Thirty observations will be completed each month and reported monthly for three months at the Quality/Risk Committee Meeting, starting August 17, 2017. Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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A 0747	<p>Continued from page 37</p> <p>Based on a review of medical record (MR1), facility documents, and interview with facility staff (EMP), it was determined that UPMC Bedford failed to follow their adopted Infection Control Plan by failing to conduct active surveillance and to restrict unnecessary traffic in the Surgical Suite, by failing to follow policies related to cleaning and to wearing surgical attire outside of the Surgical Suite.</p> <p>Findings Include:</p> <p>UPMC Bedford Memorial, Title: Infection Control Plan and Risk Assessment ... Section IC-01 ... Revised ... 8/16 ... "Purpose: The purpose of this Plan is to provide for a program of surveillance, prevention and control of infection at UPMC Bedford Memorial and the population we serve in our geographical location. In keeping with the mission, vision and value of UPMC Bedford Memorial, the goal of the Infection Control Program is to identify and reduce the risk of acquiring and transmitting infections among patients, employees, physicians and other licensed independent practitioners, contract service workers, volunteers,</p>	A 0747		

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A 0747	Continued from page 38 students and visitors, with attention to: Addressing our prioritized risks. Limiting unprotected exposure to pathogens. Limiting the transmission of infections associated with procedures. Limiting the transmission of infections associated with use of medical equipment, devices and supplies. ... Surveillance, prevention and control of infections cover a broad range of processes and activities. ... The Infection Control Committee and the hospital wide Infection Control Program develop the type of prevention, surveillance and management procedures that relate to infection control as appropriate to UPMC Bedford Memorial. ... 10. Evaluate all procedures and policies pertaining to infection control throughout the organization. This includes but is not limited to, evaluation of housekeeping methods/agents and evaluation of outpatient and ambulatory settings for sound infection prevention/control practices. 11. Revising, updating and approving the Infection Control Departmental guidelines" UPMC Policy and Procedure Manual ... Policy:	A 0747		

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A 0747	Continued from page 39 HS-HM0238-PRO ... Subject: Operating Room Cleaning Procedure, Date: August 5, 2016. "Procedure: It is the procedure of the UPMC to provide clean and safe hospital environment for our patients, visitors and employees, that reduces the possibility of cross infection and enhances the image of the facility. ... II. Purpose: The purpose of this procedure is to establish a standardized cleaning process to properly clean and disinfect the operating room and surgical area immediately after a case is completed and to terminally clean after the last cases of the day. This procedure should be utilized in all highly sterile areas including, but not limited to main OR suites, ... V. Procedure for Between Case Cleaning ... VI. Procedure for Terminal Cleaning" UPMC Bedford Memorial, Title: Cleaning of Operating Rooms, Section OR-07 ... Reviewed 8/16."Purpose: To establish and maintain a clean environment. To reduce the possibility of cross infection among surgical patients and among the surgical patient and operating room personnel."	A 0747		

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A 0747	Continued from page 40 UPMC Bedford Memorial Hospital ... Surgical Services Policy/Procedure Manual ... Section SS-PO-006 ... Title: Patient Safety in the OR. Revision Date 1/14. "... Standard: All patients will be provided safe environment by operating room (OR) personnel while they are in the Surgical Suite. OR personnel include: surgeon and their extender(s), Anesthesiologist and Certified Registered Nurse Anesthetists, Circulating Nurse, Surgical Technician and Environmental Support staff. Policy: ... 8. All personnel in the OR will comply with the UPMC System dress code" UPMC Policy and Procedure Manual, Policy: HS-OR0010. Index Title: Operating Room. ... Subject: Dress Code in the Operating Room, Date: January 27, 2017. "I. Policy: It is the policy for the operating room departments that personnel maintain clean and professional appearance by wearing facility-approved surgical attire ... within the perioperative environment. ... II. Purpose: To provide guidelines to the operating room staff about	A 0747		

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A 0747	Continued from page 41 a professional appearance and overall cleanliness in order to reduce the external source of contamination in semirestricted and restricted areas of the operating room ... III. Scope: This policy applies to all personnel working in the restricted and semirestricted areas of the operating room departments ... IV. Definitions: A. Restricted Area: Includes the operating and procedure rooms and, in some hospitals, the clean core. People in this area are required to wear full surgical attire ... C. Surgical Attire: Non-sterile apparel designated for perioperative practice setting that includes two-piece pantsuits, cover jackets, head coverings, shoes, masks, and protective eyewear. ...V. Procedure: A. ... 5. Worn surgical attire should be changed and returned to scrub exchange system/laundry hamper at the end of the shift and when it becomes visibly soiled, contaminated or wet. ... b) Surgical attire should not be worn to and from home. 6. Visitors are required to be in proper Operating Room attire. This includes either freshly laundered surgical attire or single-use attire. ... B.	A 0747		

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A 0747	Continued from page 42 Head Covering ... 2. When leaving the Surgical Services Department, the disposable head covers should be removed and discarded. ... C. Footwear ... 1. ... c) Shoe covers should be removed when leaving the surgical department. ... 3. Surgical masks should be removed and discarded when leaving the semirestricted areas. Masks should not be worn hanging down from the neck or placed into pockets." 1. A review of UPMC Bedford Incident Report Summary, dated December 2016, through present was conducted and revealed a total of 58 incidents that included but were not limited to: ... infection/return to OR, faulty equipment, missing instrumentation, incorrect sponge count, OR not terminally cleaned (operating room not terminally cleaned (feces on the floor and on the kick bucket), laparoscopic instrumentation not clean prior to start of case, and cancelled OR procedures 2. A request was made to review documentation providing evidence of the "daily" and "between	A 0747		

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A 0747	Continued from page 43 cases" cleaning as per facility policy. EMP25 stated, "I double checked and they are not logging their daily and between case cleanings for the ORs." 3. A request was made to review documentation providing evidence of the Infection Control Officer surveillance rounds in the OR, to monitor the traffic flow (i.e. additional staff in the OR who may not be scrubbed in), proper surgical attire, personal cell phone usage, during procedures on a routine basis. EMP1 confirmed with EMP26 that this has not been done at Bedford in the past. 4. A review of Surgical Quality Assurance/Performance Improvement documentation for the Operating Room dated July 2016, through May 2017, included but was not limited to cleanliness of OR. There was no measurement data entered in the space provided from July 2016, through May 2017. 5. On May 23, 2017, at approximately 11:00 AM, the survey team observed through the Vreeland	A 0747		

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A 0747	Continued from page 44 Conference Room windows, a man exiting the facility and getting into a vehicle wearing blue hospital scrub shirt and pants, shoe coverings, and a cloth hair covering. EMP1 identified the man as EMP6. EMP1 stated that some of the physicians go back and forth between the hospital and their office. The man was not observed returning to the facility, however, the vehicle was returned to it's former parking spot a short time later. 6. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM and revealed, "... EMP20 came up from my office, but did not assist in the case. When I'm doing a case, I get interrupted for calls, people come in all the time. ... usually a lot of traffic into the Operating Room." 7. The Operative Record and the "Time Out" in MR1 indicated that EMP5, EMP6, EMP7, EMP8, EMP9, and EMP10 were directly involved in the patient's care." EMP20, EMP19, EMP16, EMP11, EMP21 and	A 0747		

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A 0747	Continued from page 45 EMP18 were not documented in MR1 as a care provider during the procedure. Cross Reference: 482.13 Patient Rights 482. 51 Surgical Services	A 0747		
A 0940		A 0940		

