

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 07/17/2009
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 410009 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 07/08/2009 |
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| NAME OF PROVIDER OR SUPPLIER KENT COUNTY MEMORIAL HOSPITAL | STREET ADDRESS, CITY, STATE, ZIP CODE 455 TOLL GATE RD WARWICK, RI 02886 |
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| A 000 | INITIAL COMMENTS A federal complaint investigation was conducted at this facility. State and Federal deficiencies were cited. | A 000 | | |
| A 528 | 482.26 RADIOLOGIC SERVICES The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This CONDITION is not met as evidenced by: Based on medical record review, review of hospital policies and procedures, surveyor observations, and interview with staff, it is determined the hospital failed to provide radiologic therapeutic services that meet professionally approved standards for safety and personnel qualifications for 6 of 8 relevant sample records reviewed. This is related to the occurrence of a wrong side (arm) PICC line insertion, performing a wrong side (hip) arthrogram, failure to perform time out procedures in accordance with policy and procedures in the Interventional Radiology area, failure to inspect image equipment timely, and failure to ensure only qualified staff use fluoroscopic radiological equipment. Findings are as follows: 1) The hospital failed to properly conduct time out procedures in accordance with hospital policy and procedures for 6 of 8 relevant sample patients that received interventional radiologic procedures (Patient ID #'s 1, 19, 20, 21, 27, and 31). | A 528 | | |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A 528 | Continued From page 1 The Hospital policy entitled, "Universal Protocol for Correct Person. Procedure, and Site/Procedure Surgery" states: Under Policy Statement, "It is the policy of Kent Hospital to identify and verify patient, consent, and procedures, including site, side, and levels if applicable for all patients who will undergo surgery or an invasive procedure. Active communication and collaboration between all perioperative/procedural team members is expected. Surgical/Procedural site verification requires a standard procedure with multiple checks in the system to minimize the risk of surgery/procedure on the wrong patient or body part". Under Definitions: Invasive Procedure, it states, "Any procedures involving puncture/incision of the skin or insertion of an instrument or foreign material into the body, including, but not limited to: 1. Procedures performed in Interventional Radiology....." Under VII. Procedures Performed Outside of the Operating Room, it states, under Action, "Four patient identifiers will be used to verify patient ." The Attending Physician, Procedural RN, and patient or patient representative are listed as responsible persons. The four patient identifiers are listed as: name, date of birth, medical record #, and Fin #. For Action requiring "Site Mark", under the Responsible Person, the Attending Physician and patient are listed. Under Special Steps, "Site is marked for all procedures involving laterality. Attending physician will verify and mark site with | A 528 | | | |

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| A 528 | <p>Continued From page 2 the patient".</p> <p>Under Action, "Time Out", the Attending Physician, Procedural RN, and patient/patient representative are listed under Responsible Persons. Under Special Steps, "Prior to performing the procedure physician will initiate Time Out. Physician and RN will verify patient identification, procedure, and site with patient. If there are any discrepancies, the procedure will not be performed until they are resolved".</p> <p>Also, a directive issued from the Educational Department of the hospital to the staff revealed that "Hospital Identification Band Color Coded", relative to red arm bands, Color red states: "DO NOT USE THIS ARM</p> <p>A) Record review for patient ID #1 revealed that on 6/6/09 the patient's right upper extremity was documented as being warm, red, tender, and edematous. A subsequent ultrasound revealed that there was a thrombus involving the basilic vein which was occlusive. There was a partial thrombus in the axillary and subclavian veins. During the patient's stay in the Intensive Care Unit, a red arm band was placed on her right arm to alert staff not to use the right extremity.</p> <p>On 6/10/09 the patient was brought to Interventional Radiology to have a scheduled insertion of a PICC (Peripherally Inserted Central Catheter) line. There was a physician order dated 6/10/09 for "PICC line today please (L) arm".</p> <p>Interview on 6/24/09 at 9:30 AM with two nurses assigned to that case for the day, revealed that the patient arrived in Radiology with a red band on the right arm. Despite the noted red band, the</p> | A 528 | | | |

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| A 528 | <p>Continued From page 3</p> <p>patient's right arm was prepped and draped for the insertion of the PICC line. At 1:54 PM, a PICC line was inserted into the patient's right arm.</p> <p>A subsequent interview on 6/24/09 at 11:00 AM with the Interventional Radiologist revealed that he was not aware that the patient had a red band on the right arm, or that there was a recent thrombus of the right arm.</p> <p>A review of the "Immediate Pre-Procedure Time Out" checklist revealed:</p> <ul style="list-style-type: none"> i) This form was completed by a nurse who did not assist with the procedure, and was completed prior to the procedure's start; ii) A straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out checklist; iii) Under procedure, only "PICC" is listed. No laterality is identified on this form; iv) The form inaccurately indicates that the physician order was verified on two items; v) Although the form indicates that the site was marked with "Visibility of marking within surgical/procedural field", the procedure was performed on the incorrect arm; and, vi) This form indicated that only a physician and a nurse (not the nurse who the completed the form) were in attendance, however a subsequent interview on 6/24/09 with three Radiology Department staff members revealed that staff who were actually in attendance included the physician, an RN, and a Radiologic Technologist. This team did not collaboratively verify procedural site/site in accordance with hospital policy. <p>B) Patient ID #21 had a physician order for a left hip arthrogram on 6/25/09. When the patient was</p> | A 528 | | | |

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| A 528 | <p>Continued From page 4</p> <p>seen by the Radiology team, the patient indicated that it was the right hip that was involved, and the Radiologist proceeded to perform a right hip arthrogram. It was later confirmed on MRI (Magnetic Resonance Imaging) that the involved hip was the left, and the patient returned to Special Procedures for the confirmed left hip arthrogram.</p> <p>Although the patient received the procedure on the incorrect hip, the "Immediate Pre-Procedure Time Out" checklist indicates that the physician order, informed consent, and site were verified.</p> <p>C) Surveyor observation in Interventional Radiology on 6/30/09 at 10:50 AM revealed that Patient ID #20 was scheduled for a Fistulagram of the left arm. During the Time Out Procedure, only the validation of the correct patient and correct procedure was observed. The site was not marked or verified with the patient by the Radiologist per hospital policy.</p> <p>Additionally, the "Immediate Pre-Procedure Time Out" checklist revealed that the Time Out was conducted at 1050. Surveyor observation of this Time Out was at 1115. The required signature for the Procedural Physician was also absent on this checklist.</p> <p>D) During a review of the clinical record for patient ID #27, it was noted that an Arthrogram of the left knee was performed on 6/15/09. There was no evidence that a Time Out had been done. There was no "Immediate Pre-Procedure Time Out" checklist in the medical record. During interview with the Risk Manager on 7/1/09, she was unable to provide evidence of the required checklist.</p> | A 528 | | | |

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| A 528 | Continued From page 5 E) A review of the clinical record for patient ID # 31 revealed a left hip Cortisone injection on 6/12/09. A review of the "Immediate Pre-Procedure Time Out" checklist revealed incomplete documentation. There was no evidence of a Procedural Physician/LIP (Licensed Independent Physician) during the Time Out procedure (i. e., no name is recorded). F) A review of the "Immediate Pre-Procedure Time Out" checklist for patient ID #19 revealed that a straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out, rather than individual checks indicating that each item had been verified. 2) Three of three Fluoroscopic X-Ray units and six of six Fluoroscopic C arms were not at least annually inspected in accordance with the Rhode Island Rules and Regulations for the control of Radiation (R23-1.3-RAD). Refer to 0537. 3) The hospital failed to ensure that only personnel designated as qualified by the medical staff use fluoroscopic radiological equipment. Refer to 0547. 4) The hospital failed to properly maintain medical records for 6 of 8 relevant sampled records reviewed. Refer to 0553. | A 528 | | | |
| A 537 | 482.26(b)(2) PERIODIC EQUIPMENT MAINTENANCE Periodic inspection of equipment must be made and hazards identified must be promptly | A 537 | | | |