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A 0940	Continued from page 46 482.51 SURGICAL SERVICES If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. This REQUIREMENT is not met as evidenced by:	A 0940	To ensure surgical services are well organized and in accordance with acceptable standards of practice, the Director of Surgical Services will formulate a policy that addresses appropriate traffic control within the operating room by July 5, 2017. The policy will be submitted to the Surgery/Anesthesia Department for approval via electronic mail, with responses due by July 10th, 2017. Approval is anticipated at that time, and the policy will be effective from the date of that approval. The staff in the surgical services area will be educated regarding this new policy by the Director of Surgical Services via memo, with a read/sign accountability sheet completed by 90% of the staff members by August 1, 2017. Any staff member on leave will be required to review this information upon their return to the facility. The policy will be sent electronically with read receipt to all members of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11, 2017. The Director of Operations will	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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A 0940	Continued from page 47	A 0940	<p>in-service Environmental Staff members and members of the surgical services staff who work in surgical services regarding policy HS-FM0238-PRO Operating Room Cleaning Procedure. Education will be completed by August 1, 2017, as evidenced by read/sign accountability sheets.</p> <p>EVS staff and/or OR staff will begin to document cleaning completed between each case and terminal cleaning for each room, beginning August 1, 2017. The Director of Operations will report compliance with this documentation at the Quality/Risk Committee meeting monthly for three months, beginning with the August 17th, 2017 meeting. Thereafter the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis.</p> <p>The Director of Surgical Services reviewed the policy HS-OR0010 Dress Code in the OR with the surgical services staff at the Unit meeting on June 20th. The policy was discussed at the</p>	

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A 0940	Continued from page 48	A 0940	<p>Medical-Executive Meeting on June 20, 2017 by the Vice President of Medical Affairs. The policy will be sent electronically with read receipt to all member of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11th, 2017.</p> <p>Observations for compliance with the system dress code policy HS-OR0010 Dress Code in the OR along with observations for compliance with the OR traffic policy (to ensure that only appropriate individuals are in the operating room) will be completed monthly by the Director of Surgical Services or designee. Thirty observations will be completed each month and reported monthly for three months at the Quality/Risk Committee Meeting, starting August 17, 2017.</p> <p>Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. Any observations of non-compliance will be addressed following human resources policy for staff members, and following</p>	

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A 0940	Continued from page 49	A 0940	medical staff bylaws for members of the medical staff. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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A 0940	Continued from page 50 Based on review of facility documents and interview with facility staff (EMP), it was determined that UPMC Bedford failed to adopt policies to restrict traffic in the Operating Rooms, and failed to follow their adopted policies related to cleaning and surgical attire to ensure that surgical services are well organized and provided in accordance with acceptable standards of practice. Findings Include: A list of policies were reviewed from UPMC Bedford Memorial Hospital Surgical Services Manual policy index. There were no policies, specific to UPMC Bedford Memorial Hospital that addressed traffic flow inside the Operating Room Suite, scrub protocols or surgical attire. On May 25, 2017, EMP1 revealed, "... We cannot find the policy on OR traffic anywhere despite what the Rule and Regs refer to. There is no system policy for that, as that aspect would be specific to an institution."	A 0940		

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A 0940	Continued from page 51 UPMC Policy and Procedure Manual ... Policy: HS-HM0238-PRO. Index Title: Facilities & Safety. Subject: Operating Room Cleaning Procedure, Date: August 5, 2016. "Procedure: It is the procedure of the UPMC to provide clean and safe hospital environment for our patients, visitors and employees, that reduces the possibility of cross infection and enhances the image of the facility. ... II. Purpose: The purpose of this procedure is to establish a standardized cleaning process to properly clean and disinfect the operating room and surgical area immediately after a case is completed and to terminally clean after the last cases of the day. This procedure should be utilized in all highly sterile areas including, but not limited to main OR suites, Outpatient Surgery centers, OB, GI Lab, EP lab, Special Procedures and Cardiac Catheterization Lab. ... V. Procedure for Between Case Cleaning ... VI. Procedure for Terminal Cleaning" UPMC Bedford Memorial Title: Cleaning of	A 0940		

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A 0940	<p>Continued from page 52</p> <p>Operating Rooms ... Section OR-07 ... Reviewed 8/16. "Purpose: To establish and maintain a clean environment. To reduce the possibility of cross infection among surgical patients and among the surgical patient and operating room personnel."</p> <p>UPMC Bedford Memorial Hospital ... Surgical Services Policy/Procedure Manual ... Section SS-PO-006. Title: Patient Safety in the OR, Revision Date 1/14. "... Standard: All patients will be provided safe environment by operating room (OR) personnel while they are in the Surgical suite. OR personnel include: Surgeon and their extender(s), Anesthesiologist and Certified Registered Nurse Anesthetists, Circulating Nurse, Surgical Technician and Environmental Support staff. ... 8. All personnel in the OR will comply with the UPMC System dress code"</p> <p>UPMC Policy and Procedure Manual, Policy: HS-OR0010. Index Title: Operating Room. ... Subject: Dress Code in the Operating Room, Date:</p>	A 0940		

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A 0940	Continued from page 53 January 27, 2017. "I. Policy: It is the policy for the operating room departments that personnel maintain clean and professional appearance by wearing facility-approved surgical attire ... within the perioperative environment. ... II. Purpose: To provide guidelines to the operating room staff about a professional appearance and overall cleanliness in order to reduce the external source of contamination in semirestricted and restricted areas of the operating room ... III. Scope: This policy applies to all personnel working in the restricted and semirestricted areas of the operating room departments ... IV. Definitions: A. Restricted Area: Includes the operating and procedure rooms and, in some hospitals, the clean core. People in this area are required to wear full surgical attire ... C. Surgical Attire: Non-sterile apparel designated for perioperative practice setting that includes two-piece pantsuits, cover jackets, head coverings, shoes, masks, and protective eyewear. ... V. Procedure: A. ... 5. Worn surgical attire should be changed and returned to scrub exchange	A 0940		

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A 0940	Continued from page 54 system/laundry hamper at the end of the shift and when it becomes visibly soiled, contaminated or wet. ... b) Surgical attire should not be worn to and from home. 6. Visitors are required to be in proper Operating Room attire. This includes either freshly laundered surgical attire or single-use attire. ... B. Head Covering ... 2. When leaving the Surgical Services Department, the disposable head covers should be removed and discarded. ... C. Footwear ... 1. ... c) Shoe covers should be removed when leaving the surgical department. ... 3. Surgical masks should be removed and discarded when leaving the semirestricted areas. Masks should not be worn hanging down from the neck or placed into pockets. ... "	A 0940		
	1. UPMC Position Description, Job Title ... Surgical Technician, revealed, "... Job Purpose: ... Perform a variety of tasks in the operating room that assist the surgical team. ... Responsibilities: ... Ensure clean, safe environment through continued alertness to safety and explosive hazards and aseptic technique.			

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A 0940	Continued from page 55 Standard Responsibilities Performs in accordance with system-wide competencies/behaviors." 2. An interview was conducted with EMP5 on May 23, 2017, at approximately 2:20 PM. "The surgeon is in control ultimately. Anesthesia can take charge in a crisis. EMP19 was there. EMP19 should have taken full responsibility for the OR staff's behavior." 3. A review of UPMC Bedford Incident Report Summary, dated December 2016, through present was conducted and revealed a total of 58 incidents that included but were not limited to: ... infection/return to OR, faulty equipment, missing instrumentation, incorrect sponge count, OR not terminally cleaned (operating room not terminally cleaned (feces on the floor and on the kick bucket), laparoscopic instrumentation not clean prior to start of case, and cancelled OR procedures 4. A request was made to review documentation	A 0940		