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| A 537 | <p>Continued From page 6 corrected.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations and staff interview, it was determined that the hospital failed to periodically conduct inspections for 3 of 3 Fluoroscopic X-Ray units, 6 of 6 Fluoroscopic C arms, and failed to inspect the CT equipment, in accordance with the Rhode Island Rules and Regulations for the control of Radiation (R 23-1.3-RAD).</p> <p>Findings are as follows:</p> <p>Rhode Island Rules and Regulations For The Control Of Radiation" (R23-1.3-RAD), Section F.4.7 state:</p> <p>"...These measurements shall be performed for both maximum and typical values and shall be made at least annually or after any maintenance of the system which might affect the EXPOSURE rate."</p> <p>Surveyor observation on 7/1/09 at 9:30 AM revealed that 3 of 3 Fluoroscopy X-Ray units, that are used for diagnostic X-ray in the Radiology Department, were overdue for annual inspections. In room 3, the last dated inspection was 3/11/08, in room 4 the last dated inspection was 4/6/08, and in room 7 the last dated inspection was 3/16/08.</p> <p>In addition, 6 of 6 Fluoroscopic C-arms in the Main Operating Room were either overdue for inspection or had not been inspected . The Philips C-arm which was in use, had not been inspected. The Philips C-arm for pain management was last inspected on 3/18/07. Two mini C-arms were last</p> | A 537 | | | |

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| A 537 | Continued From page 7 inspected on 3/18/07 and on 12/19/07. Of the two remaining C-arms, one was last inspected on 3/8/07 and the other lacked any inspection date. In addition, surveyor review the of the GE 16 slice CT tube revealed that the tube had been changed on 9-16-08. There was no evidence that a survey of that CT tube was conducted following this maintenance. On 7/1/09, during interview, the Physicist was unable to provide evidence that the image equipment had been inspected on a timely basis. | A 537 | | | |
| A 547 | 482.26(c)(2) QUALIFIED STAFF Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures. This STANDARD is not met as evidenced by: Based on surveyor observation, staff interview, and hospital policy review, it was determined that the hospital failed to ensure that only personnel designated as qualified by the medical staff use radiologic equipment, for 1 of 2 patients who were observed during procedures which required diagnostic fluoroscopy. (Patient ID # 22). Findings are as follows: On 7/2/09 at at 10:40 AM, patient ID # 22 was brought into a procedure room to have a scheduled right hip aspiration under fluoroscopy. Surveyors who were seated in the observation room with the Assistant Vice President (VP) of Diagnostic Imaging observed the Radiologic Technologist position the patient, and then position and operate the fluoroscopic device over the patient's right hip. At that time, the | A 547 | | | |

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| A 547 | Continued From page 8 Technologist was alone in the procedure room with the patient. When questioned, the Assistant VP of Diagnostic Imaging confirmed that the Radiologic Technologist was not qualified to operate the equipment independantly. In addition, the hospital has a policy which states that, "Radiologic Technologists do not perform fluoroscopy procedures independently". | A 547 | | |
| A 553 | 482.26(d) RECORDS FOR RADIOLOGIC SERVICES Records of radiologic services must be maintained. This STANDARD is not met as evidenced by: Based on record review, staff interview, and review of the hospital policy entitled, "Universal Protocol for Correct Person, Procedure and Site Procedure Surgery", it was determined that the hospital failed to properly maintain medical records in accordance with policies and procedures for 6 of 8 relevant sampled medical records reviewed (ID#'s 1,19, 20, 21, 27 and 31). Findings are as follows: The Hospital policy entitled, "Universal Protocol for Correct Person. Procedure, and Site/Procedure Surgery" states: Under Policy Statement, "It is the policy of Kent Hospital to identify and verify patient, consent, and procedures, including site, side, and levels if applicable for all patients who will undergo surgery or an invasive procedure. Active communication and collaboration between all perioperative/procedural team members is expected. Surgical/Procedural site verification requires a standard procedure with multiple | A 553 | | |