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A 0940	Continued from page 56 providing evidence of the "daily" and "between cases" cleaning as per facility policy. EMP25 stated, "I double checked and they are not logging their daily and between case cleanings for the ORs." 5. A request was made to review documentation providing evidence of the Infection Control Officer surveillance rounds in the OR, to monitor the traffic flow (i.e. additional staff in the OR who may not be scrubbed in), proper surgical attire, personal cell phone usage, during procedures on a routine basis. EMP1 confirmed with EMP26 that this has not been done at Bedford in the past. 6. On May 23, 2017, at approximately 11:00 AM, the survey team observed through the Vreeland Conference Room windows, a man exiting the facility and getting into a vehicle wearing blue hospital scrub shirt and pants, shoe coverings, and a cloth hair covering. EMP1 identified the man as EMP6. EMP1 stated that some of the physicians go	A 0940		

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A 0940	<p>Continued from page 57</p> <p>back and forth between the hospital and their office. The man was not observed returning to the facility, however the vehicle was returned to it's former parking spot a short time later.</p> <p>7. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM and revealed, "... EMP20 came up from my office, but did not assist in the case. When I'm doing a case, I get interrupted for calls, people come in all the time. ... usually a lot of traffic into the Operating Room."</p> <p>8. The Operative Record and the "Time Out" in MR1 indicated that EMP5, EMP6, EMP7, EMP8, EMP9, and EMP10 were directly involved in the patient's care." EMP20, EMP19, EMP16, EMP11, EMP21 and EMP18 were not documented in MR1 as a care provider during the procedure.</p> <p>Cross Reference:</p>	A 0940		

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A 0940	Continued from page 58 482.13 Patient Rights 482.22(c) Medical Staff Bylaws 482.42 Infection Control	A 0940			

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P 0000	INITIAL COMMENT This report is the result of an unannounced onsite complaint investigation (JOH17C031J) conducted on May 23, 2017, and completed on June 9, 2017, at UPMC Bedford Memorial. It was determined that the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Hospitals, 28 PA Code, Part IV, Subparts A and B, November 1987, as amended June 1998.	P 0000		
P 0345		P 0345		
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE		TITLE:		(X6) DATE:

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P 0345	Continued from page 1 103.22 (a) IMPLEMENTATION 103.22 Implementation (a) The hospital governing body shall establish a Patient's Bill of Rights not less in substance and coverage that the minimal Patient's Bill of Rights provided by subsection (b) of this section This REGULATION is not met as evidenced by:	P 0345	To ensure that UPMC Bedford protects the personal privacy, dignity and respect of each patient in the future, the facility has completed the following steps: (1) The Director of Nursing sent a memo to all clinical staff members on 1/20/17 highlighting the need to adhere to current health system policies: HS-FM 0214: Photographing, Filming and Recording within UPMC Facilities; HSRI-1305: Initial Incident/Event Reporting (IIER); and HS-HD-PR-01, Patient's notice and Bill of rights and responsibilities. All clinical staff members reviewed this memo and the three attached policies, and indicated that review with read/sign accountability forms, which were returned to the HR Manager by 2/1/17. Additionally, all staff members in the surgical services department attended a mandatory in-service on privacy and confidentiality, presented by a health system attorney on January 27, 2017. Attendance is evidenced by a signed class roster.	Completion Date: 08/01/2017 Status: APPROVED Date: 07/11/2017

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P 0345	Continued from page 2	P 0345	<p>Following investigation of the reported event, all involved staff members were disciplined per existing human resources policies for the institution. Evidence of this discipline was placed into each individual's human resource file. The existing camera in the operating room was examined after this event and found to work correctly. Staff were educated by the clinical coordinator of the operating room regarding correct operation of the camera on January 26, 2017. Attendance at this training is evidenced by a signed roster. An additional camera has also been ordered by the director of surgical services and will be received by August 1st to ensure availability for patient needs/documentation. A change in surgical services leadership was made with the appointment of a new Surgical Services Nursing director on April 19th, 2017. The Medical-Executive Committee was notified of this event on January 10, 2017 by the Vice President of</p>	

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P 0345	Continued from page 3	P 0345	<p>Medical Affairs. Investigation was then started. One of the attending physicians in the case was summarily suspended on January 13, 2017 by the CEO.</p> <p>A special Medical-Executive Committee meeting was held January 19th, 2017. At that meeting, the suspension of the physician was lifted, effective January 21, 2017.</p> <p>The third physician, not involved in the direct care of the patient, but present in the operating room was summarily suspended by the CEO on January 19, 2017.</p> <p>A special Medical-Executive Committee meeting was held on January 26, 2017. At that meeting, the suspension of the third physician not involved in the direct care of the patient, but present in the operating room was lifted effective January 26, 2017. Additionally, the Medical-Executive Committee determined to begin a formal investigation. A sub-committee of two physicians from the Medical-Executive Committee and the Director of Nursing were</p>	

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P 0345	Continued from page 4	P 0345	<p>appointed to conduct this investigation and submit the report to the Medical Executive Committee for action per section 7.2-4 of the Medical staff bylaws.</p> <p>A special Medical-Executive Committee meeting was held on February 14, 2017. At this meeting, one of the physicians previously selected to serve on the formal investigation committee was recused due to a potential conflict of interest with one of the physicians being reviewed. A member of the board was selected to replace the physician on the committee. The formal investigation committee was reformed, and was comprised of one physician from the Medical-Executive Committee, one individual from the Facility Board of Directors and the Director of Nursing.</p> <p>A special Medical-Executive Committee meeting was held on April 4, 2017. The formal investigation committee presented their findings and written report to the full Medical-Executive</p>	

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P 0345	Continued from page 5	P 0345	Committee. After that presentation, the Medical-Executive Committee determined the following actions would be taken: One of the attending physicians involved in the case was provided a letter of guidance on April 12th, 2017, from the Medical-Executive Committee. The attending physician's staff appointment and clinical privileges were suspended by the Medical-Executive Committee for 7 days. Additionally, this physician had to complete six CME hours related to HIPAA, patient privacy and medical ethics. This physician was suspended June 24, 2017 through July 1, 2017. CME hours were completed on April 26th, 2017. The third physician, not involved in the care of the patient, but present in the room had the medical staff appointment and clinical privileges suspended for 28 days, pending completion of 18 CME category 1 credits related to HIPAA, privacy and ethics. Failure to complete those credits would result in a six-week suspension. The physician	

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P 0345	Continued from page 6	P 0345	completed the required CME credits on May 21st, 2017. The physician was suspended from April 26th, 2017 through May 25, 2017. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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P 0345	Continued from page 7 Based on a review of medical record (MR), facility documents, and interview with facility staff (EMP), it was determined that UPMC Bedford failed to protect the personal privacy, dignity and respect of the patient, failed to utilize good management techniques, and failed to maintain patient confidentiality, by permitting people not directly involved in the patient's care to be present in the Operating Room, and by taking photos of the patient using their personal devices, and sharing those photos for one of one patient (MR1). Findings Include: UPMC Policy and Procedure Manual, Index: HS-HD-PR-01 Index Title: Patient Rights/Organizational Ethics. Subject: Patients Notice and Bill of Rights and Responsibilities. Date: December 4, 2015. "I. Policy: It is the policy of the UPMC to promote the interest and well-being of patients served ... f. informed by your physician and making decision if you will give or withhold your informed consent before your physician starts and	P 0345		

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P 0345	Continued from page 8 procedure or treatment with you, unless it is an emergency ... Privacy, Respect, Dignity and Comfort. You have a right to: 1. Personal privacy, including: a, during personal hygiene activities, treatments or examinations; b. sharing your personal information only with your consent unless otherwise permitted or required by law ... 3. Give or withhold consent for the facility to produce or use recordings, films or other images of you for purposes other than your care. Staff and environment you have a right to: 1. Receive respectful care given by competent personnel in a setting that: a. is safe and promotes your dignity, positive self-image and comfort ... c. is free from all forms of abuse, exploitation or harassment or neglect ... Personal Health Information. 1. You have the right to appropriate management of your personal health information as set forth in our Notice of Privacy Practices ... Quality, Support, Advocacy. You have the right to ... 2. Quality care and high professional standards that continually are maintained and reviewed. 3. Have the facility implement good management	P 0345		

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P 0345	Continued from page 9 techniques that consider the effective use of your time and avoid your personal discomfort" UPMC Policy and Procedure Manual, Index: HS-HR0736 ... Human Resources. Subject: Confidential Information, date: February 29, 2016, ... revealed, "I. Policy: It is the policy of UPMC to protect confidential information from disclosure to any person or entity without a legitimate business or medical need to access the information. Confidential Information must only be accessed by and disclosed to individuals with appropriate authorization and a legitimate business need to have access to the information. ... II. Scope/Purpose: The purpose of this policy is to ensure that all Confidential Information is only accessed and disclosed on a need to know basis. ... 'Need to Know' means that the recipient of the information must have access to the information to fulfill his or her job duties. It is the responsibility of all staff members of UPMC to safeguard Confidential Information against inappropriate disclosure, loss, tampering, or use by	P 0345		

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P 0345	Continued from page 10 unauthorized persons. This policy applies to all persons who have access to Confidential Information, including but not limited to UPMC domestic staff-members, students, volunteers, employed physicians and contract workers. ... in no case should Confidential Information be conveyed to individuals outside the organization, including family or associates, or to other UPMC staff members, who do not need the information to perform their job duties ... 2. Each staff member, student, volunteer, contract worker and physician shall exercise caution and discretion in discussing any matters concerning a patient's name, diagnosis and treatment or the patient's other Protected Health Information." UPMC Policy and Procedure Manual, Index: HS-EC1900 ... Title: Ethics & Compliance. Subject: Code of Conduct. Date: June 3, 2016. "I. Policy: UPMC has a Code of Conduct (Code) policy that governs the actions of individuals employed by or associated with UPMC and its	P 0345		

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P 0345	Continued from page 11 affiliates. The Code's written guidelines which are based on UPMC's mission, vision, values, and ethics, outline how people must conduct themselves when providing any service on behalf of UPMC ... II. Purpose: UPMC endorses the Code because: A. At the core of our business, we are focused on providing compassionate high quality, cost-effective services in a safe, efficient and effective manner. B. We demonstrate honesty, fairness, respect and dignity to everyone within a safe and healthy work environment ... H. We value the patient-caregiver relationship by demonstrating our accountability for patient safety ad by safeguarding patient trust, particularly for our most vulnerable patients... Examples of unacceptable behaviors include but not limited to: ... g. Breaching confidentiality of patient, ... h. Behaviors and/or actions that could or do compromise patient safety, including those that are malicious, careless or risky ... l. Misusing electronic media, including electronic mail, text messaging, instant messaging, Internet/web technology, etc. ... or by viewing, sending, or receiving pornography,	P 0345		

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P 0345	Continued from page 12 obscene jokes, or sexually harassing content" UPMC Policy and Procedure Manual ... Policy: HS-FM0214 ... Index Title: Facilities & Safety ... Subject: Photographing, Filming and Recording or making Recordings within UPMC Facilities ... Date: August 5, 2016. " ... II. Policy/Scope ... B. No Photographing, Filming, or Recording by UPMC employees, staff or contractors should occur within a UPMC facility unless it is appropriate and necessary for a business, education or patient care purpose ... E. Where photographing, Filming or Recording also involves a patient, as specific separate authorization (which includes the circumstances of the use of Photographing, Filming or Recording) must be signed by the patient or the patient's designated representative prior to Photographing, Filming or Recording the patient, except: ... III. Definitions: A. 'Photographing' refers to the taking of an image using a digital camera (including camera phones and other devices that are capable of capturing a photographic image) or film	P 0345		

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P 0345	Continued from page 13 camera. B. 'Filming' refers to the taking of a motion image using a video camera (including camera phones ... IV. Procedure A. UPMC employees, staff and contractors should only use photography, film, and recording that has been provided or specifically approved by UPMC for such purposes. Provided that a personal smartphones may be used when: a. There is a business requirement for use of the personal device; b. The device is securely managed with UPMC's mobile device management solution; c. Images can only be capture [sic] through an application supplied through mobile device management solution (APPS@WORK); and d. Requirement set forth in the Mobile Device Network and Exchange Access Standard (ISD-EMM003) are met. ... 2. When photographs, Films, or Recordings are to be used for other internal purposes (for example, inclusion in the caregiver's private teaching files), written patient authorization is required. The authorization form must ... include a statement providing sufficient details to allow the patient to fully understand the	P 0345		

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P 0345	Continued from page 14 intended use, as well as whether the images or use would result in the patient's face or other identifying features being visible. ... C. Photography, Film and Recording equipment should be provided by UPMC (personal equipment should not be used)." 1. Review of MR1 History and Physical, dated December 23, 2016, revealed, "... Urology. ... Hospital Course: Briefly, ... The Emergency Room physician described [genital injury] ... Clinical Discharge Summary ... Admission Date/Time: 12/23/16 9:36 AM ... Reason For Visit: Genital Injury ... Attending: [EMP6] ... Surgeon: [EMP6] ... Surgery: Removal Foreign Body" 2. An interview was conducted with EMP1 on May 23, 2017, at approximately 9:15 AM. "In January, a hospital employee came forward to complain about photographs that were circulating around the hospital, of a patient under anesthesia while in the OR. The patient had a genital injury and OR staff	P 0345		

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P 0345	Continued from page 15 had apparently taken photos and video of the patient using their personal cell phones, and were showing the photos to other hospital staff. We started an investigation into this. EMP6 wanted a photo taken to use for future medical lectures. We have a camera in the OR for that purpose, but it was reportedly broken and so personal phones were used. Initially, we thought there was only one picture taken but later we learned of others. We also had the camera checked out, it is working, it is just too complicated to use." 3. An interview was conducted with EMP5 on May 23, 2017, at approximately 2:20 PM. "... There were more people in the OR than usual ... I was attending to the patient and at one point when I looked up there were so many people it looked like a cheerleader type pyramid. EMP6 asked one of the staff to take a photo. Because they had gloves on and were sterile I took the picture. I don't take my phone into the OR, so I went to my drawer and got my phone. I only took a photo of the operative	P 0345		

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P 0345	Continued from page 16 area, and a second one after the procedure was completed. The OR camera was dysfunctional, not working. The surgeon requested a picture, I didn't over-analyze. I can take a picture without compromising the patient's identity. I did witness other staff taking pictures. ... The surgeon said, 'That's enough, we have to get going.' ... I did not harm the patient, no delay to take pictures. The patient went to Recovery timely." 4. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM. "... I do take pictures of genitourinary anomalies for educational purposes. The OR camera was not working so I had my assistant take the picture. ... I have many pictures of genitourinary anomalies for teaching and documentation purposes. I was very busy taking care of patients that day, can't read words verbatim on the consent, but I know the consent covers it. I did not ask the patient for permission to photograph their genital area prior to the start of the procedure. Generally, we don't tell	P 0345		

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P 0345	Continued from page 17 that to the patient. I don't recall inviting others into the OR to watch. We are a small hospital, it is commonplace for everyone in the facility to know what cases are coming in. It was a medical curiosity. I respected the patient, I did say, 'Stop, this is a HIPAA violation.' I could not hold anyone back, in the spirit of a medical anomaly I told them they could come in once the patient was asleep. EMP20 came up from the office but did not assist in the case. Whenever I'm doing a case, I get interrupted for calls, there are people coming in and out of the OR all the time."	P 0345		

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P 0345	Continued from page 18	P 0345		
P 0758		P 0758		