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| A 553 | <p>Continued From page 9</p> <p>checks in the system to minimize the risk of surgery/procedure on the wrong patient or body part".</p> <p>Under Definitions: Invasive Procedure, it states, "Any procedures involving puncture/incision of the skin or insertion of an instrument or foreign material into the body, including, but not limited to: 1. Procedures performed in Interventional Radiology....."</p> <p>Under VII. Procedures Performed Outside of the Operating Room, it states, under Action, "Four patient identifiers will be used to verify patient ." The Attending Physician, Procedural RN, and patient or patient representative are listed as responsible persons. The four patient identifiers are listed as: name, date of birth, medical record #, and Fin #.</p> <p>For Action requiring "Site Mark", under the Responsible Person, the Attending Physician and patient are listed. Under Special Steps, "Site is marked for all procedures involving laterality. Attending physician will verify and mark site with the patient".</p> <p>Under Action, "Time Out", the Attending Physician, Procedural RN, and patient/patient representative are listed under Responsible Persons. Under Special Steps, "Prior to performing the procedure physician will initiate Time Out. Physician and RN will verify patient identification, procedure, and site with patient. If there are any discrepancies, the procedure will not be performed until they are resolved".</p> <p>1. Record review for patient ID #1 revealed that</p> | A 553 | | |

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| A 553 | <p>Continued From page 10</p> <p>on 6/6/09 the patient's right upper extremity was documented as being warm, red, tender, and edematous. A subsequent ultrasound revealed that there was a thrombus involving the basilic vein which was occlusive. There was a partial thrombus in the axillary and subclavian veins. During the patient's stay in the Intensive Care Unit, a red arm band was placed on her right arm to alert staff not to use the right extremity.</p> <p>On 6/10/09 the patient was brought to Interventional Radiology to have a scheduled insertion of a PICC (Peripherally Inserted Central Catheter) line. There was a physician order dated 6/10/09 for "PICC line today please (L) arm".</p> <p>Interview on 6/24/09 at 9:30 AM with two nurses assigned to that case for the day, revealed that the patient arrived in Radiology with a red band on the right arm. Despite the noted red band, the patient's right arm was prepped and draped for the insertion of the PICC line. At 1:54 PM, a PICC line was inserted into the patient's right arm.</p> <p>A subsequent interview on 6/24/09 at 11:00 AM with the Interventional Radiologist revealed that he was not aware that the patient had a red band on the right arm, or that there was a recent thrombus of the right arm.</p> <p>A review of the "Immediate Pre-Procedure Time Out" checklist revealed:</p> <p>a) This form was completed by a nurse who did not assist with the procedure, and was completed prior to the procedure's start;</p> <p>b) A straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out checklist;</p> | A 553 | | | |

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| A 553 | <p>Continued From page 11</p> <p>c) Under procedure, only "PICC" is listed. No laterality is identified on this form;</p> <p>d) The form inaccurately indicates that the physician order was verified on two items;</p> <p>e) Although the form indicates that the site was marked with "Visibility of marking within surgical/procedural field", the procedure was performed on the incorrect arm; and,</p> <p>f) This form indicated that only a physician and a nurse (not the nurse who completed the form) were in attendance, however a subsequent interview on 6/24/09 with three Radiology Department staff members revealed that staff who were actually in attendance included the physician, an RN, and a Radiologic Technologist. This team did not collaboratively verify procedural site/side in accordance with hospital policy.</p> <p>2) Patient ID #21 had a physician order for a left hip arthrogram on 6/25/09. When the patient was seen by the Radiology team, the patient indicated that it was the right hip that was involved, and the Radiologist proceeded to perform a right hip arthrogram. It was later confirmed on MRI (Magnetic Resonance Imaging) that the involved hip was the left, and the patient returned to Special Procedures for the confirmed left hip arthrogram.</p> <p>Although the patient received the procedure on the incorrect hip, the "Immediate Pre-Procedure Time Out" checklist indicates that the physician order, informed consent, and site were verified.</p> <p>3. Observation in Interventional Radiology on 6/30/09 at 10:50 AM revealed that Patient ID #20 was scheduled for a Fistulagram of the left arm. During the Time Out Procedure, only the validation of the correct patient and correct</p> | A 553 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 07/17/2009
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 410009 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 07/08/2009 |
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| A 553 | Continued From page 12 procedure was observed. The site was not marked or verified with the patient by the Radiologist per hospital policy. Additionally, the "Immediate Pre-Procedure Time Out" checklist revealed that the Time Out was conducted at 1050. Surveyor observation of this Time Out was at 1115. The required signature for the Procedural Physician was also absent on this checklist. 4. During a review of the clinical record for patient ID #27, it was noted that an Arthrogram of the left knee was performed on 6/15/09. There was no evidence that a Time Out had been done. There was no "Immediate Pre-Procedure Time Out" checklist in the medical record. During interview with the Risk Manager on 7/1/09, she was unable to provide evidence of the required checklist. 5. A review of the clinical record for patient ID # 31 revealed a left hip Cortisone injection on 6/12/09. A review of the "Immediate Pre-Procedure Time Out" checklist revealed incomplete documentation. There was no evidence of a Procedural Physician/LIP (Licensed Independent Physician) during the Time Out procedure (i. e., no name is recorded). 6. A review of the "Immediate Pre-Procedure Time Out" checklist for patient ID #19 revealed that a straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out, rather than individual checks indicating that each item had been verified. | A 553 | | | |
| A 959 | 482.51(b)(6) OPERATIVE REPORT An operative report describing techniques, findings, and tissues removed or altered must be | A 959 | | | |

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| A 959 | Continued From page 13 written or dictated immediately following surgery and signed by the surgeon. This STANDARD is not met as evidenced by: Based on medical record review and staff interview, it was determined that the hospital failed to ensure that Operative Reports include the times of surgery for 4 of 4 relevant sample patients (ID #'s 4, 5, 6 and 7). Findings are as follows : A review of the Operative Reports for patient ID #'s 4, 5, 6 and 7 revealed no evidence that the times of surgery were included in this report. During an interview on 6/30/09 at 2:15 PM with the Manager of HIS (Health Information Systems), a "Documentation Guide" designed to be used for the development of Operative Reports was provided, and this did not include the time of surgery. | A 959 | | |
| A1045 | 482.53(c) EQUIPMENT MAINTENANCE [The equipment must be--] Maintained in safe operating condition; and Inspected, tested and calibrated at least annually by qualified personnel. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, it was determined that the hospital failed to perform dose calibrator accuracy tests on Nuclear Medicine equipment annually. Findings are as follows: | A1045 | | |

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| A1045 | <p>Continued From page 14</p> <p>According to the Rhode Island Rules and Regulations For The Control Of Radiation (R23-1.3-RAD), Paragraph C.8.14(b)(1)(ii) of the RI RCA Regulations requires that a licensee shall possess a dose calibrator test for accuracy upon installation, and at intervals not to exceed 12 months thereafter by assaying a reference source of the most frequently used radionuclide.</p> <p>On 7/2/09 at 11:30 AM, a tour of the Nuclear Medicine Department revealed that annual accuracy tests and calibration had not been done within twelve months of the last test. As of 7/2/09, the dose calibrator accuracy test had not been accomplished since May 2008, a period in excess of 12 months. Specifically, the Nuclear Medicine Department dose calibrator, Capintec CRC-15W S/N 17007, was last tested for accuracy on 5/22/08.</p> <p>Additionally, this instrument was previously tested for accuracy in May 2006 and not again until July 2007, a period in excess of 12 months. During an interview with the Nuclear Medicine Supervisor on 7/2/09, it was confirmed that the dose calibrator accuracy tests had not been done.</p> <p>1</p> | A1045 | | | |

RI Department of Health

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| Z 160 | <p>ORGANIZATION & MANAGEMENT 12.2 Organization</p> <p>12.2 Each hospital department and service shall maintain:</p> <p>a) clearly written definitions of its organization, authority, responsibility and relationships;</p> <p>b) written patient care policies and procedures; and</p> <p>c) written provision for systematic evaluation of programs and services.</p> <p>This Requirement is not met as evidenced by: Based on clinical record review, staff interview, and review of the hospital policy entitled "Universal Protocol for Correct Person, Procedure and Site Procedure Surgery", it was determined that the hospital failed to follow this policy, related to the Interventional Radiology Time Outs, for 6 of 8 relevant sampled patients (ID#'s 1, 19, 20, 21, 27 and 31), and failed to follow the "Hospital Identification Band Color Coded" directive related to red arm bands for 1 of 1 relevant sample patient (ID #'s 1).</p> <p>Findings are as follows:</p> <p>The Hospital policy entitled, "Universal Protocol for Correct Person. Procedure, and Site/Procedure Surgery" states:</p> <p>Under Policy Statement, "It is the policy of Kent Hospital to identify and verify patient, consent, and procedures, including site, side, and levels if applicable for all patients who will undergo surgery or an invasive procedure. Active communication and collaboration between all perioperative/procedural team members is expected. Surgical/Procedural site verification requires a standard procedure with multiple checks in the system to minimize the risk of surgery/procedure on the wrong patient or body</p> | Z 160 | | |