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P 0758	Continued from page 19 107.51 (a)(1-3) MEDICAL CARE REVIEW - RESPONSIBILITIES 107.51 Medical staff responsibilities (a) In order for the medical staff to take reasonable steps to ensure clinical practice of the highest quality, each staff member should endeavor to: (1) provide his patients with the best quality of care consistent with the circumstances of each case; (2) conduct his professional activities in accordance with the bylaws, rules and regulations of the medical staff; and (3) assist in the promotion and maintenance of high quality care through the analysis, review, and evaluation of the clinical practice which exists within the hospital. This REGULATION is not met as evidenced by:	P 0758	To ensure that UPMC Bedford protects the personal privacy, dignity and respect of each patient in the future, the facility has completed the following steps: (1) The Director of Nursing sent a memo to all clinical staff members on 1/20/17 highlighting the need to adhere to current health system policies: HS-FM 0214: Photographing, Filming and Recording within UPMC Facilities; HSRI-1305: Initial Incident/Event Reporting (IIER); and HS-HD-PR-01, Patient's notice and Bill of rights and responsibilities. All clinical staff members reviewed this memo and the three attached policies, and indicated that review with read/sign accountability forms, which were returned to the HR Manager by 2/1/17. Additionally, all staff members in the surgical services department attended a mandatory in-service on privacy and confidentiality, presented by a health system attorney on January 27, 2017. Attendance is evidenced by a signed class roster.	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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P 0758	Continued from page 20	P 0758	<p>Following investigation of the reported event, all involved staff members were disciplined per existing human resources policies for the institution. Evidence of this discipline was placed into each individual's human resource file. The existing camera in the operating room was examined after this event and found to work correctly. Staff were educated by the clinical coordinator of the operating room regarding correct operation of the camera on January 26, 2017. Attendance at this training is evidenced by a signed roster. An additional camera has also been ordered by the director of surgical services and will be received by August 1st to ensure availability for patient needs/documentation. A change in surgical services leadership was made with the appointment of a new Surgical Services Nursing director on April 19th, 2017. The Medical-Executive Committee was notified of this event on January 10, 2017 by the Vice President of</p>	

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P 0758	Continued from page 21	P 0758	<p>Medical Affairs. Investigation was then started. One of the attending physicians in the case was summarily suspended on January 13, 2017 by the CEO.</p> <p>A special Medical-Executive Committee meeting was held January 19th, 2017. At that meeting, the suspension of the physician was lifted, effective January 21, 2017.</p> <p>The third physician, not involved in the direct care of the patient, but present in the operating room was summarily suspended by the CEO on January 19, 2017.</p> <p>A special Medical-Executive Committee meeting was held on January 26, 2017. At that meeting, the suspension of the third physician not involved in the direct care of the patient, but present in the operating room was lifted effective January 26, 2017. Additionally, the Medical-Executive Committee determined to begin a formal investigation. A sub-committee of two physicians from the Medical-Executive Committee and the Director of Nursing were</p>	

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P 0758	Continued from page 22	P 0758	<p>appointed to conduct this investigation and submit the report to the Medical Executive Committee for action per section 7.2-4 of the Medical staff bylaws.</p> <p>A special Medical-Executive Committee meeting was held on February 14, 2017. At this meeting, one of the physicians previously selected to serve on the formal investigation committee was recused due to a potential conflict of interest with one of the physicians being reviewed. A member of the board was selected to replace the physician on the committee. The formal investigation committee was reformed, and was comprised of one physician from the Medical-Executive Committee, one individual from the Facility Board of Directors and the Director of Nursing.</p> <p>A special Medical-Executive Committee meeting was held on April 4, 2017. The formal investigation committee presented their findings and written report to the full Medical-Executive</p>	

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P 0758	Continued from page 23	P 0758	Committee. After that presentation, the Medical-Executive Committee determined the following actions would be taken: One of the attending physicians involved in the case was provided a letter of guidance on April 12th, 2017, from the Medical-Executive Committee. The attending physician's staff appointment and clinical privileges were suspended by the Medical-Executive Committee for 7 days. Additionally, this physician had to complete six CME hours related to HIPAA, patient privacy and medical ethics. This physician was suspended June 24, 2017 through July 1, 2017. CME hours were completed on April 26th, 2017. The third physician, not involved in the care of the patient, but present in the room had the medical staff appointment and clinical privileges suspended for 28 days, pending completion of 18 CME category 1 credits related to HIPAA, privacy and ethics. Failure to complete those credits would result in a six-week suspension. The physician	

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P 0758	Continued from page 24	P 0758	completed the required CME credits on May 21st, 2017. The physician was suspended from April 26th, 2017 through May 25, 2017. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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P 0758	Continued from page 25 Based on a review of MR1, facility documents, and interview with facility staff, it was determined that UPMC Bedford failed to ensure that members of the Medical Staff follow their adopted Medical Staff Bylaws, by failing to restrict the number of staff in the OR to those directly involved in the patient's care, and by permitting staff to take photographs of a patient on their personal devices, and by sharing these photos with additional hospital staff and other persons. (MR1) Findings Include: UPMC Bedford, Medical Staff Bylaws adopted by the Board October 24, 2016, revealed, "... Article III. Membership: 3.2 Qualifications. 3.2-4 Basic Qualifications. An individual meets the basic qualifications for medical staff membership only if he: a. Exercises his clinical privileges and prerogatives in a manner that will result in quality patient care, as demonstrated by evidence of ... competence, good judgment, and ... ; b. Adheres to the ethics of his profession; c. Works cooperatively with others so	P 0758		

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P 0758	Continued from page 26 as not to adversely affect quality care; ... 3.3 Responsibilities: ... 3.3-2 Basic Responsibilities. The basic responsibilities of the medical staff membership are that the member is to: a. Endeavor to exercise his clinical privileges and prerogatives and discharge his responsibilities only in a manner that will result in quality of care; b. Abide by the ethics of his profession and ethics statement signed pursuant to subsection 3.3-3; c. Cooperate with others so as not to adversely affect quality of care; d. Comply with these bylaws, the medical staff rules and regulations, Article XIV Miscellaneous Provisions 14.1 Rules and Regulations The medical staff shall initiate and adopt such rules and regulations and manuals, as required by applicable law or these bylaws, or as it may otherwise deem necessary for the proper conduct of its works, and shall periodically review and revise its rules and regulations and manuals to comply with appropriate medical staff practice. ... Applicants and practitioners shall be governed by such rules and regulations and manuals as are properly initiated and	P 0758		

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P 0758	Continued from page 27 adopted." UPMC Bedford Memorial, Department of Surgery Rules and Regulations, approved by the Medical Executive Committee, June 14, 2016. "... Pre-Operative Requirements ... 5. Operative consents shall be completed and signed prior to the patient going to the Operating Room ... Informed consent: 1. Informed surgical consent shall be obtained from the patient, and should include the practitioner's signature and the procedure to be performed, as well as who will be performing the procedure. The informed consent shall be obtained from the patient, by the responsible practitioner. It is the responsibility of that practitioner to explain to the patient, the procedure, the risk of the procedure, alternatives to the procedure and the risk of not having the procedure done. It is the responsibility of the practitioner performing the procedure to obtain the informed consent. ... Observer's in the Operating Room ... 2. Medical students, surgical tech students, nursing students, physician assistants, CRNP	P 0758		

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P 0758	Continued from page 28 Practitioners, and mid-wives are assigned a physician or staff mentor who is responsible to oversee their activity in the OR." 1. UPMC Bedford Memorial, Medical Executive Committee Meeting minutes dated January 26, 2017, revealed reports of an occurrence on December 23, 2016, where several staff members, including physicians took video and photographs of a patient during a surgical procedure, that had no clinical justification and shared those videos and photographs to others uninvolved with the patient's care. An interview was conducted with EMP3 on May 23, 2017, at approximately 9:30 AM. "it was a couple days before Christmas, I received a picture text on my phone from Anesthesia, made a comment and moved on. We do pass on interesting stuff" An interview was conducted with EMP4 on May 23, 2017, at approximately 1:50 PM. "... There	P 0758		