Facilities Regulation

TITLE

(X6) DATE

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

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| Z 160 | Continued From page 1 part". Under Definitions: Invasive Procedure, it states, "Any procedures involving puncture/incision of the skin or insertion of an instrument or foreign material into the body, including, but not limited to: 1. Procedures performed in Interventional Radiology....." Under VII. Procedures Performed Outside of the Operating Room, it states, under Action, "Four patient identifiers will be used to verify patient ." The Attending Physician, Procedural RN, and patient or patient representative are listed as responsible persons. The four patient identifiers are listed as: name, date of birth, medical record #, and Fin #. For Action requiring "Site Mark", under the Responsible Person, the Attending Physician and patient are listed. Under Special Steps, "Site is marked for all procedures involving laterality. Attending physician will verify and mark site with the patient". Under Action, "Time Out", the Attending Physician, Procedural RN, and patient/patient representative are listed under Responsible Persons. Under Special Steps, "Prior to performing the procedure physician will initiate Time Out. Physician and RN will verify patient identification, procedure, and site with patient. If there are any discrepancies, the procedure will not be performed until they are resolved". Also, a directive issued from the Educational Department of the hospital to the staff revealed that "Hospital Identification Band Color Coded", relative to red arm bands, Color red states: "DO NOT USE THIS ARM | Z 160 | | |

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| Z 160 | Continued From page 2 1) Record review for patient ID #1 revealed that on 6/6/09 the patient's right upper extremity was documented as being warm, red, tender, and edematous. A subsequent ultrasound revealed that there was a thrombus involving the basilic vein which was occlusive. There was a partial thrombus in the axillary and subclavian veins. During the patient's stay in the Intensive Care Unit, a red arm band was placed on her right arm to alert staff not to use the right extremity. On 6/10/09 the patient was brought to Interventional Radiology to have a scheduled insertion of a PICC (Peripherally Inserted Central Catheter) line. There was a physician order dated 6/10/09 for "PICC line today please (L) arm". Interview on 6/24/09 at 9:30 AM with two nurses assigned to that case for the day, revealed that the patient arrived in Radiology with a red band on the right arm. Despite the noted red band, the patient's right arm was prepped and draped for the insertion of the PICC line. At 1:54 PM, a PICC line was inserted into the patient's right arm. A subsequent interview on 6/24/09 at 11:00 AM with the Interventional Radiologist revealed that he was not aware that the patient had a red band on the right arm, or that there was a recent thrombus of the right arm. A review of the "Immediate Pre-Procedure Time Out" checklist revealed: i) This form was completed by a nurse who did not assist with the procedure, and was completed prior to the procedure's start; | Z 160 | | | |

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| Z 160 | <p>Continued From page 3</p> <p>ii) A straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out checklist;</p> <p>iii) Under procedure, only "PICC" is listed. No laterality is identified on this form;</p> <p>iv) The form inaccurately indicates that the physician order was verified on two items;</p> <p>v) Although the form indicates that the site was marked with "Visibility of marking within surgical/procedural field", the procedure was performed on the incorrect arm; and,</p> <p>vi) This form indicated that only a physician and a nurse (not the nurse who the completed the form) were in attendance, however a subsequent interview on 6/24/09 with three Radiology Department staff members revealed that staff who were actually in attendance included the physician, an RN, and a Radiologic Technologist. This team did not collaboratively verify procedural site/side in accordance with hospital policy.</p> <p>2) Patient ID #21 had a physician order for a left hip arthrogram on 6/25/09. When the patient was seen by the Radiology team, the patient indicated that it was the right hip that was involved, and the Radiologist proceeded to perform a right hip arthrogram. It was later confirmed on MRI (Magnetic Resonance Imaging) that the involved hip was the left, and the patient returned to Special Procedures for the confirmed left hip arthrogram.</p> <p>Although the patient received the procedure on the incorrect hip, the "Immediate Pre-Procedure Time Out" checklist indicates that the physician order, informed consent, and site were verified.</p> <p>3) Surveyor observation in Interventional Radiology on 6/30/09 at 10:50 AM revealed that Patient ID #20 was scheduled for a Fistulagram</p> | Z 160 | | |