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P 0758	Continued from page 29 was a suspected infraction. ... We have never had a circus like this before. Now they know. They knew, but now they really know!" A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM. "... I do take pictures of genitourinary anomalies for educational purposes. The OR camera was not working so I had my assistant take the picture. ... I was very busy taking care of patients that day, can't read words verbatim on the consent, but I know the consent covers it. I did not ask the patient for permission to photograph their genital area prior to the start of the procedure. Generally, we don't tell that to the patient. ... I could not hold anyone back, in the spirit of a medical anomaly I told them they could come in once the patient was asleep." A telephone conference call was conducted with EMP11 on May 31, 2017, at 9:00 AM. "I was doing a tendon repair, when someone, I don't remember who, one of the OR staff, came into the	P 0758		

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P 0758	Continued from page 30 room and said that there was a patient in the ER with a genital injury. I thought, how does this happen? I was curious, I couldn't imagine how the patient did it. I finished my case and ran into EMP6 in Recovery and said, 'What the hell, how does this happen?' I don't know who was or wasn't in the room, but there was quite a crowd. I had nothing else scheduled for the rest of the day so I stayed and watched. I did not have a purpose to be in there. It was sheer curiosity. I did take pictures and shared them with my spouse."	P 0758		
	2) A review of the facility's internal investigation revealed the following statments made by employees who were in the Operating Room on December 23, 2016: EMP19 remembered looking in the window of the Operating Room door and saw EMP5 and someone else in front of EMP19. EMP14 stated that the patient was the focal point of all the chaos and that there was a "ton" of people in the room. EMP14 told EMP12 to clear the area			

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P 0758	Continued from page 31 and that EMP19 came in with a poster that said, "No pics." EMP14 heard that pictures were sent to a surgical tech at a Pittsburgh facility. EMP15 stated EMP20 and EMP6 took pictures and multiple people lined up at the door to take pictures. EMP21 recalled that EMP6 said wait until the patient is asleep before taking pictures. EMP21 took their phone out and took a picture, kept it until the Tuesday after Christmas and asked EMP22 to send the picture to Medical Records. EMP21 admitted showing the picture to their spouse, however, did recall EMP6 saying that the pictures are to go nowhere. EMP16 stated that EMP6 said once the patient was asleep anyone can come in, and that EMP11 had their phone out before the case was done. EMP18 stated they were working in another OR with EMP11 when they heard about this case coming in and were excited to see it. EMP16 and EMP11 were beside EMP18 and that it was okay to take pictures as long as they were not	P 0758		

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P 0758	Continued from page 32 distributed. EMP18 stated EMP20 used EMP6 phone to take the pictures and that EMP8 "shooed" them out of the OR. EMP8 stated that after the patient was asleep, they went to get supplies and told the others to leave because they did not have enough eye protection for everyone due to the sparks flying from the tools that were being used.	P 0758		
P 3506		P 3506		

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P 3506	Continued from page 33 135.11 (a) POLICIES AND PROCEDURES 135.11 Policies and procedures (a) The surgical division of the medical staff shall develop written policies and procedures for surgical services. These policies shall be made available to the medical staff and surgical nursing personnel. This REGULATION is not met as evidenced by:	P 3506	To ensure surgical services are well organized and in accordance with acceptable standards of practice, the Director of Surgical Services will formulate a policy that addresses appropriate traffic control within the operating room by July 5, 2017. The policy will be submitted to the Surgery/Anesthesia Department for approval via electronic mail, with responses due by July 10th, 2017. Approval is anticipated at that time, and the policy will be effective from the date of that approval. The staff in the surgical services area will be educated regarding this new policy by the Director of Surgical Services via memo, with a read/sign accountability sheet completed by 90% of the staff members by August 1, 2017. Any staff member on leave at that time will be required to review the information upon their return to the facility. The policy will be sent electronically with read receipt to all members of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11, 2017. The Director of Operations will	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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P 3506	Continued from page 34	P 3506	<p>in-service Environmental Staff members and members of the surgical services staff who work in surgical services regarding policy HS-FM0238-PRO Operating Room Cleaning Procedure. Education will be completed by August 1, 2017, as evidenced by read/sign accountability sheets.</p> <p>EVS staff and/or OR staff will begin to document cleaning completed between each case and terminal cleaning for each room, beginning August 1, 2017. The Director of Operations will report compliance with this documentation at the Quality/Risk Committee meeting monthly for three months, beginning with the August 17th, 2017 meeting. Thereafter the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis.</p> <p>The Director of Surgical Services reviewed the policy HS-OR0010 Dress Code in the OR with the surgical services staff at the Unit meeting on June 20th. The policy was discussed at the</p>	

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P 3506	Continued from page 35	P 3506	<p>Medical-Executive Meeting on June 20, 2017 by the Vice President of Medical Affairs. The policy will be sent electronically with read receipt to all member of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11th, 2017.</p> <p>Observations for compliance with the system dress code policy HS-OR0010 Dress Code in the OR along with observations for compliance with the OR traffic policy (to ensure that only appropriate individuals are in the operating room) will be completed monthly by the Director of Surgical Services or designee. Thirty observations will be completed each month and reported monthly for three months at the Quality/Risk Committee Meeting, starting August 17, 2017. Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. Any observations of non-compliance will be addressed following human resources policy for staff members, and following</p>	

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P 3506	Continued from page 36	P 3506	medical staff bylaws for members of the medical staff. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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P 3506	Continued from page 37 Based on review of facility documents and interview with facility staff (EMP), it was determined that UPMC Bedford failed to adopt policies to restrict traffic in the Operating Rooms, and failed to follow their adopted policies related to cleaning and surgical attire to ensure that surgical services are well organized and provided in accordance with acceptable standards of practice. Findings Include: A list of policies were reviewed from UPMC Bedford Memorial Hospital Surgical Services Manual policy index. There were no policies, specific to UPMC Bedford Memorial Hospital that addressed traffic flow inside the Operating Room Suite, scrub protocols or surgical attire. On May 25, 2017, EMP1 confirmed, "... We cannot find the policy on OR traffic anywhere despite what the Rule and Regs refer to. There is no system policy for that, as that aspect would be specific to an institution."	P 3506		

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P 3506	Continued from page 38 UPMC Policy and Procedure Manual ... Policy: HS-HM0238-PRO. Index Title: Facilities & Safety. Subject: Operating Room Cleaning Procedure, Date: August 5, 2016. "Procedure: It is the procedure of the UPMC to provide clean and safe hospital environment for our patients, visitors and employees, that reduces the possibility of cross infection and enhances the image of the facility. ... II. Purpose: The purpose of this procedure is to establish a standardized cleaning process to properly clean and disinfect the operating room and surgical area immediately after a case is completed and to terminally clean after the last cases of the day. This procedure should be utilized in all highly sterile areas including, but not limited to main OR suites, Outpatient Surgery centers, OB, GI Lab, EP lab, Special Procedures and Cardiac Catheterization Lab. ... V. Procedure for Between Case Cleaning ... VI. Procedure for Terminal Cleaning" UPMC Bedford Memorial Title: Cleaning of	P 3506		

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P 3506	Continued from page 39 Operating Rooms ... Section OR-07 ... Reviewed 8/16. "Purpose: To establish and maintain a clean environment. To reduce the possibility of cross infection among surgical patients and among the surgical patient and operating room personnel." UPMC Bedford Memorial Hospital ... Surgical Services Policy/Procedure Manual ... Section SS-PO-006. Title: Patient Safety in the OR, Revision Date 1/14. "... Standard: All patients will be provided safe environment by operating room (OR) personnel while they are in the Surgical suite. OR personnel include: Surgeon and their extender(s), Anesthesiologist and Certified Registered Nurse Anesthetists, Circulating Nurse, Surgical Technician and Environmental Support staff. ... 8. All personnel in the OR will comply with the UPMC System dress code" UPMC Policy and Procedure Manual, Policy: HS-OR0010. Index Title: Operating Room. ... Subject: Dress Code in the Operating Room, Date:	P 3506		

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P 3506	Continued from page 40 January 27, 2017. "I. Policy: It is the policy for the operating room departments that personnel maintain clean and professional appearance by wearing facility-approved surgical attire ... within the perioperative environment. ... II. Purpose: To provide guidelines to the operating room staff about a professional appearance and overall cleanliness in order to reduce the external source of contamination in semirestricted and restricted areas of the operating room ... III. Scope: This policy applies to all personnel working in the restricted and semirestricted areas of the operating room departments ... IV. Definitions: A. Restricted Area: Includes the operating and procedure rooms and, in some hospitals, the clean core. People in this area are required to wear full surgical attire ... C. Surgical Attire: Non-sterile apparel designated for perioperative practice setting that includes two-piece pantsuits, cover jackets, head coverings, shoes, masks, and protective eyewear. ... V. Procedure: A. ... 5. Worn surgical attire should be changed and returned to scrub exchange	P 3506		

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P 3506	Continued from page 41 system/laundry hamper at the end of the shift and when it becomes visibly soiled, contaminated or wet. ... b) Surgical attire should not be worn to and from home. 6. Visitors are required to be in proper Operating Room attire. This includes either freshly laundered surgical attire or single-use attire. ... B. Head Covering ... 2. When leaving the Surgical Services Department, the disposable head covers should be removed and discarded. ... C. Footwear ... 1. ... c) Shoe covers should be removed when leaving the surgical department. ... 3. Surgical masks should be removed and discarded when leaving the semirestricted areas. Masks should not be worn hanging down from the neck or placed into pockets. ... "	P 3506		
	1. UPMC Position Description, Job Title ... Surgical Technician, revealed, "... Job Purpose: ... Perform a variety of tasks in the operating room that assist the surgical team. ... Responsibilities: ... Ensure clean, safe environment through continued alertness to safety and explosive hazards and aseptic technique.			

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P 3506	Continued from page 42 Standard Responsibilities Performs in accordance with system-wide competencies/behaviors." 2. An interview was conducted with EMP5 on May 23, 2017, at approximately 2:20 PM. "The surgeon is in control ultimately. Anesthesia can take charge in a crisis. EMP19 was there. EMP19 should have taken full responsibility for the OR staff's behavior." 3. A review of UPMC Bedford Incident Report Summary, dated December 2016, through present was conducted and revealed a total of 58 incidents that included but were not limited to: ... infection/return to OR, faulty equipment, missing instrumentation, incorrect sponge count, OR not terminally cleaned (operating room not terminally cleaned (feces on the floor and on the kick bucket), laparoscopic instrumentation not clean prior to start of case, and cancelled OR procedures 4. A request was made to review documentation	P 3506		

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P 3506	Continued from page 43 providing evidence of the "daily" and "between cases" cleaning as per facility policy. EMP25 stated, "I double checked and they are not logging their daily and between case cleanings for the ORs." 5. A request was made to review documentation providing evidence of the Infection Control Officer surveillance rounds in the OR, to monitor the traffic flow (i.e. additional staff in the OR who may not be scrubbed in), proper surgical attire, personal cell phone usage, during procedures on a routine basis. EMP1 confirmed with EMP26 that this has not been done at Bedford in the past. 6. On May 23, 2017, at approximately 11:00 AM, the survey team observed through the Vreeland Conference Room windows, a man exiting the facility and getting into a vehicle wearing blue hospital scrub shirt and pants, shoe coverings, and a cloth hair covering. EMP1 identified the man as EMP6. EMP1 stated that some of the physicians go	P 3506		

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P 3506	Continued from page 44 back and forth between the hospital and their office. The man was not observed returning to the facility, however the vehicle was returned to it's former parking spot a short time later. 7. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM and revealed, "... EMP20 came up from my office, but did not assist in the case. When I'm doing a case, I get interrupted for calls, people come in all the time. ... usually a lot of traffic into the Operating Room." 8. The Operative Record and the "Time Out" in MR1 indicated that EMP5, EMP6, EMP7, EMP8, EMP9, and EMP10 were directly involved in the patient's care." EMP20, EMP19, EMP16, EMP11, EMP21 and EMP18 were not documented in MR1 as a care provider during the procedure.	P 3506		

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P 3506	Continued from page 45	P 3506		
P 4603		P 4603		

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P 4603	Continued from page 46 146.1 (b)(1) PRINCIPLE 146.1 (b) The multidisciplinary committee described in section (a) shall do the following: (1) develop written standards for hospital sanitation and medical asepsis. Copies of the standards shall be made available to all appropriate personnel. Adequate standards should comply with those described in Infection Control in the Hospital, published by the American Hospital Association, Chicago, Illinois. This REGULATION is not met as evidenced by:	P 4603	To ensure compliance with the facility's Infection Control Plan, the Infection Control Coordinator will round in the operating room/surgical services biweekly and as needed, beginning the week of July 24th, 2017 utilizing a checklist to observe for compliance with infection control standards and appropriate environmental controls. The Infection Control Coordinator will report findings and discuss any observed deviations at the Quality/Risk Management meeting monthly for three months, beginning with the August 17th meeting. Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. The Director of Surgical Services will formulate a policy that addresses appropriate traffic control within the operating room by July 5, 2017. The policy will be submitted to the Surgery/Anesthesia Department for approval via electronic mail, with responses due by July 10th, 2017. Approval is anticipated at that time,	Completion Date: 08/18/2017 Status: APPROVED Date: 07/11/2017

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P 4603	Continued from page 47	P 4603	<p>and the policy will be effective from the date of that approval. The staff in the surgical services area will be educated regarding this new policy by the Director of Surgical Services via memo, with a read/sign accountability sheet completed by 90% of the staff members by August 1, 2017. Any staff on leave will be required to review this information on their return to the facility. The policy will be sent electronically with read receipt to all members of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11, 2017.</p> <p>The Director of Operations will in-service Environmental Staff members and members of the surgical services staff who work in surgical services regarding policy HS-FM0238-PRO Operating Room Cleaning Procedure. Education will be completed by August 1, 2017, as evidenced by read/sign accountability sheets.</p> <p>EVS staff and/or OR staff will begin to document cleaning completed between each case and terminal</p>	

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P 4603	Continued from page 48	P 4603	<p>cleaning for each room, beginning August 1, 2017. The Director of Operations will report compliance with this documentation at the Quality/Risk Committee meeting monthly for three months, beginning with the August 17th, 2017 meeting. Thereafter the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis.</p> <p>The Director of Surgical Services reviewed the policy HS-OR0010 Dress Code in the OR with the surgical services staff at the Unit meeting on June 20th. The policy was discussed at the Medical-Executive Meeting on June 20, 2017 by the Vice President of Medical Affairs. The policy will be sent electronically to all member of the Surgery/Anesthesia Department by the Vice President of Medical Affairs by July 11th, 2017.</p> <p>Observations for compliance with the system dress code policy HS-OR0010 Dress Code in the OR, along with observations for compliance with the OR traffic policy</p>	

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P 4603	Continued from page 49	P 4603	(ensuring only appropriate individuals are in the operating rooms) will be completed monthly by the Director of Surgical Services or designee. Thirty observations will be completed each month and reported monthly for three months at the Quality/Risk Committee Meeting, starting August 17, 2017. Thereafter, the information will be reviewed at the regularly scheduled Infection Control meeting on a quarterly basis. Any non-compliance will be addressed with staff following human resources policy. Any non-compliance by members of the medical staff will be addressed as per the medical staff bylaws. All actions described in this plan of correction will be reviewed with the Joint Conference committee at the July 24th, 2017 meeting. This committee consists of the executive board leadership and physician leadership group for the facility.	