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| Z 160 | Continued From page 4 of the left arm. During the Time Out Procedure, only the validation of the correct patient and correct procedure was observed. The site was not marked or verified with the patient by the Radiologist per hospital policy. Additionally, the "Immediate Pre-Procedure Time Out" checklist revealed that the Time Out was conducted at 1050. Surveyor observation of this Time Out was at 1115. The required signature for the Procedural Physician was also absent on this checklist. 4) During a review of the clinical record for patient ID #27, it was noted that an Arthrogram of the left knee was performed on 6/15/09. There was no evidence that a Time Out had been done. There was no "Immediate Pre-Procedure Time Out" checklist in the medical record. During interview with the Risk Manager on 7/1/09, she was unable to provide evidence of the required checklist. 5) A review of the clinical record for patient ID # 31 revealed a left hip Cortisone injection on 6/12/09. A review of the "Immediate Pre-Procedure Time Out" checklist revealed incomplete documentation. There was no evidence of a Procedural Physician/LIP (Licensed Independent Physician) during the Time Out procedure (i. e., no name is recorded). 6). A review of the "Immediate Pre-Procedure Time Out" checklist for patient ID #19 revealed that a straight line had been drawn down this form, indicating "Yes" to all requirements on the Time Out, rather than individual checks indicating that each item had been verified. | Z 160 | | | |
| Z 370 | PATIENT CARE SERVICES 19.6 Patient Care Management | Z 370 | | | |

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| Z 370 | Continued From page 5 19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by: Based on record review and staff interview, it was determined that the hospital failed to provide care and services in accordance with the prevailing community standard of care related to the failure to implement physician orders for 2 of 2 relevant sample patients (ID #'s 1 and 21). Findings are as follows: 1. Record review for patient ID #1 revealed a physician order dated 6/10/09 for "PICC line today please (L) arm". On 6/10/09 the patient was brought to Interventional Radiology for the scheduled insertion of the PICC (Peripherally Inserted Central Catheter) line. However, the PICC line was inserted by the Radiologist in the right arm. 2. Patient ID #21 had a physician order for a left hip arthrogram on 6/25/09. A Hospital Occurrence Report review revealed that when the patient was seen by the Radiology team, the patient indicated that it was the right hip that was involved, and the Radiologist proceeded to perform a right hip arthrogram. | Z 370 | | | |
| Z 940 | PATIENT CARE SERVICES 34.8 Reportable Incidents 34.8 Any reportable incident occurring on or after June 30, 1994 shall be reported in writing to the Department of Health within seventy-two (72) hours of when the hospital has reasonable cause | Z 940 | | | |

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| Z 940 | Continued From page 6 to believe an incident has occurred. Any incident(s) occurring prior to June 30, 1994 need not be reported. This Requirement is not met as evidenced by: Based on review of hospital occurrence reports submitted to the Department of Health, it was determined that the hospital failed to report to the Department of Health, within 72 hours, reportable incidents for 2 of 2 relevant sampled patients (ID #'s 1 and 21). Findings are as follows: 1. Patient ID #1 had a physician order for a PICC (Peripherally Inserted Central Catheter) line to be placed in the left arm . On 6/10 /09 the Radiologist placed this PICC line in the right arm. This was not reported to the Department of Health until 6/19/09. 2. Patient ID # 21 had an arthrogram performed on 6/25/09 on the right hip, instead of the intended left hip. This was verbally reported to the Department of Health on 6/30/09. | Z 940 | | | |