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P 4603	Continued from page 50 Based on a review of medical record (MR1), facility documents, and interview with facility staff (EMP), it was determined that UPMC Bedford failed to follow their adopted Infection Control Plan by failing to conduct active surveillance and to restrict unnecessary traffic in the Surgical Suite, by failing to follow policies related to cleaning and to wearing surgical attire outside of the Surgical Suite. Findings Include: UPMC Bedford Memorial, Title: Infection Control Plan and Risk Assessment ... Section IC-01 ... Revised ... 8/16 ... "Purpose: The purpose of this Plan is to provide for a program of surveillance, prevention and control of infection at UPMC Bedford Memorial and the population we serve in our geographical location. In keeping with the mission, vision and value of UPMC Bedford Memorial, the goal of the Infection Control Program is to identify and reduce the risk of acquiring and transmitting infections among patients, employees, physicians and other licensed independent practitioners, contract service workers, volunteers,	P 4603		

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P 4603	Continued from page 51 students and visitors, with attention to: Addressing our prioritized risks. Limiting unprotected exposure to pathogens. Limiting the transmission of infections associated with procedures. Limiting the transmission of infections associated with use of medical equipment, devices and supplies. ... Surveillance, prevention and control of infections cover a broad range of processes and activities. ... The Infection Control Committee and the hospital wide Infection Control Program develop the type of prevention, surveillance and management procedures that relate to infection control as appropriate to UPMC Bedford Memorial. ... 10. Evaluate all procedures and policies pertaining to infection control throughout the organization. This includes but is not limited to, evaluation of housekeeping methods/agents and evaluation of outpatient and ambulatory settings for sound infection prevention/control practices. 11. Revising, updating and approving the Infection Control Departmental guidelines" UPMC Policy and Procedure Manual ... Policy:	P 4603		

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P 4603	Continued from page 52 HS-HM0238-PRO ... Subject: Operating Room Cleaning Procedure, Date: August 5, 2016. "Procedure: It is the procedure of the UPMC to provide clean and safe hospital environment for our patients, visitors and employees, that reduces the possibility of cross infection and enhances the image of the facility. ... II. Purpose: The purpose of this procedure is to establish a standardized cleaning process to properly clean and disinfect the operating room and surgical area immediately after a case is completed and to terminally clean after the last cases of the day. This procedure should be utilized in all highly sterile areas including, but not limited to main OR suites, ... V. Procedure for Between Case Cleaning ... VI. Procedure for Terminal Cleaning" UPMC Bedford Memorial, Title: Cleaning of Operating Rooms, Section OR-07 ... Reviewed 8/16."Purpose: To establish and maintain a clean environment. To reduce the possibility of cross infection among surgical patients and among the surgical patient and operating room personnel."	P 4603		

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P 4603	Continued from page 53 UPMC Bedford Memorial Hospital ... Surgical Services Policy/Procedure Manual ... Section SS-PO-006 ... Title: Patient Safety in the OR. Revision Date 1/14. "... Standard: All patients will be provided safe environment by operating room (OR) personnel while they are in the Surgical Suite. OR personnel include: surgeon and their extender(s), Anesthesiologist and Certified Registered Nurse Anesthetists, Circulating Nurse, Surgical Technician and Environmental Support staff. Policy: ... 8. All personnel in the OR will comply with the UPMC System dress code" UPMC Policy and Procedure Manual, Policy: HS-OR0010. Index Title: Operating Room. ... Subject: Dress Code in the Operating Room, Date: January 27, 2017. "I. Policy: It is the policy for the operating room departments that personnel maintain clean and professional appearance by wearing facility-approved surgical attire ... within the perioperative environment. ... II. Purpose: To provide guidelines to the operating room staff about	P 4603		

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P 4603	Continued from page 54 a professional appearance and overall cleanliness in order to reduce the external source of contamination in semirestricted and restricted areas of the operating room ... III. Scope: This policy applies to all personnel working in the restricted and semirestricted areas of the operating room departments ... IV. Definitions: A. Restricted Area: Includes the operating and procedure rooms and, in some hospitals, the clean core. People in this area are required to wear full surgical attire ... C. Surgical Attire: Non-sterile apparel designated for perioperative practice setting that includes two-piece pantsuits, cover jackets, head coverings, shoes, masks, and protective eyewear. ...V. Procedure: A. ... 5. Worn surgical attire should be changed and returned to scrub exchange system/laundry hamper at the end of the shift and when it becomes visibly soiled, contaminated or wet. ... b) Surgical attire should not be worn to and from home. 6. Visitors are required to be in proper Operating Room attire. This includes either freshly laundered surgical attire or single-use attire. ... B.	P 4603		

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P 4603	Continued from page 55 Head Covering ... 2. When leaving the Surgical Services Department, the disposable head covers should be removed and discarded. ... C. Footwear ... 1. ... c) Shoe covers should be removed when leaving the surgical department. ... 3. Surgical masks should be removed and discarded when leaving the semirestricted areas. Masks should not be worn hanging down from the neck or placed into pockets." 1. A review of UPMC Bedford Incident Report Summary, dated December 2016, through present was conducted and revealed a total of 58 incidents that included but were not limited to: ... infection/return to OR, faulty equipment, missing instrumentation, incorrect sponge count, OR not terminally cleaned (operating room not terminally cleaned (feces on the floor and on the kick bucket), laparoscopic instrumentation not clean prior to start of case, and cancelled OR procedures 2. A request was made to review documentation providing evidence of the "daily" and "between	P 4603		

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P 4603	Continued from page 56 cases" cleaning as per facility policy. EMP25 stated, "I double checked and they are not logging their daily and between case cleanings for the ORs." 3. A request was made to review documentation providing evidence of the Infection Control Officer surveillance rounds in the OR, to monitor the traffic flow (i.e. additional staff in the OR who may not be scrubbed in), proper surgical attire, personal cell phone usage, during procedures on a routine basis. EMP1 confirmed with EMP26 that this has not been done at Bedford in the past. 4. A review of Surgical Quality Assurance/Performance Improvement documentation for the Operating Room dated July 2016, through May 2017, included but was not limited to cleanliness of OR. There was no measurement data entered in the space provided from July 2016, through May 2017. 5. On May 23, 2017, at approximately 11:00 AM, the survey team observed through the Vreeland	P 4603		

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P 4603	Continued from page 57 Conference Room windows, a man exiting the facility and getting into a vehicle wearing blue hospital scrub shirt and pants, shoe coverings, and a cloth hair covering. EMP1 identified the man as EMP6. EMP1 stated that some of the physicians go back and forth between the hospital and their office. The man was not observed returning to the facility, however, the vehicle was returned to it's former parking spot a short time later. 6. A telephone interview was conducted with EMP6 on May 24, 2017, at approximately 3:40 PM and revealed, "... EMP20 came up from my office, but did not assist in the case. When I'm doing a case, I get interrupted for calls, people come in all the time. ... usually a lot of traffic into the Operating Room." 7. The Operative Record and the "Time Out" in MR1 indicated that EMP5, EMP6, EMP7, EMP8, EMP9, and EMP10 were directly involved in the patient's care." EMP20, EMP19, EMP16, EMP11, EMP21 and	P 4603		

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P 4603	Continued from page 58 EMP18 were not documented in MR1 as a care provider during the procedure.	P 4603			



Certified End Page

UPMC BEDFORD

STATE LICENSE NUMBER: 650501

SURVEY EXIT DATE: 06/09/2017

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Handwritten signature of Shannon M. Baker in black ink on a light gray background.

Shannon M. Baker
Acting Deputy Secretary for Quality Assurance

Handwritten signature of Rachel L. Levine, MD in black ink on a light gray background.

Rachel L. Levine, MD
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY