

**State of Connecticut  
Department of Public Health  
Division of Health Systems Regulation**

IN RE: Connecticut Children's Medical Center  
282 Washington Street  
Hartford, CT 06106

CONSENT AGREEMENT

WHEREAS, Connecticut Children's Medical Center of Hartford, CT. (hereinafter the "Licensee"), has been issued License No. 2-CH to operate a Children's Hospital (hereinafter the "Facility") under Connecticut General Statutes Section 19a-490, by the Department of Public Health (hereinafter the "Department"); and

WHEREAS, the Department's Division of Health Systems Regulation (DHSR) conducted unannounced inspections at the Facility on various dates commencing July 1, 2004 and concluding on August 10, 2004 and additional unannounced visits commencing February 20, 2005 and concluding March 31, 2005, for the purposes of conducting multiple investigations; and

WHEREAS, during the course of the aforementioned inspections, violations of the Regulations of Connecticut State Agencies were identified in violation letters dated September 2, 2004 (Exhibit A), October 27, 2004 (Exhibit B), and April 11, 2005 (Exhibit C); and

WHEREAS, office conferences regarding the September 2, 2004 and April 11, 2005 violation letters were held between the Department and the Licensee on September 21, 2004 and April 19, 2005 respectively; and

WHEREAS, the Licensee without admitting any wrongdoing is willing to enter into this Consent Agreement and agrees to the conditions set forth herein.

NOW THEREFORE, the Division of Health Systems Regulation of the Department of Public Health of the State of Connecticut, acting herein by and through Marianne Horn, its Director, and the Licensee, acting herein by and through Larry M. Gold, its President and Chief Executive Officer, hereby stipulate and agree as follows:

1. The Licensee shall within fourteen (14) days of the execution of this Consent Agreement select an established Medical Management Consultant Firm (MMCF) that has expertise in professional and medical health care services.
2. The Department shall approve the MMCF selected by the Licensee prior to the Licensee contracting with the MMCF. The Licensee shall enter into a contract with the MMCF within fourteen (14) days of approval by the Department.
3. The MMCF shall, at a minimum, conduct onsite reviews of hospital systems and direct observations of Connecticut Children's Medical Center's (CCMC) staff performance as further specified in paragraph 4 of the Agreement. The MMCF team shall consist of the following professionals:
  - a. Radiologist;
  - b. Emergency Department (ED) Trauma Physician;
  - c. Security Consultant;
  - d. ED Trauma Nurse; and
  - e. Other individuals as deemed necessary by the MMCF to fulfill the requirements of this Consent Agreement.

The Licensee and its staff shall cooperate fully with the MMCF team as it conducts its review and observations.

4. The MMCF shall be contracted to review the following professional and hospital services and systems and to make recommendations for improvements:
  - a. Systems and mechanisms relative to safety and security involving patients;
  - b. Systems for the exchange of diagnostic information relative to patients receiving services in the ED with an emphasis on radiological services when the Facility's radiologist is not available, and on timely sharing of diagnostic information;

- c. Review of health care services not directly provided by the Facility (e.g. contracted services including, but not limited to, off hours radiology, shared ED staffing, pharmacy and laboratory services);
  - d. Review of findings identified in violation letters identified as Exhibits A, B and C, and the Plans of Correction (Exhibits D and E);
  - e. Review of the Facility's Patient Safety and Performance Improvement Programs with emphasis on their ability to detect and respond to system failures;
  - f. Review of the Facility's professional credentialing process, assessment process for evaluating competency and remediation mechanisms; and
  - g. Review of systems for coordination of interdisciplinary ED patient assessments, documentation and triage.
5. The MMCF and the Licensee shall enter into a written contract that includes the following requirements of this Consent Agreement: timeframes for the initial evaluation, the number and the credentials of individuals conducting the review, and the timeframes for the analysis and development of recommendations. Initial onsite review shall be completed within thirty (30) days of the execution of the contract. The contract shall also specify that the MMCF shall return to the Facility six (6) months after the issuance of its report to review the Licensee's implementation and monitoring of recommendations set forth in the report.
  6. The MMCF shall have thirty (30) days after the completion of the initial onsite review, to develop a report(s) and provide copies to the Licensee and Department. Neither party shall be provided with the opportunity to review the report(s) prior to release and both parties shall receive copies of the documents simultaneously. The report(s) shall identify methods utilized for the analysis, areas reviewed and process, findings and recommendations. If the Licensee disagrees with any MMCF findings or recommendations, the Licensee, the MMCF and the Department shall meet to discuss issues of disagreement and the Licensee shall have the right to present information relating to the Licensee's areas of disagreement. The Department shall have the final determination to accept or reject the MMCF's recommendations should the parties not be able to reach a

mutual agreement. The MMCF recommendations with DPH revisions, if any shall be considered part of this Agreement and may be enforced, if not complied with, as provided in paragraph 19, below.

7. The Licensee shall provide the Department with a proposed timeframe for implementation of the MMCF recommendations, within twenty-one (21) days of receipt of the report(s). The timeframes shall be subject to approval by the Department and shall become operative upon the Department approval. All recommendations shall be implemented in accordance with the Department's approved timeframe.
8. The Licensee shall provide copies of this executed Agreement, including Exhibits A, B, C, D and E to all medical and professional nursing staff in the Performance Improvement, Security, Radiology and Emergency Departments at CCMC and solicit comments for improvements of systems management within the Facility. The Licensee shall also provide an in-service program to all medical and professional staff regarding the content of the Consent Agreement, including the exhibits, for the purpose of soliciting comments for improvement of systems management within the Facility.
9. The Licensee shall institute the mechanisms established in the Licensee's Plans of Correction (Exhibits D and E) in accordance with the timeframes specified in those Plans of Correction, after such Plans of Correction are approved by the Department to protect the patient population and ensure quality of care and services during the time period when the MMCF is performing its review and evaluation at the Facility. Such mechanisms shall be monitored and evaluated on an ongoing basis.
10. The Licensee shall provide an in-service program prior to January 1, 2006 available to all Connecticut hospitals relative to the issues identified as a result of this MMCF review process.
11. The program identified in paragraph 10 shall be videotaped and made available to Connecticut health care institutions, upon request, and without charge.

12. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Agreement shall be made available to the Department upon request.
13. The Licensee shall designate a physician on all shifts who has responsibility for supervision of physician patient care in the ED including the assessment of patients, interpretation and/or communication of radiology interpretations and the care provided by ED staff. The supervising physician shall maintain a record of any physician /patient care related issue(s) or problem(s) identified by or reported to such supervising physician. The Medical Director of the Emergency Department shall maintain a record of subsequent action taken to resolve such problem(s) and shall include staff competency evaluation(s) as necessary. Said documents shall be available to the Department and shall be retained for a period of three (3) years.
14. The Licensee shall designate one individual who shall assume the overall responsibility for full implementation of this Consent Agreement. The Department shall be notified as to the identity of this person within seven (7) days of the effective date of this Consent Agreement. A report regarding Licensee compliance with this Consent Agreement shall be forwarded to the Department on a monthly basis for the first six (6) months and every three (3) months thereafter, by the individual identified by the Licensee.
15. The terms of the Consent Agreement shall remain in effect for a period of two (2) years from the effective date of this document, subject to the requirement that the recommendations referred to in paragraph 7 of the Consent Agreement shall be implemented prior to the expiration of the term of the Consent Agreement.
16. The Licensee agrees to a monetary payment of a total of two hundred and fifty thousand dollars (\$250,000.00). An initial payment of one hundred thousand dollars (\$100,000.00) shall be made by money order or bank check payable to the Treasurer of the State of Connecticut and sent to the Department within two (2) weeks after the execution of this Consent Agreement by the Licensee and the Department. The reasonable and verified costs of the in-service program described in paragraph 10 of this Agreement may be deducted from the remaining

one hundred fifty thousand dollars (\$150,000.00) monetary payment after approval of such costs by the Department. The balance of the monetary payment shall be made by money order or bank check payable to the Treasurer of the State of Connecticut and sent to the Department within two (2) weeks after the completion date of the in-service program.

17. In accordance with Connecticut General Statutes Section 19a-494(a)(5), the license of Connecticut Children's Medical Center is placed on probation for a period of the term of this Consent Agreement. After this Consent Agreement has been in effect for one full year, the Licensee may request that the Department terminate the probation on the license of Connecticut Children's Medical Center. The Department may, in its sole discretion, grant such a request, taking into consideration the Licensee's compliance with this Consent Agreement over the course of its effective period.
18. All meetings, documents and the monetary payments required by this document shall be scheduled with or sent to:

Ann Marie Montemerlo, R.N.  
Supervising Nurse Consultant  
Department of Public Health  
Division of Health Systems Regulation  
410 Capitol Avenue, MS #12HSR  
P.O. Box 340308  
Hartford, CT 06134-0308

19. All parties agree that this Consent Agreement is an order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of this Consent Agreement or of any statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, or any other administrative and judicial relief provided by law. This Consent Agreement may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. At any such proceeding, the sole issue that may be contested is compliance with the terms of this Agreement. The Licensee otherwise retains all of its rights under applicable law.

20. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the DCJ's Statewide Prosecution Bureau.

IN WITNESS WHEREOF, the parties hereto have caused this Consent Agreement to be executed by their respective officers and officials, which Consent Agreement is to be effective as of the later of the two dates noted below.

CONNECTICUT CHILDREN'S MEDICAL CENTER OF HARTFORD, CT. - LICENSEE

May 3, 2005  
Date

By: [Signature]  
Larry M. Gold, President and Chief Executive Officer

State of Connecticut)  
County of Hartford

ss 3rd of May, 2005

Personally appeared the above named Larry M. Gold and made oath to the truth of the statements contained herein.

My Commission Expires: 10/31/2006

[Signature]  
Notary Public   
Justice of the Peace   
Town Clerk   
Commissioner of the Superior Court

STATE OF CONNECTICUT,  
DEPARTMENT OF PUBLIC HEALTH

May 3, 2005  
Date

By: [Signature]  
Marianne Horn, R.N., J.D., Director  
Division of Health Systems Regulation

DATES OF VISITS: July 1, 2, 6 and 10, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

1. Based on clinical record review and interviews, the hospital failed to ensure that Patient #1 received care in a safe setting. The findings include:
  - a. Patient #2, born on 5/23/04, was in the process of being remitted to the care of DCF due to safety concerns regarding the patient's mother. Review of the clinical record and interviews with facility staff identified that on 6/30/04 at 8:20 AM, the baby was seen in the mother's arms, walking on unit. A "few minutes later," the mother and baby were nowhere to be found and staff began looking for them. Instead of activating the hospital's "Part A" abduction policy, staff notified 1st floor security that Patient #2 could not be located, and security stated they would "keep an eye out for them." The director of nurses was then notified of the issue and called another security staff member, who then activated "Part A" at 8:33 AM. Patient #2 was taken from the hospital on 6/30/04 at about 8:20 AM and was not returned until 7/1/04 at 11:45 PM. Review of the hospital's "Part A" policy identified that if staff suspected a patient was abducted, they should immediately contact security at a specific telephone number, and security would initiate the Emergency Operations Plan that included securing all entrances and exits. Then a search of the unit would take place. Interview with the VP of patient care services identified that both calls to security staff were made to internal security staff and not to the hospital's main number, per policy.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and/or (i) General (7).

2. Based on clinical record review and interviews, the hospital failed to develop and/or keep current, a care plan to ensure the safety of Patients #2 and #23. The findings include:
  - a. Patient #2 was born on 5/23/04, and was being treated for drug withdrawal. Patient #2 was in the process of being remitted to the care of DCF. The patient's parents were active in the patient's care and treatment and although social workers and DCF had met with the mother, there was no evidence that a clear plan of care and/or discharge plan had been established or that the mother was included in the discharge plans. A nurse's note dated 6/29/04 identified that a 72-hour hold was to be placed on the baby and it was unclear if the baby's mother knew about the DCF plan. Patient #2 was taken from the hospital by the mother prior to the initiation of the hold.
  - b. Patient #2's physician and social worker submitted affidavits to the court dated 6/22/04 that identified the patient would be at risk for abuse/neglect in the care of the mother. Also, on 6/22/04 a resident physician identified that the mother needed supervised visits due safety concerns regarding care and also posed a

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flight risk. Social workers discussed the issue of the mother being a flight risk, DCF was contacted regarding that risk, and DCF identified that the mother still retained custody of the baby and may visit unsupervised. There were no interventions initiated by the hospital, in response to the identified risks. On 6/30/04 at about 8:20 AM, the mother left the hospital with Patient #2 without the knowledge of staff and without discharge orders. Following police intervention, Patient #2 was returned on 7/1/04 at 11:45 PM without incident or harm.

- c. Patient #23 was born on 7/7/04 and had a problem of withdrawal due to drug dependency. A nursing progress note dated 7/23/04 identified a problem with the mother being a potential "flight risk" in that she had expressed an interest in taking the baby into her custody. The current discharge plan identified that the baby was to go home with the paternal aunt. The Department of Children and Families was also involved in this decision. A review of the nursing care plan did not identify any concerns and/or interventions relative to the assessment that the baby's mother was a potential flight risk.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (c) Nursing Service (1).

3. The hospital failed to ensure that the emergency needs of Patients #3, #5, #7 and #8 were met in that abnormal radiology tests were incorrectly interpreted and/or emergency department physicians failed to identify diagnosis identified by radiology staff. The findings are based on clinical record reviews and staff interviews and include the following:
  - a. Review of the medical record identified that Patient #3 had a past medical history of Sickle Cell Disease (SS type), acute splenic sequestration (5/02, 11/02, 4/03 and 8/03), acute chest syndrome (12/3/03) and asthma. On 3/17/04 at 9:05 PM, Patient #3 presented to the ED with complaints of fever, cough and cold symptoms. Review of MD #2's assessment dated 3/17/04 at 10:50 PM documented that the patient has had an upper respiratory infection over the past week with cough and occasional wheeze with a two day history of Albuterol treatments being administered every four hours, a recent back pain crisis for seven days (treated at home) and a temperature of 102.0 on 3/17/04. Review of MD #2's examination dated 3/17/04 identified that the patient's spleen was enlarged approximately 5 centimeters (cm) to tip of umbilicus and was non-tender. Review of the clinical record and interview with MD #2 identified that APRN #1 was consulted following her assessment on 3/17/04 and confirmed the patient's baseline spleen size was approximately 5 cm's in

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- size. A chest x-ray was performed on 3/17/04 and read by MD #2 as no active disease. At 12:00 AM on 3/18/04 the patient was discharged home on oral antibiotics and instructed to follow up with the hematology clinic the next day (3/18/04). On 3/18/04, MD #12 (Radiologist) reviewed Patient #3's chest x-ray performed on 3/17/04 and made a diagnosis of left lower lobe infiltrate consistent with acute chest. Subsequently the ED completed a follow-up record dated 3/18/04 that identified the Radiology reading results and APRN #1 was faxed the history, physical and discharge instructions. Review of the facility's policy for Acute Chest Syndrome in Sickle Cell Disease defined Acute Chest Syndrome as a new infiltrate on chest x-ray with one or more of the following: tachypnea, fever greater than 101.3, chest pain, cough, wheezing and hypoxemia (room air SaO<sub>2</sub> 3-5% points less than baseline). Management included admission to the regular inpatient care unit and administration of intravenous antibiotics. Upon interview MD #7 stated that he reviewed Patient #3's record and chest x-ray film from the ED visit on 3/17/04 and felt as though the linear opacity was not consistent with a significant infiltrate, did not notify the parents and had planned to follow-up with the patient the next day (3/19/04). Interview with MD #14 (Director of Hematology/Oncology) identified that a left lower lobe infiltrate was not considered a normal chest x-ray and he would expect staff to inform the parents of these results. Upon interview Person #1 stated that she called APRN #1 on 3/18/04 in the morning, was told that the IV Rocephin would provide 24 hour coverage, to continue with the oral antibiotics and bring the patient back into the ED with an elevated temperature. Person #1 and Person #3 stated that they were never informed of their child's positive x-ray results.
- b. Patient #5 presented to the Emergency Department (ED) on 12/16/03 at 11:30 AM with abdominal pain and fever. Past medical history included ileal atresia and a question of intussusception. Patient #5's temperature at 1:30 PM on 12/16/03 was identified to be 102.9 degrees and staff administered an antipyretic. An abdominal film (KUB) was ordered to rule out small bowel obstruction. At 4:13 PM on 12/16/03 the x-ray was taken and read by MD #5 (Radiologist). MD #5 stated he reviewed the film and wrote "pneumonia" on the x-ray sleeve then sent the x-ray back to the ED. Review of the clinical record with MD #8 identified that the pneumonia diagnosis written on the x-ray sleeve was missed and the patient was subsequently discharged home at 7:30 PM on 12/16/03 with a diagnosis of vomiting and dehydration. Review of the dictated abdominal film reflected the date of the exam was 12/16/03 and identified a likely middle lobe pneumonia right lower lung. On 12/22/03,

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- Patient #5 returned to the ED via ambulance with difficulty breathing and was subsequently admitted to the hospital. Admission diagnosis included right middle and lower lobe pneumonia with a significant pleural effusion that required a chest tube for drainage and intravenous antibiotics for the pneumonia. On 1/2/04 the patient was discharged home. Interview with MD #5 and review of the facility's policy for x-rays identified that between the hours of 8:00 AM and 5:00 PM, the Radiologist will read the x-ray, write the report immediately on the insert of the x-ray and the Technologist returns the x-ray jacket to the ED. The Radiologist dictates the report as he is writing on the jacket and the report is available within 24 to 48 hours. After 5:00 PM Monday through Friday and Weekends, the ED physicians read their own films with the availability of the Radiology Resident in the ED at Hartford Hospital and the Attending Radiologist on call. The following morning the Radiologist will read all ED cases from the previous night and fill out a discrepancy form when required. This form is hand delivered by the Radiologist to the ED Attending where it then becomes the responsibility of the ED physician to follow-up as needed.
- c. Patient #7 presented to the Emergency Department (ED) on 6/14/04 at 10:25 AM with a five (5) day history of coughing, vomiting, decreased food/fluid intake and an elevated temperature. Patient #7 was noted to have a past medical history of asthma. Review of facility documentation identified that a chest x-ray was performed at 11:46 am on 6/14/04 and a diagnosis of left lower lobe pneumonia with effusion was transcribed onto the sleeve of the x-ray jacket by the Radiologist. Review of the ED record with MD #9 (ED physician) revealed documentation that the patient had slightly decreased aeration at the right lung base therefore a chest x-ray was performed. MD #9 stated she interpreted the film as: lungs "hyperinflated". Subsequently the patient was discharged home at 1:00 PM on 6/14/04 with a diagnosis of cough and exacerbation of asthma. Upon interview with MD #9 stated that she was not aware of the Radiologists impression transcribed on the x-ray. Review of the ED follow-up record dated 6/15/04 reflected that the patients Primary Care Physician was contacted on 6/15/04 related to the pneumonia diagnosis and antibiotic therapy was prescribed.
- d. Patient #8 presented to the Emergency Department (ED) on 3/21/04 at 5:45 PM with right inguinal pain. Review of the ED record with MD #6 identified that an abdominal film was performed at 6:52 PM on 3/21/04, was unremarkable, a diagnosis of constipation was concluded and the patient was discharged home at 8:05 PM on 3/21/04. Review of the ED follow-up record

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dated 3/22/04 reflected that the abdominal film was reviewed by the Radiologist and identified possible left lower lobe pneumonia. Subsequently, MD #9 informed Patient #8's Primary Care Physician on 3/22/04 of the above finding for appropriate follow-up. Interview with MD #6 stated that the focus of the x-ray was on the abdomen and that based upon assessment, she had no reason to suspect pneumonia and/or have the film reviewed by the ED Radiologist at Hartford Hospital.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (j) Emergencies (2) and/or (i) General (7).

4. Based on clinical record review and staff interviews, the facility failed to ensure that policies and procedures governing medical care were followed for one Patient (Patient #3). In addition, for Patient #19, #20, #21 and #22, the facility failed to ensure that the radiology Requisition/Preliminary Interpretation report was complete. The findings include the following:
  - a. Review of a Referral Call Form dated 3/19/04 at 1:45 AM identified that MD #14 (Director of Hematology) notified MD #3 (ED Attending) that Patient #3 had a history of sickle cell disease and would be coming to the ED secondary to back pain unrelieved with Tylenol with Codeine and Motrin. MD #14 requested IV fluid, morphine and Toradol be utilized as part of the treatment plan. Review of the ED triage record with RN #2 dated 3/19/04 identified that the patient arrived at 3:00 AM on 3/19/04, medications received prior to arrival included one teaspoon of Tylenol with Codeine at 11:30 PM (3/18/04) and Motrin two-teaspoons at 12:00 am (3/19/04). Review of Patient #3's vital signs upon arrival to the ED identified a temperature of 96.7 (route not specified), pulse 96, respirations 22 and blood pressure 110/51. The record lacked documentation that an oxygen saturation was assessed. Review of MD #4's (Resident) assessment dated 3/19/04 at 3:45 AM identified that the patient's past medical history included sickle cell disease (SS) and asthma. MD #4 documented that the patient presented with reported lower back pain per parents, which began at 11:00 PM on 3/18/04 and did not respond to Tylenol with Codeine or Motrin. Review of MD #4's examination performed at 3:45 AM on 3/19/04 lacked documentation that a complete review of systems was completed (sections included: general, head, ears, nose, nodes, chest, genitourinary, rectal, neurologic and psychologic). Interview with MD #4 stated that although specifics are not described in these areas, he documented in the review of systems (ROS) box that all systems were

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negative. Review of the abdominal assessment was not clearly documented as evidenced by an erroneous mark that was unclear. Interview with MD #4 stated that this mark was a zero sign which meant no HSM (hepatic splenomegaly). MD #4 stated that he did not remark on the size of the liver or spleen because he was not able to palpate these organs. Two days prior to this examination, the patient's abdominal assessment identified that the patient's spleen was enlarged, which was baseline for this patient. MD #4 stated that although he did not observe the patient to be in pain, he directed that Tylenol with Codeine and Motrin be administered to keep the patient comfortable. Upon interview MD #4 stated blood work was not drawn because labs from the 3/17/04 visit were good, blood culture results were negative for 24 hours and that IV fluids were not indicated because the patient's vital signs were stable and the patient had a moist oral mucosa. Review of the ED record with MD #3 identified that Patient #3 was comfortable and sleeping, the patient's pain was referred to as a vaso-occlusive crisis common in sickle cell patient's and the physician did not feel as though IV fluid, morphine or toradol were warranted. MD #3 stated that he examined the patient's abdomen and could not recall any significant findings concurred with MD #4's assessment (no abnormal abdominal assessment) and signed off on the record. MD #3 and MD #4 stated that they were not aware of the (abnormal) chest x-ray result from 3/17/04 but did review prior lab results and MD #2's assessment from that ED visit dated 3/17/04. Upon interview with Person #1 and Person #3 stated they remained with their child (Patient #3) during the entire ED visit dated 3/19/04 and the only assessment performed by MD #4 was to assess capillary refill by touching Patient #3's finger. Person #1 and Person #3 stated that no other assessments were conducted. Upon additional interviews Person #1 and Person #3 stated that MD #3 never examined their child (Patient #3). Review of the facility's policy for Acute Pain in Sickle Cell Disease directed that the physical exam would be inclusive of an oxygen saturation, inspection of the penis (priapism) and a complete blood count. In addition the policy for documentation identified that each form used should be completed. Any sections that do not apply to the patient should be crossed out, and "N/A" written on that section. If a section of the form applies, but cannot be completed for some reason, an explanation should be recorded on the Progress Notes. Approximately four hours after the Emergency Room discharge on 3/19/04 Patient #3 arrived in the ED of another hospital at 6:55 AM on 3/19/04 in full cardiorespiratory arrest and was pronounced dead at 7:25 AM. Review of autopsy results dated 3/19/04 identified primary cause of death was

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marked splenomegaly consistent with splenic sequestration, cardiomegaly, bilateral bronchitis, bronchiolitis, interstitial pneumonia, bilateral pulmonary edema and generalized non-specific lymphadenitis of the cervical, mediastinal, peripancreatic and mesenteric lymph nodes. MD #7 stated that acute splenic sequestration can occur rapidly (one to two hours) as hemoglobin levels go from normal to extremely anemic therefore monitoring of hemoglobin levels is critical. On 8/18/04, the facility provided an immediate action plan that identified that effective 8/18/04 all emergency department radiology films will be read by a radiologist prior to discharging a patient.

- b. Review of the policy regarding "The Role of ED Staff Physician and Midlevel Practitioner" identified that the Physician or Midlevel Practitioner will contact the family/patient with positive culture results that require further follow-up treatment and provide the appropriate instructions. The policy lacked clear direction as to when the family is to be informed of any abnormal radiology findings. Upon query of above policy and procedure with the VP of Patient Care Services on 8/17/04, she identified that it is the responsibility of the (ED) physician to contact patient/family of all "positive" results inclusive of radiology findings. The VP of Patient Care Services further identified that staff complete the "Emergency Department Follow-up Record" which identifies who was contacted by ED, inclusive of calls to primary care physician.
- c. Patient #19 arrived in the ED on 8/6/04 with left wrist pain following a fall experienced while playing ball. The radiology requisition/preliminary interpretation report was initiated by the ED physician on 8/6/04 which identified that the patient had a Foosh deformity and a radiology examination of the left forearm was requested. The radiology testing was performed and read by the radiologist as positive, indicative of a fracture injury. Although the facility's policy directed that the ED physician sign and date the form to indicate that the ED physician reviewed the radiology interpretation, this failed to be completed. Upon review of the above mentioned policy with the Vice President of Patient Care on 8/10/04 she identified that ED physicians should be completing the emergency department interpretation of this newly developed report, as part of the policy and procedure for Emergency Department Radiology Exams.
- d. Patient #20 arrived in the ED on 8/3/04 with right leg pain after playing. The radiology requisition/preliminary interpretation report was initiated by the ED physician on 8/6/04 which identified that the patient had a new gait favoring

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extraversion of the right foot and a radiology examination of the right knee and tibia and fibula were requested. The radiology testing was performed and read by the radiologist and identified no fracture or dislocations. Although the facility's policy directed that the ED physician sign and date the form to indicate that the ED physician reviewed the radiology interpretation, this failed to be completed.

- e. Patient #21 arrived in the ED on 8/3/04 with vomiting and bloody diarrhea and there was a question of intussusception. The radiology requisition/preliminary interpretation report was initiated by the ED physician (undated), which identified that the patient had bloody stool and possible history of intussusception and a radiology examination of the abdomen was requested. The radiology testing was performed and signed as read by the radiologist on 8/6/04 and identified "Barium in Colon." Although the facility's policy directed that the ED physician sign and date the form to indicate that the ED physician reviewed the radiology interpretation, this failed to be completed.
- f. Patient #6 arrived in the ED on 8/8/04 with pain and deformity of the left arm after a fall. The radiology requisition/preliminary interpretation report was initiated by the ED physician on 8/8/04, which identified that the patient had pain and deformity of the left arm and requested a radiology examination of the left arm. Although the radiologist signed the radiology preliminary interpretation, there was no identification of the finding and/or that the form was checked to indicate agreement with ED.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (j) Emergencies (2) and/or (d) Medical Records (3).

- 5. Patient #1, 6 months old, was admitted to the facility on 1/6/04 for a right inguinal hernia repair, left inguinal exploration and circumcision. A surgical consent was obtained. Intra-operative and post-operative documentation identified that a left inguinal hernia repair and circumcision were performed, however, the right side hernia repair was not done. Interviews with operating room staff and MD #10 identified that a time-out was conducted just prior to the start of surgery, everyone was in agreement with the procedure to be done. Following the completion of above surgery and a discussion with the patient's family, the patient returned to surgery for the right inguinal hernia repair. Interview with MD #10 identified that he approached the patient from the left side of the body, thinking he was on the right side of the body. He repaired the hernia and when he attempted to scope the opposite side inguinal area and couldn't see any abnormality, felt

DATES OF VISITS: July 1, 2, 6 and 10, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
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WERE IDENTIFIED

surgery was not warranted. Interviews with the operating room staff identified that although the surgical site had been marked, the mark was no longer present at the time of the surgery. Staff identified that the babies diaper, moist skin, and/or surgical prep could have caused the mark to disappear. Review of five additional surgical records identified that in all cases, the surgical procedure that was planned was the procedure that was performed.

6. Patient #1, 6 months old, was admitted to the facility on 1/6/04 for a right inguinal hernia repair, left inguinal exploration and circumcision. Review of Patient #1's peri-operative nursing record dated 1/6/04 at 8:00 AM identified that the pre-operative diagnosis, post-operative diagnosis, scheduled procedure, and performed procedure were all obliterated rendering them unreadable. Interviews with staff identified that this did not follow the hospital policy for correcting a documentation error.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (7).

7. Patient #5 presented to the Emergency Department (ED) on 12/16/03 at 11:30 AM with abdominal pain and fever. Review of physician's orders dated 12/16/03 at 3:15 PM directed that Normal Saline 150cc intravenously (IV) be administered. Review of the nursing flow sheet dated 12/16/03 at 4:00 PM identified that the IV infused as ordered. Review of the nursing flow sheet further identified that an additional 150cc of Normal Saline was administered at 4:30 PM on 12/16/03. Review of the clinical record and interview with the ED Manager identified that a physician's order for the second administration of Normal Saline 150 cc IV was lacking but could have been a verbal order and not recorded in the medical record.  
In addition, review of a physician's order dated 12/16/03 at 5:00 PM directed that Dextrose with ½ Normal Saline 300cc IV be administered. Review of the ED record with the Nurse Manager identified that the IV solution was initiated but lacked documentation for the amount of IV solution that had infused. Review of the documentation policy identified that fluid volumes are to be totaled and recorded on the flow sheet.
8. Patient #5 presented to the Emergency Department (ED) on 12/16/03 at 11:30 AM with abdominal pain and fever. An abdominal film (KUB) was ordered to rule out small bowel obstruction. At 4:13 PM on 12/16/03 the X-ray was performed and read by MD #5 (Radiologist). Review of the clinical record with Quality Improvement staff failed to

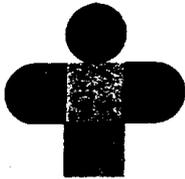
DATES OF VISITS: July 1, 2, 6 and 10, 2004

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WERE IDENTIFIED

locate the dictated X-ray report in the patient's clinical record. Subsequent to surveyor inquiry a dictated abdominal X-ray film dated 12/16/03 was provided.

9. According to the triage record dated 3/19/04, Patient #3 in the ED at 3:00 AM. MD #4's assessment dated 3/19/04 identified that the patient was evaluated at 3:45 AM. Review of the Nursing Flow Sheet with RN #2 identified that the patient was discharged home at 3:45 AM following the administration of medications. Review of the Discharge instructions with MD #4 identified that the patient was discharged at 3:40 AM. Interview with MD #4 stated that the record was incorrect because the patient was observed for about one hour after the medication was administered and discharged home at 4:30 AM on 3/19/04. Interview with Person #1 and Person #3 stated that they arrived home from the ED on 4:00 AM.  
Review of the Discharge instructions with MD #4 identified that the patient was discharged at 3:40 AM. Interview with MD #4 stated that this was incorrect because the patient was observed for about one hour after the medication was administered (3:30 AM) and discharged 4:30 AM.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing Service (1).



**Connecticut  
Children's**  
MEDICAL CENTER

September 15, 2004

Joan Leavitt, R.N, M.S. Public Health Systems Manager  
Judy MacDonald, R.N., Supervising Nurse Consultant  
Division of Health Systems Regulation  
Department of Public Health  
State of Connecticut  
P.O. Box 340308  
Hartford, CT 06134

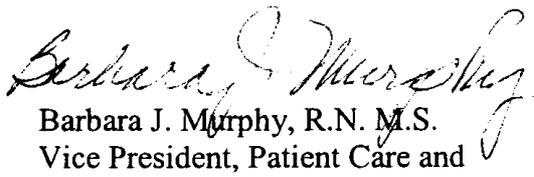
Dear Joan and Judy:

Enclosed please find Connecticut Children's Medical Center's response to your letter of September 2, 2004

We have detailed our corrective action plans for each of the deficiencies cited, and have included Appendices with additional policies, forms, and evidence of staff education as required to support the plan.

Please contact either of us with any questions or concerns you may have. Thank you.

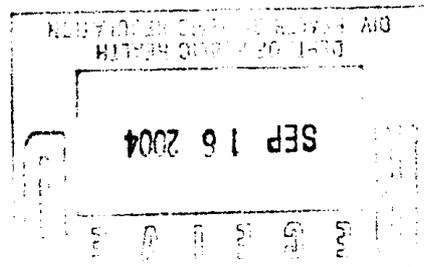
Sincerely,



Barbara J. Murphy, R.N. M.S.  
Vice President, Patient Care and  
Human Resource Services



Paul H. Dworkin, M.D.  
Physician-in-Chief



OK JFM/ps  
9/17/04

FACILITY: **Connecticut Children's Medical Center**

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1. **Response to Violation of Regulations Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (7).**

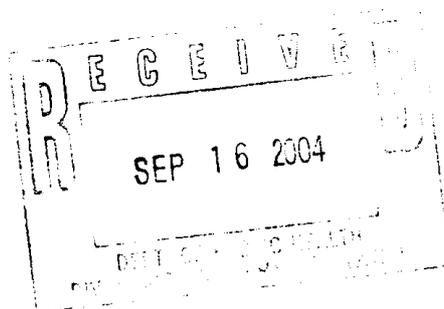
OK  
PMS.

a. CCMC has re-educated all staff on the proper procedure to activate the "Part A" abduction policy, including the correct phone number to notify Security immediately in the event a child is missing. The procedure was reviewed in detail at a leadership meeting, and handouts were e-mailed to every staff member, with hard copies given to managers for use in staff education. Managers have reviewed the policy at staff meetings. It has also been incorporated into New Employee orientation.

In addition, the physical security of the inpatient units was enhanced by the addition of exit controls to all three med/surg units and the NICU. Staff have been educated on the proper approach to screening visitors. Visitors are visualized and screened by a staff member before being allowed to enter or exit the patient care unit. (Completed 9/15/04) Responsible person: Vice President, Patient Care & Human Resource Services.

**Appendix A** includes the Security teaching tool, revised visitor policy and minutes of staff meetings in which both were reviewed.

Regular abduction drills are conducted to monitor staff's performance and compliance with policy. Drill debriefings are used to target specific education or follow-up. A training drill was held on September 1, 2004. Unannounced drills will occur monthly through the end of 2004.



FACILITY: Connecticut Children's Medical Center

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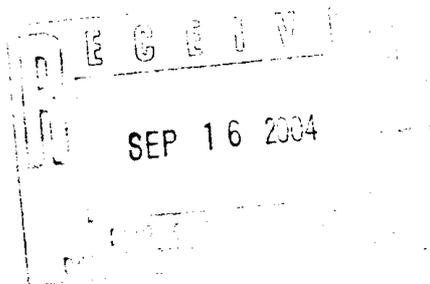
2. Response to Violation of Regulations Section 19-13-D3 (d) Medical Records (3) and/or (c) Nursing Service (1)

a, b, c. Daily multidisciplinary rounds on each unit include a review of the child's family/social situation. If there are issues, which potentially put the child at risk, a referral is made to the Family Support Clinician (FSC), who assesses the patient/family situation and assumes responsibility for notifying all appropriate parties, including security, if restrictions are required. A "restriction database" is currently being developed to allow lobby-based security officers to view online the list of patients with visitor restrictions. The implementation date of the restriction database is 9/15/04. All other aspects of the system have been implemented as described above. FSC's have been educated, and additional staff education on this process is underway to be completed in September staff meetings. (Completed 9/15/04)

OK  
PMS

A meeting was held with DCF leadership on 7/29/04, at which it was agreed that CCMC's FSC and DCF's workers would each complete risk assessments, and in the event they did not agree, (CCMC believed there was a greater risk than did DCF) CCMC would implement appropriate precautions based on its own findings. Care plans and discharge plans are part of the ongoing concurrent chart review, and the Nursing Director has directed that Unit Nurse Managers or their designees will personally audit the care plans of children for whom there is potential flight risk to assure that the appropriate interventions are in place and documented fully, and that the discharge plan is in place. Weekly audits by Family Support and Nursing will monitor compliance beginning 9/20/04. Responsible Person: Vice President of Patient Care and Human Resource Services.

**Appendix B** contains Visitation Guidelines for Child Protection, as well as staff meeting minutes and a status report on Security implementation progress.



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3. Response to (Violation of regulations section 19-13-D3 (b) Administration (2) and/or (i) Emergencies (2) and/or (i) General (7)).

a, b, c, d. In August 2004, CCMC implemented a policy that both Emergency Department (ED) and Radiology physicians review radiology examinations requested through the ED prior to the patient's release from the ED. Discrepant results are reviewed and communicated in a timely manner. A procedure has been developed and implemented for requesting a radiology examination and communicating the interpretation to the appropriate caregivers using the Radiology Request/Preliminary Interpretation Form. The policy addresses both weekday and off-hours, weekends and holidays to ensure radiology interpretation at all times. Emergency Department and Radiology staff have been notified of this procedure. Compliance with the policy is monitored by weekly medical record review of the completed Radiology Request/Preliminary Interpretation Report effective 9/20/04.

T.C. B. Murphy  
JFM 9/17/04

Emergency Department performance improvement activities will include monitoring of overall compliance with the policy, and accuracy of ED physicians' readings, as determined by agreement with radiology reports. Monitoring will be implemented 9/27/04 with monthly audits of Emergency MD/Radiologist concordance of interpretations. Ongoing in-service education of ED providers will enhance radiology interpretation skills ~~beginning October 2004~~. Remediation will address those ED providers who demonstrate discrepancies from radiology interpretations. Responsible party for implementation of performance improvement process: Medical Director, Emergency Department.

started  
by  
9/27/04 to

A survey of children's hospitals ~~will be~~ <sup>has been</sup> completed by the ~~end~~ of September to determine the standard of care for interpretation of radiology examinations within the ED setting. Review of the results of this survey will determine the opportunity for CCMC to revise its policy. Standard of care and competency assessments of ED physicians will inform the long-term plan for radiology interpretations within the ED. Responsible person: Physician-in-Chief

9/15, 2004

A Policy on Post-Discharge Follow-up from an ED Visit was developed in August 2004 to ensure that test results with significant findings received following the discharge of a patient from the ED will be communicated in a timely manner to the primary care physician (PCP) and/or the patient/family. The Emergency Department Follow Up Record form was revised to specify the action required, who was contacted, and when. If the ED physician/mid-level practitioner (MLP) is unable to contact the PCP or patient/guardian with results requiring emergent action, the policy specifies that the police be notified to contact the patient/guardian. All staff were educated on the revised policy upon its implementation. Monitoring of the content of the ED Follow-up Record by the

FACILITY: Connecticut Children's Medical Center

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ED Medical Director will ensure compliance with the policy. Monitoring of this process will begin on 9/20/04. The first audit will be completed by 9/27/04. This will be monitored on a monthly basis for a period of 6 months.  
Responsible Person: Physician-in-Chief

Appendix C contains Policy on ED Radiology Exams, Radiology Request/Preliminary Interpretation Form, Policy on Post-Discharge Follow-up from an ED Visit, and Emergency Department Follow Up Record.

4. **Response to Violation of Regulations Section 19-13-D3 (b) Administration (2) and/or (j) Emergencies (2) and/or (d) Medical Records (3).**

a. Sick cell disease guidelines for acute complications and emergency care were reviewed to ensure compliance with current standards of the New England Pediatric Sickle Cell Consortium (NEPSCC). These include guidelines for pain in sickle cell disease, acute chest syndrome, fever in the functionally asplenic patient, and stroke in the sickle cell patient. The acute chest guideline directs admission of all patients with acute chest syndrome and the monitoring of oxygen saturation via oximetry. The acute pain guideline directs that the physical examination be inclusive of oxygen saturation, inspection of the penis for priapism, and a complete blood count. Guidelines were distributed to the Emergency Department in 2003. Updated guidelines were distributed in early September 2004. ED Staff members are required to review the guidelines and have been requested to provide feedback by the end of September regarding their availability, appropriateness, clarity, and effectiveness. A feedback form has been developed for this purpose. Guidelines will be monitored on at least an annual basis by the CCMC Hematology-Oncology Care Committee to ensure appropriateness and compliance with NEPSCC standards. In-service education on the revised guidelines will be completed for Emergency Department physicians and nurses by the end of September. In addition, pediatric residents will receive a quick reference on the assessment and management of the patient with sickle cell disease by the end of September. (9/27/04)

9/17/04  
T.C.B.M.  
Jfm

→ 9/27/04

→ Content of

→ (9/27/04)

Performance Improvement activities will ensure compliance with stated policies. Adherence to the acute chest syndrome policy will be monitored by record review and data extraction by hematology-oncology staff on the Acute Chest Syndrome Episode Form. Implementation began on September 1, 2004 and will be monitored on a monthly basis. Individual responsible for monitoring: Medical Director, Hematology/Oncology. Failure to follow the treatment guideline will result in feedback to the Emergency Department provider and the development of a remediation plan.

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A policy for follow-up on hematology-oncology patients (including those with sickle cell disease) seen within the Emergency Department has been implemented by the Hematology-Oncology Program on September 1, 2004. All patients seen in the ED will either be seen in the hematology-oncology clinic or be contacted by phone within 24 hours by a hematology-oncology staff physician or nurse. Abnormal laboratory results will be discussed with the family by the physician or nurse. The results of the phone call, including test results from the ED visit, is documented on an Hematology-Oncology Emergency Department Visit Follow-up Form. The form will be entered into the patient's clinic chart. Monitoring will occur on a monthly basis beginning on ~~October 1, 2004~~ and will be conducted by outpatient clinical staff. Individual responsible for monitoring: Medical Director, Hematology/Oncology

Responsible Person: Physician-in-Chief

**Appendix D** contains guidelines for pain in sickle cell disease, acute chest syndrome, fever in the functionally asplenic patient, and stroke in sickle cell disease; the Feedback Form; Sickle Cell Disease Quick Reference for Residents; Acute Chest Syndrome Episode Form; Hematology-Oncology Emergency Department Visit Follow-Up Form.

4. b. A Policy on Post-Discharge Follow-up from an ED Visit was developed in August 2004 to ensure that test results with significant findings received following the discharge of a patient from the ED will be communicated in a timely manner to the primary care physician (PCP) and/or the patient/family. The Emergency Department Follow Up Record form was revised to specify the action required, who was contacted, and when. If the ED physician/mid-level practitioner (MLP) is unable to contact the PCP or patient/guardian with results requiring emergent action, the policy specifies that the police be notified to contact the patient/guardian. All staff were educated on the revised policy upon its implementation. Monitoring of the content of the ED Follow-up Record by the ED will ensure compliance with the policy. Monitoring of this process will begin on 9/20/04. The first audit will be completed by 9/27/04. This will be monitored on a monthly basis for a period of 6 months. (See Appendix C)

**4 c, d, e and f:** Please reference detailed plan of correction under violation #3  
Responsible Person: Physician-in-Chief

9/27/04  
Resp. Person - Med Director  
ED.

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5. **Response to violation of Regulations Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (7).**

A root cause analysis team was chartered to examine contributing factors to this event, and to recommend process improvement to prevent recurrence.

As a result of the root cause analysis, the Site Identification policy was revised effective April 2004 to add additional safety checks and to put "hard stops" into the process. Self-learning packets were distributed to all staff and physicians along with a mandatory sign-off indicating that the individual agreed to and understood the process. Re-education was done at staff meetings for Operating Room and PACU Staffs and reviewed at OR Committee and Surgical Chiefs meetings. Audits were changed from retrospective to concurrent and conducted weekly beginning May 2004. Monitoring is done by a designated Operating Room Staff RN. Responsible person: Surgeon-in-Chief.

**Appendix E** contains the revised policy and memo as well as a sample of signoff sheet and examples of chart audits, as well as Operating Room and PACU staff meeting minutes, and those of both Surgical Chiefs and Operating Room Committee. A teaching tool for families regarding correct site surgery is also included.

6. **Response to violations of Regulations Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).**

Operating Room Staff have been re-educated on the proper procedure for correcting a documentation error. Monitoring: Chart audits monthly. Responsible person: Vice President, Patient Care and Human Resources.

**Appendix F** contains Connecticut Children's Medical Center's documentation policy and evidence of staff re-education.

FACILITY: **Connecticut Children's Medical Center**

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**Numbers 7, 8, and 9 are Responses to Violations of Regulations Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1)**

7. Emergency Department staff were re-educated on September 14, 2004 on the documentation policy, including the importance of totaling fluid volumes administered. The Emergency Department's documentation audit tool and content of staff in-service will be modified to reflect this emphasis by ~~October 1, 2004~~ *9/27/04*. Monthly documentation audits will reflect documentation of total fluid volumes beginning with the October 2004 audit. Responsibility for monitoring: Manager, Emergency Department.
- The Emergency Department is also working to replicate the success obtained on the inpatient service in eliminating or minimizing verbal orders. Nursing staff have been advised not to accept verbal orders, with the support of both their manager and the Medical Director, Emergency Department. Compliance with the requirement for written orders for all treatments and medications will be included in all Emergency Departments chart audits beginning ~~with the October, 2004~~ *ON 9/27/04* audit process. Responsible parties: Emergency Department Manager and Medical Director

**Appendix G** includes minutes from the Emergency Department in-service on September 14, 2004 and E-mail sent to staff who were not present at the in-service.

8. The Director, Child and Family Support Services has redrafted radiology's procedures to assure that the final dictated report of any radiologic procedure is married to the correct clinical record. He has established clear accountabilities for each step of the process. Transition to a new transcription vendor in October 2004 will reduce turnaround time from the current twenty-four hour timeframe to eight hours.

On a daily basis, radiology's administrative assistant will review a sampling of reports to assure distribution is complete. Our long-term solution will be a fully automated radiology system. Effective date for implementation of procedure and audit: September 20, 2004. Responsible person: Director, Clinical and Family Support Services.

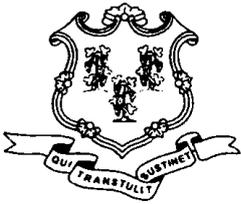
**Appendix H** contains detailed procedure for final radiology reports.

9. The importance of accurate documentation of discharge times, reflecting the conclusion of all patient care activities including monitoring and observation, was

reinforced with Emergency Department Staff providers on September 13, 2004 by the Medical Director.

This monitoring will start 9/27/04 and discharge times will be added to monthly Auditing Tool.

9/21/04  
I. C. to  
D. Murphy, MD



# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

October 27, 2004

Larry Gold, President and CEO  
 Connecticut Children's Medical Center  
 282 Washington Street  
 Hartford, CT 06106

Dear Mr. Gold:

Unannounced visits were made to Connecticut Children's Medical Center on September 28, 29 and 30, 2004 by representatives of the Division of Health Systems Regulation for the purpose of conducting a full survey at the request of CMS, follow-up to a statement of deficiencies for a survey completed on August 24, 2004 and follow-up to a violation letter dated September 2, 2004.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by November 10, 2004 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please address each violation with a prospective plan of correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Respectfully,

Ann Marie Montemerlo, RN  
 Supervising Nurse Consultant  
 Division of Health Systems Regulation

AMM:zbj

cc: Director of Nurses  
 vlctmedctr.doc



Phone:  
 Telephone Device for the Deaf: (860) 509-7191  
 410 Capitol Avenue - MS # \_\_\_\_\_  
 P.O. Box 340208 Hartford, CT 06134

DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

1. Patient #48 underwent a colonoscopy on 9/27/04. A review of the patient's medical record reflecting monitoring parameters during sedation and analgesia reflected that the patient received 8 mg of Versed by mouth at 8:10 AM, Fentanyl 45 mcg intravenously (IV) at 9:10 AM, Versed 3 mg IV at 9:14 AM, Versed 1 mg IV at 9:20 AM and Versed 1 mg IV at 9:37 AM. Although the heart rate, respiratory rate and oxygen saturation was recorded throughout the procedure, the patient's vital signs failed to be documented prior to the onset of medication and/or procedure and the patient's blood pressure readings were lacking during the procedure while receiving intravenous sedation. A review of the facility policy for Sedation and Analgesia directed that a record of pre-procedure vital signs should be documented on the patient's sedation flowsheet and then at least every 10 minutes during moderate sedation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (d) Medical records (3).

2. Review of the medical record for Patient #29 indicated that the patient was admitted on 9/27/04 with pneumonia. Review of the admission database indicated that the patient had no skin issues. The nursing flow sheet dated 9/27/04 indicated that the patient did not have an alteration in skin integrity. Review of the nursing flow sheets dated 9/28/04 and 9/29/04 indicated that the patient had stage one-pressure areas on his scrotum, diaper area and groin. Review of the care plan dated 9/27/04 indicated that the patient's active problem was his respiratory status. The care plan failed to address the patient's actual/potential skin integrity issues. The nurse's progress notes lacked identified interventions for the patient's skin issue. Review of the facility policy indicated that all patients should have nursing care goals for those items that must happen for the patient to go home.
3. Patient #42 was re-admitted to the hospital on 9/24/04 following surgery at a specialty hospital. Review of the patient's clinical record identified that the Department of Children and Families had a temporary order of custody but the patient's mother retained full medical decision-making rights. The patient's care plan lacked information relative to the patient's safety and any restrictions that may have been in force due to potential custodial issues. Interview with Clinician #1 identified that the patient was re-admitted on Friday, 9/24/04 and that she was off duty that day and did not return to work until Monday, 9/27/04. She did not conduct an assessment of risk until 9/27/04, and did not document that assessment. Interview with the VP of Patient Care Services identified that the facility policy was for nursing or clinicians to perform a risk assessment within 24 hours and that the assessment was to be incorporated into the patient's care plan. Further

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THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

the hospital did have a clinician on-call for patients admitted during off hours and on weekends.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (d) Medical records (3) and/or (e) Nursing service (1).

4. During tours of MS 8 and PICU on 9/28/04, refrigerator temperatures were noted to be outside established parameters. The MS 8 "family pantry" refrigerator was noted to have an internal temperature of 51 degrees, as displayed on the digital thermometer. The refrigerator contained milk, milk products, and other food items belonging to patients and their families. The thermometer's temperature parameters were set at between 50 and 86 degrees. There was no mechanism in place for the purpose of monitoring refrigerator temperatures. Interview with the nurse manager identified that they rely on the digital thermometer's alarm to alert staff to temperatures outside the normal ranges. Hospital policy identified that refrigerator temperatures were to be maintained between 33 and 40 degrees. Further, during a tour of the PICU on 9/28/04, the refrigerator's digital thermometer was observed set within the hospital's parameters, however, the alarm was not in the "on" position.
5. Tour of the seventh floor treatment rooms on 9/29/04 identified that there were outdated blood collection tubes. Tour of both treatment rooms indicated that there were red top and green top blood collection tubes that had expired on 11/03, 7/04 and 8/04.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).

6. Patient #48 underwent a colonoscopy on 9/27/04. A review of the medical record with the Director of Peri-operative Services reflected that although the patient received a pre-procedure assessment on 9/27/04, the "review of systems" and/or "current H & P in medical record" was blank. A review of the facility policy for Sedation and Analgesia reflected that the credentialed physician ordering the sedation must perform a thorough health examination including a review of systems prior to administration of the sedation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (c) Medical staff (4)(A) and/or (d) Medical record (2).

FACILITY: Connecticut Children's Medical Center

Page 4 of 4

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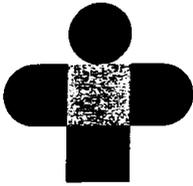
THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

7. A review of the controlled drug log located in the Fluoroscopy Area of the Radiology Department reflected that the daily count of controlled drugs utilized in the area was completed by one registered nurse for the month of September 2004. During interview, the pharmacist stated that the failure to complete the daily controlled drug audit with two nurses was an oversight.

The above is a violation of the Regulation of Connecticut State Agencies Section 19-13-D4a (e) Nursing service (1) and/or (g) Pharmacy (2).

8. A review of the Emergency Department log for Behavioral Restraints through 9/28/04 reflected a failure to document identified behavior that warranted the use of four point restraints. Facility documentation reflected that "danger to self and others" was most often the explanation for use of four point restraints. During interview the Manager of the Emergency Department stated that staff categorized the type of behavior rather than specific behaviors requiring the restraint.

The above is a violation of the General Statutes of Connecticut Section 46a-153 (1).



**Connecticut  
Children's**  
MEDICAL CENTER

Accepted  
9/16  
11/23/04

November, 5, 2004

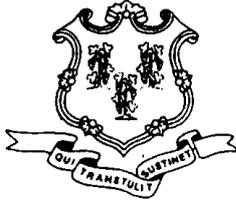
Ann Marie Montemerlo, RN  
Supervising Nurse Consultant  
Division of Health Systems Regulations  
Department of Public Health  
410 Capital Avenue  
Hartford, CT 06134

Dear Ann Marie:

Enclosed is Connecticut Children's Medical Center's response to your letter of October 27, 2004. Please let us know if you have any questions or concerns. Thank you.

Sincerely,

Barbara J. Murphy  
Vice President, Patient Care & Human Resource Services



# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

October 27, 2004

Larry Gold, President and CEO  
Connecticut Children's Medical Center  
282 Washington Street  
Hartford, CT 06106

Dear Mr. Gold:

Unannounced visits were made to Connecticut Children's Medical Center on September 28, 29 and 30, 2004 by representatives of the Division of Health Systems Regulation for the purpose of conducting a full survey at the request of CMS, follow-up to a statement of deficiencies for a survey completed on August 24, 2004 and follow-up to a violation letter dated September 2, 2004.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by November 10, 2004 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please address each violation with a prospective plan of correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Respectfully,

Ann Marie Montemerlo, RN  
Supervising Nurse Consultant  
Division of Health Systems Regulation

AMM:zsj

cc: Director of Nurses  
vlctmedctr.doc



Phone:  
Telephone Device for the Deaf: (860) 509-7191  
410 Capitol Avenue - MS # \_\_\_\_\_

DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

1. Patient #48 underwent a colonoscopy on 9/27/04. A review of the patient's medical record reflecting monitoring parameters during sedation and analgesia reflected that the patient received 8 mg of Versed by mouth at 8:10 AM, Fentanyl 45 mcg intravenously (IV) at 9:10 AM, Versed 3 mg IV at 9:14 AM, Versed 1 mg IV at 9:20 AM and Versed 1 mg IV at 9:37 AM. Although the heart rate, respiratory rate and oxygen saturation was recorded throughout the procedure, the patient's vital signs failed to be documented prior to the onset of medication and/or procedure and the patient's blood pressure readings were lacking during the procedure while receiving intravenous sedation. A review of the facility policy for Sedation and Analgesia directed that a record of pre-procedure vital signs should be documented on the patient's sedation flowsheet and then at least every 10 minutes during moderate sedation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (d) Medical records (3).

2. Review of the medical record for Patient #29 indicated that the patient was admitted on 9/27/04 with pneumonia. Review of the admission database indicated that the patient had no skin issues. The nursing flow sheet dated 9/27/04 indicated that the patient did not have an alteration in skin integrity. Review of the nursing flow sheets dated 9/28/04 and 9/29/04 indicated that the patient had stage one-pressure areas on his scrotum, diaper area and groin. Review of the care plan dated 9/27/04 indicated that the patient's active problem was his respiratory status. The care plan failed to address the patient's actual/potential skin integrity issues. The nurse's progress notes lacked identified interventions for the patient's skin issue. Review of the facility policy indicated that all patients should have nursing care goals for those items that must happen for the patient to go home.
3. Patient #42 was re-admitted to the hospital on 9/24/04 following surgery at a specialty hospital. Review of the patient's clinical record identified that the Department of Children and Families had a temporary order of custody but the patient's mother retained full medical decision-making rights. The patient's care plan lacked information relative to the patient's safety and any restrictions that may have been in force due to potential custodial issues. Interview with Clinician #1 identified that the patient was re-admitted on Friday, 9/24/04 and that she was off duty that day and did not return to work until Monday, 9/27/04. She did not conduct an assessment of risk until 9/27/04, and did not document that assessment. Interview with the VP of Patient Care Services identified that the facility policy was for nursing or clinicians to perform a risk assessment within 24 hours and that the assessment was to be incorporated into the patient's care plan. Further

FACILITY: Connecticut Children's Medical Center

Page 3 of 4

DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
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the hospital did have a clinician on-call for patients admitted during off hours and on weekends.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (d) Medical records (3) and/or (e) Nursing service (1).

4. During tours of MS 8 and PICU on 9/28/04, refrigerator temperatures were noted to be outside established parameters. The MS 8 "family pantry" refrigerator was noted to have an internal temperature of 51 degrees, as displayed on the digital thermometer. The refrigerator contained milk, milk products, and other food items belonging to patients and their families. The thermometer's temperature parameters were set at between 50 and 86 degrees. There was no mechanism in place for the purpose of monitoring refrigerator temperatures. Interview with the nurse manager identified that they rely on the digital thermometer's alarm to alert staff to temperatures outside the normal ranges. Hospital policy identified that refrigerator temperatures were to be maintained between 33 and 40 degrees. Further, during a tour of the PICU on 9/28/04, the refrigerator's digital thermometer was observed set within the hospital's parameters, however, the alarm was not in the "on" position.
5. Tour of the seventh floor treatment rooms on 9/29/04 identified that there were outdated blood collection tubes. Tour of both treatment rooms indicated that there were red top and green top blood collection tubes that had expired on 11/03, 7/04 and 8/04.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).

6. Patient #48 underwent a colonoscopy on 9/27/04. A review of the medical record with the Director of Peri-operative Services reflected that although the patient received a pre-procedure assessment on 9/27/04, the "review of systems" and/or "current H & P in medical record" was blank. A review of the facility policy for Sedation and Analgesia reflected that the credentialed physician ordering the sedation must perform a thorough health examination including a review of systems prior to administration of the sedation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (c) Medical staff (4)(A) and/or (d) Medical record (2).

FACILITY: Connecticut Children's Medical Center

Page 4 of 4

DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
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7. A review of the controlled drug log located in the Fluoroscopy Area of the Radiology Department reflected that the daily count of controlled drugs utilized in the area was completed by one registered nurse for the month of September 2004. During interview, the pharmacist stated that the failure to complete the daily controlled drug audit with two nurses was an oversight.

The above is a violation of the Regulation of Connecticut State Agencies Section 19-13-D4a (e) Nursing service (1) and/or (g) Pharmacy (2).

8. A review of the Emergency Department log for Behavioral Restraints through 9/28/04 reflected a failure to document identified behavior that warranted the use of four point restraints. Facility documentation reflected that "danger to self and others" was most often the explanation for use of four point restraints. During interview the Manager of the Emergency Department stated that staff categorized the type of behavior rather than specific behaviors requiring the restraint.

The above is a violation of the General Statutes of Connecticut Section 46a-153 (1).

## **APPENDIX**

)

# Violation #3

## **Risk of Flight Assessment Process Meeting**

**October 1, 2004**

**2 PM – 3 PM**

**Conference Room C**

**ATTENDANCE:** Beth Cannon, Theresa Hendricksen, Mary Ellen Mooney, Ann Taylor, Patricia McIntosh, Bill Agostinucci, Barbara Murphy, Leigh Cowels, Lori Notowitz, Trish Farmer, Erica Siddell

### **Requirements:**

1. Any patient who fits risk criteria and/or has DCF involvement.
2. The risk assessment must be documented even if there is no risk of flight.
3. The risk assessment must be completed within 24 hours of admission.
4. Results of assessment must be documented on the care plan

### **Additional Process Steps:**

1. The Manager of CFSS will forward her "risk assessment" list to the appropriate Nurse Manager so those patient's charts may be audited.
2. RNs will be instructed to notify the social worker immediately for any patient admitted where there is a patient and/or family history of DCF involvement.

**CONNECTICUT CHILDREN'S MEDICAL CENTER**  
**Corrective Action Plan**

For

**Department of Public Health Visit:**  
**September 28, 29 30, 2004**

<b>Violation #</b>	<b>Corrective Action Plan</b>	<b>Resolution/Responsible Person</b>	<b>Effective Date</b>
1. Section 19-13-D4a (b) Administration (2) and/or (d) Medical records (3)	Documentation issue reviewed on 9/30/04 by manager with staff person involved. Chart audits for Endoscopy are comprehensive and address vital signs with feedback to individuals based on audit.	Surgeon in Chief Manager, PACU	10/1/04
2. Section 19-13-D4a (d) Medical records, (3) and/or (e) Nursing service (1)	Unit Manager reminded all staff of importance of stating a goal on the care plan for each identified issue requiring intervention, and provided them with an example of an effective goal for the identified patient. Care plans are included in concurrent chart audits.	Manager, M/S 7	10/1/04
3. Section 19-13-D4a (d) Medical records, (3) and/or (e) Nursing service (1)	Meeting held on 10/1/04 with nurse managers, director, and risk management to clarify risk assessment process, timelines, and need to include all patients with DCF involvement. RNS instructed to notify Social Worker immediately, including weekends and holidays, when patient admitted who meets these criteria. Social worker will document results of assessment on care plan. (Please see minutes in appendix)	Director, Med Surg Units Manager, Child & Family Support	October 1, 2004
4. Section 19-13-D4a (b) Administration (2) and/or (i) General (6)	Clinical and Support staff leadership have collaborated and developed revised policy clearly articulating each discipline's responsibility in assuring appropriate temperature maintenance. Policy to be implemented 11/10/04 following leadership education. (Please see Appendix for policy)	Director, Med Surg Units Manager, General Support	November 10, 2004

<p>5. Section 19-13-D4a (b) Administration (2) and/or (i) General (6)</p>	<p>Manager of unit removed all blood collection tubes from treatment rooms, re-educated staff that IV carts are the proper location for these, and instituted weekly checks by a Patient Care Assistant to insure that they are not stored there.</p>	<p>Manager, Med Surg- 7</p>	<p>October 11, 2004</p>
<p>6. Section 19-13-D4a (c) Medical staff (4)(A) and/or (d) Medical Record (2)</p>	<p>Surgeon-in-Chief has reviewed requirements for a complete H&amp;P and review of systems prior to procedure with each GI physician. He reminded them that their charts would be regularly reviewed, with individual follow up if any issues are present.</p>	<p>Surgeon in Chief Manager, PACU</p>	<p>November 4, 2004</p>
<p>7. Section 19-13-D4a (e) Nursing Service (1) and/or (g) Pharmacy (2)</p>	<p>Director immediately reviewed appropriate controlled drug count procedure with radiology RNs. Log reviewed daily to assure audit completed with two nurses beginning 10/1/04. New form introduced 11/1/04 to facilitate documentation of double signatures at beginning and end of shift. (Please see Appendix for example)</p>	<p>Director, Clinical &amp; Family support Serv. Manager, Radiology</p>	<p>October 1, 2004 (New form November 1, 2004)</p>
<p>8. Section 46a0153 (1)</p>	<p>ED Manager educated staff on need to specifically identify (on restraint log) behaviors requiring initiation of restraints. More specific documentation initiated 10/15/04, and new forms requiring specific description of the issue were put into service on 11/1/04 (please see Appendix for form)</p>	<p>Manager, ED</p>	<p>October 15, 2004 (New form November 1, 2004)</p>

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CONNECTICUT CHILDREN'S MEDICAL CENTER

Hospital Operations

**Title: Refrigerator Alarm Policy**

Purpose: To ensure that Medications, formulas and Pantry Standards are stored in a safe and appropriate environment.

**Medication Refrigerators:**

1. Medication refrigerators are to be kept at temperatures between 34-46° F (2-8° C). Each refrigerator and freezer (when appropriate) is equipped with a digital sensor that audibly alarms when the refrigerator's internal temperature is out of the appropriately set range.
2. Staff is directed to notify the pharmacy when they detect a thermometer alarming between the hours of 7:00am to 10:00 pm. Upon notification, a pharmacy employee will be dispatched to investigate the alarm cause and assess product integrity. The pharmacy extension number is 5-9935
3. If the Medication refrigerator alarm is detected after 10 pm.
  - Staff is directed to check the internal temperature of the refrigerator to verify the temperature reading on the digital sensor.
  - If a failure to maintain appropriate temperature is identified, unit staff must transfer the product to one of the other medication refrigerators in the area
  - Leave a voice mail message with the pharmacy for immediate follow up at 7am
  - Call 5-team to notify them of a repair need for the refrigerator unit.
4. Pharmacy staff will verify correct temperature settings and unit functionality of all medication refrigerator alarms weekly or as needed on a specific unit basis.

**Formula Refrigerators/Freezers**

1. Formula refrigerators are to be kept at temperatures between 33-40° F and Freezers are to be kept at temperatures between -4 to 14. Each refrigerator and freezer is equipped with a digital sensor that audibly alarms when the refrigerator's internal temperature is out of the appropriately set range.
2. Staff is directed to notify the Diet Technician when they detect a thermometer alarming between the hours of 7:00am to 6:00 pm. Upon notification, a Diet Technician will be dispatched to investigate the alarm cause and product integrity. The Diet Technician's pager number 220-3896 or extension 5-8759.
3. If the formula refrigerator or freezer alarm is detected after 6 pm, the following steps should be taken:
  - Staff is directed to check the internal temperature of the refrigerator to verify the temperature reading on the digital sensor.
  - If the refrigerator unit is failing to maintain the appropriate temperature, unit staff must transfer the formula product to one of the other refrigerators in the area

- Leave a voice mail message with the Diet Tech office, 5-8759 for immediate follow up at 7am
  - Call 5-team to notify them of a repair need for the refrigerator unit.
4. Nutrition staff will verify correct temperature settings and unit functionality of all formula refrigerator alarms weekly or more frequently on a unit specific basis.

### **Pantry Refrigerators:**

1. Formula refrigerators are to be kept at temperatures between 33-40° F and Freezers are to be kept at temperatures between -4 to 14.
2. Environmental Services Staff will monitor pantry refrigerator and freezer temperatures and will manually record temperatures daily on our temperature log sheet.
3. Should the temperature of a refrigerator or freezer be observed to be out of range between the hours of 5:30am to 8:00pm, the staff member is directed to call the kitchen to notify them of the issue. The kitchen will dispatch a representative to the area to investigate the cause of the problem, evaluate the integrity of the stored product and to determine if any other action is necessary. (i.e. 5-team is to be called if the refrigerator is in need of repair).
4. If the refrigerator fails after 8:00. Staff is to transfer food product into another refrigerator on the unit for safe keeping, the Kitchen is to be notified by leaving a voice mail on the Production Manager's telephone, extension 5-9015, and 5-team must be called to be notified of the repair need.

Departments that do not operate 7 days a week have Digital Alarming Sensors placed on all their refrigeration equipment. Should a staff member come in to hear a sensor alarming, the "history" function on the alarm should be viewed to determine whether or not a temperature variance occurred while the department was closed. A staff member should be assigned to check the alarm as soon as the department reopens and sign a log indicating that no alarm conditions occurred while the department was closed.

It is the responsibility of all staff to check refrigerator temperatures every time the refrigerators are used. If a unit is not working, products should be moved to a working refrigerator.



Violation #7

**\*COTROLLED DRUG CHANGE OF SHIFT AUDIT**  
Key Record

NURSING UNIT Radiology

MONTH Nov. YEAR 04

Day	Licensed Practitioners Start-of-Shift Count		Licensed Practitioners End-of-Shift Count	
1	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
2	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

\*Two signatures required if any C II control drugs counted.





**STATE OF CONNECTICUT**  
**DEPARTMENT OF PUBLIC HEALTH**

April 11, 2005

Mr. Larry Gold, President and CEO  
Connecticut Children's Medical Center  
282 Washington Street  
Hartford, CT 06106

Dear Mr. Gold:

Unannounced visits were initiated on February 20, 2005 to Connecticut Children's Medical Center by representatives of the Division of Health Systems Regulation for the purpose of conducting multiple investigations and a full federal survey with additional information received through March 31, 2005.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for April 25, 2005 at 10:00 AM in the Division of Health Systems Regulation, Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Sincerely,

John D. Leavitt, R.N., M.S.  
Public Health Services Manager  
Division of Health Systems Regulation

Ann Marie Montemerlo, R.N.  
Supervising Nurse Consultant  
Division of Health Systems regulations

JDL:AMM:zsj

c. Director of Nurses  
2.vlconnctmed.doc  
CT #3485, CT #3786  
CT #3745



Phone:

Telephone Device for the Deaf: (860) 509-7191  
410 Capitol Avenue - MS # \_\_\_\_\_  
P.O. Box 340308 Hartford, CT 06124

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (1)(A) and/or (2) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).

1. Connecticut Children's Medical Center (CCMC) was unable to provide a written and executed contract with Acute Care Hospital #2 for the reading of x-rays by Acute Care Hospital #2 during periods when CCMC's radiologist was unavailable (e.g. off shift and/or weekend hours and/or holidays). Interview with the DNS on 3/10/05 identified that CCMC did not have a contract delineating radiology services provided by Acute Care Hospital #2 on off-hours, weekends and holidays. A review of CCMC's policy for Emergency Department (ED) Radiology Exams approved in August 2004 for off-hours, weekends and holidays, indicated in part, that the CCMC ED physician reads the film and writes his/her interpretation on the form (the Radiology Request/Preliminary Interpretation form attached to the film's jacket). The ED physician then places the film in the upright file for delivery to Acute Care Hospital #2 Radiology by a CCMC radiology "runner" who brings the film to the radiology resident at Acute Care Hospital #2. The Acute Care Hospital #2 radiology resident reviews the film, writes a preliminary interpretation on the form and the "runner" brings the film back to CCMC and places it on the counter in front of the ED radiology view box for the CCMC ED attending to review. The policy lacked expected time frames for either initial or radiology interpretation, a communication process between the radiologist and the ED physician and lacked an identified process for emergent and/or trauma readings.
2. The facility failed to develop and/or maintain an executed contract and/or a written protocol for the joint Acute Care Hospital #2/CCMC system for pediatric trauma care. Interview with the CCMC Trauma Coordinator identified that although there is no single formal written document which outlines the shared program there are various documents which identify the various aspects of the program such as a Pediatric Surgeon Response Document and the Radiological Services Procedure. In addition to these documents, there is the joint monthly meeting of the Trauma Steering Committee. He added that the function of the Trauma Steering Committee is to review cases and set policy. A review of the Trauma Steering Committee meeting minutes for the period of 10/14/04 through 1/21/05 identified that shared services between CCMC and Acute Care Hospital #2 relative to the joint trauma program included pediatric nursing education at Acute Care Hospital #2, Acute Care Hospital #2 on-call lists for both trauma and neurosurgery physicians, back-up by Acute Care Hospital #2 for pediatric trauma and radiology services.  
Further review identified that as of the last meeting on 1/21/05 of the Trauma steering Committee identified an update was provided on the status of the joint trauma center's

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Memorandum of Understanding (MOU). Discussion was held on the status of the document and "how to expedite its completion." A review of the Trauma Program meeting minutes dated June 23, 2004 identified that it was agreed that for Acute Care Hospital #2/CCMC to function as a level 1 trauma center, a contractual administrative agreement that effectively makes them one administrative unit "should be developed." It was agreed that the best approach would be to develop a joint administrative agreement formalizing operating authority for CCMC.

Interview with the CCMC Director of Trauma Service on 3/9/05, identified that there is an "informal plan with Acute Care Hospital #2" relative to the trauma program. The Director stated that the program is an evolving trauma system with the goal to have CCMC classified as a level 1 trauma facility. There is a sharing of staff and programs. There is in place at this time at least an oral agreement with Acute Care Hospital #2. CCMC is not currently classified as a level 1 trauma facility in accordance with American College of Surgeons (ACS) accreditation and Public Health Code Section 19a-177-4(a).

3. Patient #4 arrived in CCMC's ED at 1:50 PM from another Acute Care Facility where it was determined that the patient's hematocrit level was 18 (normal 32.0% to 43.8%). Patient #4 was evaluated in the ED and a diagnosis of resolving cerebrovascular accident (CVA) was determined. Subsequent to consultation between MD #4 and MD #1 at approximately 2:15 to 2:30 PM on 3/13/04, plans to provide an exchange transfusion were initiated. Review of the ED record and interview with RN #3 identified that a type and screen was obtained at 3:45 PM. Review of facility documentation with the Acute Care Hospital #2 Blood Bank Supervisor on 3/8/05 identified that Patient #4 was entered into the blood bank system at 4:12 PM and processing of the type and screen was initiated. The medical record identified that Patient #4 was admitted to the Pediatric Intensive Care Unit (PICU) at 4:40 PM with treatment plans to include an exchange transfusion. Review of the exchange transfusion orders written at 4:45 PM directed the first 100 cubic centimeters (cc) of blood to run over a two hour period. Interview with the Blood Bank Supervisor identified that the order for the exchange transfusion was received in the blood bank at 5:11 PM, nearly one half hour after the order was written. The order requested that the Packed Red Blood Cells (PRBC) be split into two (2) aliquots (units) of 100 cc's and 140 cc's. The Blood Bank Supervisor identified that the 100 cc bag of PRBC was completed and available to be picked up at 5:15 PM. The Blood Bank Supervisor further identified that the 140 cc bag of PRBC was available at 5:50 PM. Facility documentation identified that both bags of blood were released to CCMC staff from the blood bank at 5:56 PM. The Blood Bank Supervisor identified that although it is the standard practice for blood bank staff to call the nursing unit when the first unit of blood is ready, Acute Care Hospital #2 was unable to provide

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documentation as to who called the CCMC nursing unit or the time the nursing unit was notified when the first aliquot of blood was ready at 5:15 PM. Review of Blood Bank policies failed to specify the procedure that Acute Care Hospital #2 Blood Bank staff would follow to alert nursing when the ordered blood product was available. Interview with CCMC's RN #1 on 3/10/05 identified that although the unit secretary would inform her as to when the blood product was available to be picked up from the blood bank, RN #1 was unable to identify when she was made aware that the blood was ready for pickup. Review of the CCMC's nursing policy with relation to communication between the Acute Care Hospital #2 Blood Bank and CCMC's nursing units lacked specific direction for communication between the two entities. Review of the clinical record identified that RN #1 initiated the blood transfusion (100 cc of PBRC's) at 6:20 PM (more than one hour after the first aliquot of blood was available).

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (c) Medical staff (3) and/or (4)(C) and/or (d) Medical records (3).

4. CCMC was unable to provide evidence that Radiology Services were reviewed for performance quality. A review of CCMC Board Quality Improvement Committee minutes from September 15, 2004 through February 16, 2005 and/or the Performance Improvement Committee minutes from August 8, 2004 through February 3, 2005 failed to identify that the hospital had reviewed the quality of services for Radiology. Review of the Patient Safety Committee Minutes dated July 15, 2004, identified that radiology communication problems had occurred on off-shift hours and weekends when services were to have been provided to CCMC by Acute Care Hospital #2. As a result of this concern and as part of a plan of correction that was to be implemented as a result of a CMS complaint validation survey concluded on 8/24/04, an x-ray interpretation tracking quality monitor form was implemented in the Emergency Department in September 2004. The tracking form identified the dates and times the radiology exam was requested, the date, time and interpretation of the emergency physician and the dates and times of the initial and final Acute Care Hospital #2 Radiology Department interpretation. Although the physician director of CCMC's ED reported in the September 20, 2004 minutes of the Patient Safety Committee that radiology interpretations were occurring in a timely manner, a review of the x-ray interpretation tracking quality monitor forms for October 2004 through February 2005 identified that items of information on the x-ray interpretation forms were not consistently completed. Evidence of follow-up to correct system discrepancies failed to be identified in the quality minutes reviewed. During interview, the physician director of the CCMC ED stated that although data had been collected, it had not been

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interpreted. A review of the facility's Performance Improvement Plan approved in May 2004 directed that the Board Quality Improvement Committee review reports regarding specific outcome indicators and provide feedback to the Performance Improvement Committee. The plan identified that setting of priorities included a review of problem-prone processes and unusual/sentinel events. The hospital identified problems with the radiology process post-death of Patient #3 in November 2004 and proposed a policy and procedure to address the processes for radiology film interpretation. As of 3/9/05, the hospital had not implemented the plan and per interview with the VP of Patient Care Services, physicians were in the process of being educated. Further, a review of the proposed Trauma Radiology During Off-Hours for Level One and Level Two Trauma Activations procedure failed to identify an expected time frame from the completion of the x-ray to the time of the Acute Care Hospital #2 radiology interpretation and from the time of the radiology interpretation to notification of the CCMC attending surgeon.

5. Review of Patient #20's Radiology Requisition/Preliminary Interpretation Report for the CT Scan performed on 3/12/05 lacked the date and time the exam was requested.
6. Review of Patient #22's Radiology Requisition/Preliminary Interpretation Report for the x-ray performed on 1/3/05 identified that the Radiology Attending interpretation was documented on 3/8/05. In addition, final x-ray report for the exam performed on 1/3/05 lacked the date and time the exam was interpreted by the attending radiologist. Review of the medical record and interview with the Attending Radiologist on 3/10/05 at 11:05 AM identified that on 3/8/05, the Radiology Manager requested him to complete the interpretation and that the interpretation should have been performed the day after the exam (1/4/05). The Attending Radiologist further identified that the final report for the exam performed on 1/3/05 was signed on 3/8/05 and that there was no documentation on the final report to reflect when the final report was interpreted.
7. Review of Patient #30's Radiology Requisition/Preliminary Interpretation Report for the exam performed on 1/12/05 lacked the time when the exam was requested and when the Emergency Department (ED) interpreted the exam. The Radiology Attending interpretation lacked the date and time the exam was interpreted. In addition, the cervical spine film final report performed on 1/12/05, the CT of the abdomen final report performed on 1/11/05, and the CT of the brain final report performed on 1/12/05 lacked the date and time the exams were interpreted by the radiologist.
8. Review of Patient #34's Radiology Requisition/Preliminary Interpretation Report for the x-rays performed 10/3/04 lacked the date and when the Emergency Department (ED) Interpreted the exam, lacked the time of the Radiology Residents and Radiology

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Attending interpretation of the exam and the time the Radiology Attending interpreted the exam. The CT Scan requested on 10/3/04 lacked the time requested.

9. Review of Patient #40's Radiology Requisition/Preliminary Interpretation Report for the CT Scan shunt series dated 3/12/05 lacked the time the exam was requested and the time of the Radiology Resident's interpretation.
10. Review of Patient #42's Radiology Requisition/Preliminary Interpretation Report for the CT Scan dated 3/12/05 lacked the time the exam was requested. The x-rays dated 3/12/05 lacked the time the exam was requested and lacked the date and time the ED Physician interpreted the exam. The ED Radiology Exams Policy identified that the requesting practitioner completes the section for the examination requested and patient history, including signature, printed name, date and time. For off hours, the CCMC ED physician reads the film and writes the interpretation on the form, and signs the form including printed name, date, and time. An Acute Care Hospital #2 Radiology Resident reviews the film, writes a preliminary interpretation on the form, and signs with a signature, printed name, and date and time. The Radiology Attending reads the film the next morning.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (f) Diagnostic and Therapeutic facilities.

11. Patient #4 had a medical history that included sickle cell disease. Review of the Transport Program Triage Sheet dated 3/13/04 with MD #4 (ED Attending) identified that Patient #4 presented to a Community Hospital Emergency Department with headache, facial droop, left sided weakness and ptosis of the right eye. A CT Scan of the head was performed and a diagnosis of stroke was documented. The triage sheet further identified that the patient had a hematocrit level of 18 (normal hematocrit 32.0 % to 43.8%). At 12:55 PM, MD #4 accepted the transfer of this patient who subsequently arrived to CCMC at 1:50 PM. Patient #4 was immediately assessed and designated a level two (2) triage level. According to the Triage Classifications Guidelines, a patient who is designated a level two (2) requires prompt medical attention, as an extended delay might be harmful to the patient and/or result in disability or loss of life. Review of the ED record with Physician's Assistant (PA) #1 on 3/16/05 identified that she evaluated the patient at 2:00 PM, documented that ptosis of the right eye was observed; otherwise, the patient's neurological symptoms had subsided. MD #1 (Hematologist) stated during interview on 3/11/05 that MD #4 (ED Attending) consulted with him while the patient was in the ED at approximately 2:15 PM-2:30 PM, with the plan to proceed with a full exchange transfusion. At 2:55 PM, PA #1 ordered a Blood Type and Cross. MD #4 stated during interview on 3/9/05 that although the patient's neurological deficits had resolved, symptoms could

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potentially reoccur, therefore, he requested Patient #4 be moved to Room #1 (close observation room) for close monitoring of the patient's status. MD #4 stated that Patient #4 was the sickest patient in the ED at this time and directed PA #1 to expedite her care. RN #3 identified during interview on 3/14/05 that she obtained the Type and Cross at 3:45 PM. Interview with the Director of Nurses on 3/11/05 identified that ED physicians utilize the New England Pediatric Sickle Cell Disease Consortium for Routine Health Care Maintenance of Pediatric Patients with Sickle Cell Disease. According to these guidelines, exchange transfusion therapy should be initiated as soon as possible in the event of a suspected stroke. Interventions based upon evaluation provided to Patient #4 since arrival to the ED at 1:50 PM included an order for blood type and cross at 2:55 PM, Tylenol at 2:45 PM for complaints of headache, IV access placement at 3:30 PM and a type and cross specimen obtained at 3:45 PM. MD #4's discharge diagnosis from the ED to the Pediatric Intensive Care Unit (PICU) included resolving cerebrovascular accident.

Review of facility documentation dated 3/14/04 identified that RN #4 had collected the type and screen and informed the Blood Bank that the patient would receive an exchange transfusion in the PICU. At 4:03 PM, the blood specimen was received by Acute Care Hospital #2's Laboratory, logged into Blood Bank specimen processing at 4:06 PM with the type and screen initiated at 4:12 PM. On 3/14/04 at 4:40 PM, Patient #4 was admitted to the PICU with an exchange transfusion order written at 4:45 PM that directed administration of Packed Red Blood Cells (PRBC) 100 cubic centimeters (cc) intravenously to run over two hours. Interview with the Blood Bank Supervisor at Acute Care Hospital #2 and documentation review identified that this order was received in the blood bank at 5:11 PM and required the PRBC's be split into two (2) aliquots of 100 cc's and 140 cc's. The Blood Bank Supervisor identified that the 100 cc bag of PRBC was available to be picked up at 5:15 PM. According to facility documentation, both units of blood were released to CCMC staff from the Acute Care Hospital's Blood Bank staff at 5:56 PM. The Blood Bank Supervisor identified that it is the standard practice for blood bank staff to call the nursing unit when the first unit of blood is ready. The facility was unable to provide documentation that the nursing unit was notified that the first aliquot of blood was ready at 5:15 PM. Review of the clinical record with RN #3 on 3/10/05 identified that she initiated the blood transfusion (100 cc's of PBRC's) at 6:20 PM. Interview with RN #1 failed to identify why the transfusion was not initiated from 5:15 PM (blood available) until 6:20 PM. According to Blood Diseases of Infancy and Childhood, Mosby, Seventh Edition, 1995, Chapter 12, pages 433-434: "Cerebrovascular accidents are one of the most devastating complications of sickle cell disease. Immediate treatment of stroke includes intravenous hydration and general supportive care. Simple transfusion to achieve a hematocrit level of 30% to 34 % or exchange transfusion to reduce the Hb S to less than 30% should be

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undertaken as soon as possible." According to Nathan and Oski's Hematology of Infancy and Childhood, Sixth Edition, 2003, Volume 1, Chapter 19, Sickle Cell Disease, page 807: "The standard approach to treating a patient with acute infarction is exchange transfusion."

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (g) Pharmacy (4) and/or (i) General (6).

12. During a tour of Operating Room (OR) #3 on the morning of 3/8/05, multiple medication carts including the heart cart were observed unlocked and unattended. Interview with the Manager of the OR identified that the carts were utilized during an emergency in the Pediatric Intensive Care Unit on the morning of 3/8/05 and were not relocked.
13. During a tour of the cardiac cath lab on the morning of 3/8/05, liquid inhalant anesthetics were observed on the anesthesia machine that was unlocked and unattended.
14. Observations during tour of the Emergency Department on 3/12/05 at approximately 5:15 PM identified that the medication refrigerator in the trauma room was unlocked. The refrigerator contained intravenous atropine, epinephrine, and other injectable medications. Interview with the Charge Nurse identified that the refrigerator was capable of locking.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).

15. During tour of the OR on 3/8/05, blanket warmers were observed to contain multiple types of fluid containers. Although rigid fluid containers were dated with date of discard, several fluid bags were undated. A review of the facility policy for the Fluid Warming Cabinet identified a lack of specific timing for fluids that were warmed, however, the warmer's temperature log identified bottles of fluid over 72 hours old were to be discarded. During interview the DNS stated that the policy was in flux secondary to the introduction of a new OR Manager who was introducing new policies.
16. Observations during tour of the Emergency Department on 3/8/05 of the three code carts identified that the Code Cart Daily Check Log Sheets dated 1/05 through 3/8/05 lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily. The Code Blue Code Cart Policy

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identified that the integrity of the contents of the code carts would be monitored on a daily basis and that the area manager who was responsible for the cart would assign a healthcare provider to assess the integrity of the numbered, tamper-evident locks and perform the Defibrillator Function Test. This individual would ascertain whether the locks were intact and would document that on the Code Cart Daily Check Log Sheet by recording the date and time, the lock numbers and their signature.

17. Further observations during tour of the Emergency Department on 3/12/05 at 5:10 PM identified that the Code Cart Daily Check Log Sheets dated 3/12/05 for the three (3) code carts lacked documentation to reflect that the defibrillator function tests and the code cart checks were performed on 3/12/05. Interview with the Charge Nurse at 5:10 PM identified that the defibrillator and crash carts should be checked daily during the day shift. Further observations at 8:55 PM identified that the Code Cart Daily Check Log Sheets for 3/12/05 lacked documentation to reflect that the checks were performed after surveyor inquiry at 5:10 PM.
18. Observations during tour of the facility on 3/8/05, 3/09/05, 3/10/05 and 3/11/05 identified that the Code Cart Daily Check Log Sheets for Code Carts #18, #17, #16, #15, #13 and #7, lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily for the period of 11/01/04 through 3/11/05.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (3) and/or (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).

19. Patient #3, an adolescent male, was admitted to the Emergency Department (ED) on 11/10/04 at 5:25 PM following a motor vehicle accident. The ambulance run form identified that the patient had been seated in the front passenger seat of a car which had been "t-boned" by an SUV at a high rate of speed causing a 2 foot intrusion of the right front passenger side. The patient needed to be extricated from the car. He was described by the paramedics as being cold, clammy, had a tender abdomen throughout all quadrants which radiated to the back, had pain in the right hip area and pelvic region with an outward rotation and shortening to the right leg. The patient was examined on arrival at CCMC and was described as having a tender lower chest, complaining of back pain, the right leg was externally rotated, abdomen was described as rigid and tender to palpation. The patient was groaning at this time. Two intravenous lines of Normal Saline (NS) were running at a rate of "open." Documentation in the medical record identified that at 5:51 PM a portable chest and pelvic x-rays were obtained and at 5:52 PM portable c-spine films were obtained.

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Documentation further noted that at 6:15 PM the surgical attending was at the patient's bedside and at 6:18 PM the orthopedic resident was also at the bedside. At 6:25 PM a CT of the abdomen was obtained which was followed shortly thereafter with additional x-rays of the right hip, leg and pelvis. At 6:55 PM the patient was described as shivering, complaining of being cold and at 7:30 PM, his oxygen (O<sub>2</sub>) saturation level dropped to 91%. O<sub>2</sub> at 15 liters was administered. The patient's temperature was noted to be 96.2 at 7:45 PM, which was consistent with previous temperatures monitored. The patient had also been medicated with a total of 15 mg of Morphine IV during the time period of 5:25 PM through 7:40 PM. Documentation was lacking to reflect the source or location of pain for which the patient was being medicated.

A review of the radiology requisition/preliminary interpretation report identified that although the portable chest, pelvis and c-spine films had been taken at 5:51 and 5:52 PM, respectively, the chest and c-spine films were not presented to Acute Care Hospital #2 radiology until 7:30 PM. The pelvis film was not presented at this time. Documentation by the Acute Care Hospital #2 Radiology Department identified that a review of the chest x-ray identified a widened mediastinum with a questionable aortic arch injury. Once the CCMC ED physicians were made aware of this finding, the patient was then taken for a CT Scan of the chest at 8:25 PM. Documentation in the medical record identified that once the CT had been completed, the patient then was moved back to the trauma room. The patient complained of shortness of breath and his B/P deteriorated. A foley catheter was inserted and 50 cc's of urine was drained from the bladder. The patient had received at least 3000 cc's of normal saline. The patient subsequently went into cardiac arrest and the code was called at 10:06 PM. Documentation was lacking in the medical record to reflect that a physician assessment of available data was performed in the ED during the period of 5:51 PM upon completion of the portable chest x-ray until 7:30 PM when the film was presented to radiology, at Acute Care Hospital #2 for review. Following this review, emergent interventions were not implemented in response to the radiological review but instead additional diagnostic testing was initiated.

Interview conducted with MD #5, the ED attending and the physician of record for Patient #3 identified that all patients who come through the ED are her responsibility. She acknowledged that she saw Patient #3 when he arrived at the ED. The patient was in a great deal of pain, specifically his back and chest. His abdomen was also diffusely tender and he had an obvious femur or pelvic fracture. Patient's #3 chest pain seemed to be a 10 out of 10. She added that she felt that he could have had life threatening injuries. X-rays were taken, which included the chest at around 6:00 PM, however, she did not receive any data regarding these films until 7:45 PM. She also added that she did not see these x-rays herself at any time nor did she seek out this data earlier because "her assumption" was that the Trauma Surgeon (Physician #12)

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saw these films. MD #5 seeing Physician #12 in the patient's room with the patient, MD #5 did not speak to MD #12 about these films. Once MD #5 learned of the suspected aortic arch injury she thought that the child needed further evaluation and a CT chest scan was "set up to evaluate" the extent of injury.

Following the chest CT, the patient went to the orthopedic room because the orthopedists were anxious to set his leg. Shortly thereafter, the patient had a rapid decompensation. Documentation in the medical record was inconsistent with this interview in that it did not reflect the patient returning to the orthopedic room upon completion of the CT scan of the chest.

Interview with the Trauma Surgeon (MD #12) on 3/22/05 identified that he responded to an emergency page and was asked by the Trauma Coordinator to come to the ED and see a patient. When he arrived at the ED he saw Patient #3 and touched his belly, which seemed fine and not problematic from a surgical perspective. He also looked at the Abdominal CT Scan as it was being done and didn't see any problems. He directed the surgical resident (MD #11) to bring the other films to radiology but he himself did not view any of these other x-rays. He wrote a progress note confined only to his interpretation of the abdominal findings which was timed for 6:30 PM and he then went home with no plan to come back to see this patient. He did not recall if he discussed the case with the ED attending (MD #5) at any time.

Interview with the Pediatric Resident (MD #10) on 3/15/05 identified that she knew that the patient had received numerous x-rays and although she inquired of the surgical resident as to where the x-rays might be, no one knew. She added that the surgical resident (MD #11) told her that she had viewed the chest x-ray with the trauma surgeon, prior to the x-rays going to the radiologist at 7:30 and he felt that the aorta "looked a little rotated."

Interview with the Surgical Resident (MD #11) on 3/21/05, identified that she responded to a page and went to the trauma room in the ED. She assessed the patient for injuries and the only specific injury that she saw was the right femur. She then went to CT Scan and looked at the abdominal CT. Also present were MD #12 and MD #13. She then looked at the chest x-ray and stated she saw a "normal chest x-ray." She did not confer with anyone else upon reading this film. MD #12 left the ED and did not give any further directions regarding this patient. MD #13 was informed later that the patient had a transected thoracic aorta and paged MD #12 because he was not in the building. He instructed her to page the cardiothoracic service and to activate the OR; however, it was not clear if he meant the OR at Acute Care Hospital #2 or Connecticut Children's Medical Center.

Interview with the Acute Care Hospital #2 Radiology Resident on 3/15/05 identified that the first time she was apprised of the trauma case at the Hospital was when a physician, not involved in the care of Patient #3 called her and asked her if she had viewed the CT scan of the abdomen and pelvis. She added that he had also told her

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that he had looked at the films with the trauma surgeon and felt that they were okay. She did not agree with this and asked to see any other films that might have been taken. She also asked him why no one else had contacted her from the ED earlier. She then looked at the chest x-ray and saw a very abnormal mediastinum which was suggestive of an aortic arch injury. She consulted with the Acute Care Hospital #2 Pediatric Radiology Attending and he concurred. She did suggest further studies to include a chest CT which would be obtained at the discretion of the clinicians and should have been based on their assessment of the patient. She added that the only person that ever contacted her from the ED regarding the films again was the physician who was not involved in the case.

Interview with a paramedic who responded to the accident identified that she arrived on scene and it was clear that the patient needed to be extricated from the car, the car needed to be cut because the patient was pinned inside. The fire department began cutting off the roof of the car. The patient was pale and sweaty and two IV lines were initiated. The patient complained of pain in his abdomen and chest and also pain in his back upon breathing. She contacted C-Med for a patch to another hospital which was designated as a Trauma Level 1 Facility, and described the mechanism as high speed "t-bone" into passenger door with 2 foot invasion. She also described the condition of the patient. The paramedics were then told to transport to CCMC, which did not have a trauma designation. Upon arrival at the ED, she told the Trauma Coordinator, that in her opinion the patient should have gone to a level 1 trauma facility. He explained to her that CCMC had established an algorithm which was used in determining where the patient should go. Upon learning of the patient's death, the paramedic met with the Trauma Coordinator (TC) and was told that the patient had died from a "horrific injury which did not present in the usual manner." She informed the TC that her anger was based on the Hospital's slowness in responding to the emergency. He acknowledged that they are still "slow with trauma because it's new to them." Facility policy entitled ED Radiology Exams and dated 9/24/04 identifies after performing the requested exam the tech returns the film and insert to the ED and places it on the counter in front of the ED radiology view box. The ED physician reads the film and writes his/her interpretation on the form, and signs the form including printed name and date and time. The ED physician places the film in the upright file on the ED main counter for delivery to Acute Care Hospital #2's Radiology.

This policy did not, however, address time frames for the readings, delivery and/or reporting of radiology interpretations.

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The following is a violation of the Connecticut General Statutes Section 127n-2C.

20. The facility failed to submit to the Department a corrective action plan relative to an adverse event which occurred in the ED on 11/10/04 and which was subsequently reviewed under Peer Review.

The following is violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and (e) Nursing Service (1) and/or (i) General (6).

21. Patient #1 was admitted to the hospital on 7/14/04 with a diagnosis of "short term syndrome." Review of the clinical record and interview with Physical Therapist (PT) #1 on 2/23/05 identified that Patient #1 received physical therapy throughout the hospitalization and was assessed as incapable of rolling, sitting or standing independently. Interviews with RN #1 on 2/23/05 and PCA #2 on 2/22/05 identified that on 2/19/05, RN #1 and PCA #2 provided care for Patient #1 between 7:30 PM and 8:35 PM. At the conclusion of the care, Patient #1 was placed in the center of the crib, on her back with rolled blankets at her sides and the crib rails in a raised position. At approximately 8:43 PM, eight minutes later, RN #1 identified that Patient #1 was crying and she went to the room to investigate. On entering the room, RN #1 observed Patient #1 on the floor, lying face down, approximately 5-7 feet from the crib, bleeding from the head and/or face. RN #1 initiated an emergency code, the patient was intubated, resuscitated and transferred to the pediatric intensive care unit. A neurosurgical consult was obtained on 2/20/05 that identified Patient #1 had sustained a left temporal fracture extending to the external auditory canal, a comminuted left parietal/occipital fracture with fragment, had blood in the ventricles and multiple area of hemorrhage and/or contusion. Interviews with MD #1 on 2/20/05 and MD #2 on 2/22/05 identified that Patient #1's injuries were extensive, she remained in critical condition and her prognosis was poor. Patient #1 subsequently expired on 2/25/05. Interview with RN #1 on 2/23/05 identified that she saw Person #1 standing near Patient #1's bedroom when she discovered Patient #1 on the floor. Person #1 was a seven (7) year old visitor of Patient #2. Interview on 2/20/05, 2/22/05 and 2/23/05 with RNs #1, #2, #3 and PCAs #1, #2, #3 and the unit secretary revealed that Person #1 was repeatedly seen walking around the unit, unattended, on 2/18/05 and 2/19/05. Interview with PCA #3 on 2/23/05 identified that on 2/19/05 between 7:45 PM and 8:00 PM, he observed Person #1 standing in Patient #1's bedroom. Patient #1 was not in the room at the time and he instructed Person #1 to return to Patient #2's room. Although staff identified that they had periodically redirected Person #1 back to Person #2's room, Person #1 continued to walk around on the unit unattended. Additional interviews with Facility Administration identified that it was their belief that the seven (7) year old visitor was

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responsible for the injuries sustained by Patient #7. The hospital policy for visitors identified that an adult must accompany children under the age of twelve (12) at all times. None of the staff interviewed noted that they had addressed the problem with Person #1's parents.

*PAC accepted 4/28/05  
AMM  
SMC  
JDA/AMM*

necticut Children's Medical Center  
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Hartford, Connecticut 06106

**Response to Department of Public Health Findings: Feb. 25, 2005-March 31, 2005**

Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a.(b) Administration (1)(A) and/or (2) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).</p> <ol style="list-style-type: none"> <li>Connecticut Children's Medical Center (CCMC) was unable to provide a written and executed contract with Acute Care Hospital #2 for the reading of x-rays by Acute Care Hospital #2 during periods when CCMC's radiologist was unavailable (e.g. off shift and/or weekend hours and/or holidays). The hospital policy lacked expected time frames for either initial or radiology interpretation, a communication process between the radiologist and the ED physician and lacked an identified process for emergent and/or trauma readings.</li> </ol>	<p><b>#1 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC will enter into a written Medical Imaging Services Agreement with Jefferson X-Ray by April 30, 2005 for the provision of medical imaging services to CCMC 24/7, including quality assurance and compliance with all applicable CCMC policies.</li> <li>CCMC policies regarding off hours medical imaging services have been revised to provide an improved system of communication during "off hours" and to clarify each staff member's role. Procedures were modified to assure that a radiologist interpretation is available when clinically indicated, including a procedure for emergent readings (within 30 minutes of time firm taken). Hospital-based physicians and appropriate clinical staff will be trained on the revised policies.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Medical directors and department managers will implement and track hospital-based physician and appropriate clinical staff education on policy changes through training rosters.</li> <li>The Director, Clinical Services, on a weekly basis, will audit compliance with processes for ordering, completing and interpreting x-rays as described in CCMC policies. Findings will be forwarded to the Medical Directors of the ED and Radiology for review and corrective action.</li> <li>Fifty per cent of after hours x-rays that are sent for interpretation to Hartford Hospital Radiology will be audited on a weekly basis by the Director, Clinical Services for concordance with CCMC Attending Radiologist second read of radiograph. Discrepancies will be reported to the Medical Director of Radiology for review and corrective action.</li> </ol>	<p>Director, Clinical Services</p>	<p>April 30, 2005</p> <p>May 4, 2005</p>

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Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>2. The facility failed to develop and/or maintain an executed contract and/or a written protocol for the joint Acute Care Hospital #2/CCMC system for pediatric trauma care. There is in place at this time at least an oral agreement with Acute Care Hospital #2. CCMC is not currently classified as a level I trauma facility in accordance with American College of Surgeons (ACS) accreditation and Public Health Code Section 19a-177-4(a).</p>	<p><b># 2 Response:</b></p> <ol style="list-style-type: none"> <li>1. CCMC ED staff have been re-educated on the federal and state requirements for appropriate assessment, stabilization, and transfer of patients who require treatment and/or services not available at CCMC, including CCMC's Interhospital Transfer Guidelines.</li> <li>2. CCMC ED staff have been re-educated regarding CCMC's lack of status as a designated "trauma center" and the requirements of the Connecticut trauma regulations, including that patients assessed in the field as requiring services of a designated trauma center should not be transported to CCMC. In addition, education included explaining that patients presenting to the CCMC ED who meet field triage criteria for care at a trauma center are stabilized and transferred in accordance with EMTALA.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>1. Attending physician will appropriately supervise and evaluate resident performance during care and documentation. Evaluation will be reflected in resident performance reviews.</li> <li>2. Twenty ED records per month will be audited for compliance with clinical indicators related to timeliness and quality of care. ED Medical Director will institute any necessary corrective action and if warranted, will make recommendations to the Medical Staff office for further consideration and action.</li> </ol>	<p>Medical Director, ED</p>	<p>April 30, 2005</p>
<p>3. Patient #4 arrived in CCMC's ED at 1:50 PM from another Acute Care Facility where it was determined that the patient's hematocrit level was 18 (normal 32.0% to 43.8%). Patient #4 was evaluated in the ED and a diagnosis of resolving cerebrovascular accident (CVA) was determined and plans to provide an exchange transfusion were initiated. The Blood Bank Supervisor identified that the 100 ml bag of PRBC was completed and available to be picked up at 5:15 PM. The Blood Bank Supervisor further identified that the 140 ml bag of PRBC was available at 5:50 PM. Facility documentation identified that both bags of blood were released to CCMC</p>	<p><b># 3 Response:</b></p> <ol style="list-style-type: none"> <li>1. CCMC and Acute Care Hospital #2 have agreed to the following:             <ol style="list-style-type: none"> <li>a. To institute processes for communication and documentation of when blood products are ready for pick-up</li> <li>b. CCMC policy on Blood Products Administration has been modified to require CCMC employees to document date and time for pick-up. Staff has been educated on the revised policy.</li> </ol> </li> <li>2. An addendum to the existing contract will be executed to document the agreement referred to</li> </ol>	<p>Nursing Director</p>	<p>April 30, 2005</p>

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Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>staff from the blood bank at 5:56 PM. Review of the CCMC's nursing policy with relation to communication between the Acute Care Hospital #2 Blood Bank and CCMC's nursing units lacked specific direction for communication between the two entities. Review of the clinical record identified that RN #1 initiated the blood transfusion (100 ml of PBRC's) at 6:20 PM (more than one hour after the first aliquot of blood was available).</p>	<p>above by April 30, 2005. Compliance will be monitored by ongoing medical record reviews of patients receiving blood products.</p> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>All blood products issued over a period of 10 consecutive days will be audited for documentation of pick-up time and administration time.</li> <li>Thereafter, for the next 6 months, on one day per week, the records of patients who received blood will be audited for documentation of pick-up time and administration time.</li> </ol>		
<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (c) Medical staff (3) and/or (4)(C) and/or (d) Medical records (3).</p> <ol style="list-style-type: none"> <li>CCMC was unable to provide evidence that Radiology Services were reviewed for performance quality. Review of the Patient Safety Committee Minutes dated July 15, 2004, identified that radiology communication problems had occurred on off-shift hours and weekends when services were to have been provided to CCMC by Acute Care Hospital #2. As a result of this concern and as part of a plan of correction that was to be implemented as a result of a CMS complaint validation survey concluded on 8/24/04, an x-ray interpretation tracking quality monitor form was implemented in the Emergency Department in September 2004. Evidence of follow-up to correct system discrepancies failed to be identified in the quality minutes reviewed. The hospital identified problems with the radiology process post-death of Patient #3 in November 2004 and proposed a policy and procedure to address the processes for radiology film interpretation. As of 3/9/05, the hospital had not implemented the plan. The following records lacked appropriate documentation per policy:                      Patient #20's Radiology Requisition/Preliminary Interpretation Report</li> <li>Patient #22's Radiology Requisition/Preliminary Interpretation Report</li> <li>Patient #30's Radiology Requisition/Preliminary</li> </ol>	<p><b># 4-10 Response:</b></p> <ol style="list-style-type: none"> <li>The issues related to the ED/Radiology exam process were reviewed for performance quality by the Performance Improvement Committee (PIC) at a meeting on April 7, 2005.</li> <li>The hospital PIC directed that the Medical Director of Radiology collect data on the status of all after hours radiology examinations, including those from the ED. After hours radiology performance will be compared to clinical indicators including timeliness of "wet" (emergent) readings of after-hours radiological studies and concordance between such readings of Radiology residents and the subsequent interpretations of Radiology attending physicians. These data are to be reported to the PIC on a monthly basis starting May 2005.</li> <li>Policies and procedures were revised to ensure timely and accurate processing and interpretation of after hours radiological studies including:                             <ul style="list-style-type: none"> <li>Processing of physician orders shall require accurate date, time and signature</li> <li>The radiology tech will secure any missing MD data before proceeding with the x-ray</li> <li>Transmission of a radiology interpretation to CCMC shall require documentation of the radiologist interpretation, and his/her signature, date and time.</li> </ul> </li> <li>Radiology residents were re-educated on requirements for the policy on April 17, 2005. New residents will be trained on the CCMC policy.</li> </ol>	<p>Chief Medical Officer</p>	<p>April 7, 2005</p> <p>April 30, 2005</p>

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Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>Interpretation Report</p> <p>6. Patient #34's Radiology Requisition/Preliminary Interpretation Report</p> <p>7. Patient #40's Radiology Requisition/Preliminary Interpretation Report</p> <p>8. Patient #42's Radiology Requisition/Preliminary Interpretation Report</p>	<p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Results of audits for compliance with off-hours radiology policies will be reported each month for the next 6 months at the PIC starting May 2005</li> <li>Performance data for off-hours radiology readings will be reported each month for the next 6 months at the PIC starting May 2005.</li> <li>The PIC will report on these indicators quarterly to the Board Quality Improvement Committee starting May 2005.</li> </ol>	<p>Chief Medical Officer</p>	<p>May 5, 2005</p> <p>May 25, 2005</p>
<p>The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (f) Diagnostic and Therapeutic facilities.</p> <p>11. Patient #4 had a medical history that included sickle cell disease. Review of the Transport Program Triage Sheet dated 3/13/04 identified that Patient #4 presented to a Community Hospital Emergency Department with headache, facial droop, left sided weakness and ptosis of the right eye. A CT Scan of the head was performed and a diagnosis of stroke was documented. The triage sheet further identified that the patient had a hematocrit level of 18 (normal hematocrit 32.0 % to 43.8%). At 12:55 PM, MD #4 accepted the transfer of this patient who subsequently arrived to CCMC at 1:50 PM. Patient #4 was immediately assessed and designated a level two (2) triage level. At approximately 2:15 PM-2:30 PM, the plan was to proceed with a full exchange transfusion. IV access placement occurred at 3:30 PM and a type and cross specimen obtained at 3:45 PM. The Blood Bank Supervisor identified that the first bag of PRBC was available to be picked up at 5:15 PM. According to facility documentation, both units of blood were released to CCMC staff from the Acute Care Hospital's Blood Bank staff at 5:56 PM. The facility was unable to provide documentation that the nursing unit was notified that the first aliquot of blood was ready at 5:15 PM. Review of the clinical record with RN #3 on 3/10/05 identified that she initiated the blood transfusion (100 ml's of PBRC's) at 6:20 PM.</p>	<p><b># 11 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC and Acute Care Hospital #2 have agreed to the following:                     <ol style="list-style-type: none"> <li>To institute processes for communication and documentation of when blood products are ready for pick-up</li> <li>CCMC policy on Blood Products Administration has been modified to require CCMC employees to document date and time for pick-up. Staff has been educated on the revised policy.</li> </ol> </li> <li>An addendum to the existing contract will be executed to document the agreement referred to above by April 30, 2005. Compliance will be monitored by ongoing medical record reviews of patients receiving blood products.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>All blood products issued over a period of 10 consecutive days will be audited for documentation of pick-up time and administration time.</li> <li>Thereafter, for the next 6 months, on one day per week, the records of patients who received blood will be audited for documentation of pick-up time and administration time.</li> </ol> <p><b># 11 Response:</b></p> <ol style="list-style-type: none"> <li>Sickle cell disease guidelines for acute complications and emergent complications and emergency care were reviewed to ensure compliance with current standards of the New England Pediatric Sickle Cell Consortium (NEPSCC)</li> <li>Guidelines were distributed to the Emergency Department in 2003. Updated guidelines were distributed in September 2004</li> <li>Inservice education on the revised guidelines was</li> </ol>	<p>Nursing Director</p> <p>Medical Director, Hematology/Oncology</p>	<p>April 30, 2005</p> <p>September 30, 2004</p>

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Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>completed for Emergency Department physicians and nurses last fall, 2004.</p> <ol style="list-style-type: none"> <li>4. Pediatric residents received a reference guide on the assessment and management of the patient with sickle cell disease in September 2004.</li> <li>5. Training will be presented to all new Pediatric residents annually, and Medical Staff and Nursing training will be updated and documented annually to assure understanding of updated sickle cell disease guidelines.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>1. Guidelines will be reviewed at least once a year by the CCMC Hematology-Oncology Care Committee to ensure appropriateness and compliance with NEPSCC standards.</li> <li>2. The records of 5 patients with Sickle Cell Disease are audited on a monthly basis for timeliness of care and compliance with standards. Feedback is provided to the appropriate providers.</li> </ol>	<p><b># 12-14 Response:</b></p> <ol style="list-style-type: none"> <li>1. Members of the Department of Anesthesia were educated about keeping drugs, syringes and anesthetics in locked carts when the drugs and carts were not attended. Individuals signed a sheet stating they understand and will comply with this requirement.</li> <li>2. Liquid inhalant anesthetics have been placed in the locked anesthesia cart.</li> <li>3. The lock on the refrigerator in the ED Room 1 is in place.</li> <li>4. All clinical staff will be re-educated about proper storage and securing of medications and needles/syringes.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>1. Cart lock logs will be monitored daily</li> <li>2. Refrigerator locks will be monitored daily.</li> </ol> <p>Storage areas including carts will be monitored on all inpatient units weekly.</p>	<p>Nursing Director</p>	<p>April 30, 2005</p>
<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (g) Pharmacy (4) and/or (i) General (6).</p> <ol style="list-style-type: none"> <li>12. During a tour of Operating Room (OR) #3 on the morning of 3/8/05, multiple medication carts including the heart cart were observed unlocked and unattended. Interview with the Manager of the OR identified that the carts were utilized during an emergency in the Pediatric Intensive Care Unit on the morning of 3/8/05 and were not relocked.</li> <li>13. During a tour of the cardiac cath lab on the morning of 3/8/05, liquid inhalant anesthetics were observed on the anesthesia machine that was unlocked and unattended.</li> <li>14. Observations during tour of the Emergency Department on 3/12/05 at approximately 5:15 PM identified that the medication refrigerator in the trauma room was unlocked. The refrigerator contained intravenous atropine, epinephrine, and other injectable medications. Interview with the Charge Nurse identified that the refrigerator was capable of locking.</li> </ol>			

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<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).</p> <p>15. During tour of the OR on 3/8/05, blanket warmers were observed to contain multiple types of fluid containers. Although rigid fluid containers were dated with date of discard, several fluid bags were undated. A review of the facility policy for the Fluid Warming Cabinet identified a lack of specific timing for fluids that were warmed, however, the warmer's temperature log identified bottles of fluid over 72 hours old were to be discarded.</p> <p>16. Observations during tour of the Emergency Department on 3/8/05 of the three code carts identified that the Code Cart Daily Check Log Sheets dated 1/05 through 3/8/05 lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily.</p> <p>17. Further observations during tour of the Emergency Department on 3/12/05 at 5:10 PM identified that the Code Cart Daily Check Log Sheets dated 3/12/05 for the three (3) code carts lacked documentation to reflect that the defibrillator function tests and the code cart checks were performed on 3/12/05.</p> <p>18. Observations during tour of the facility on 3/8/05, 3/09/05, 3/10/05 and 3/11/05 identified that the Code Cart Daily Check Log Sheets for Code Carts #18, #17, #16, #15, #13 and #7, lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily for the period of 1/01/04 through 3/11/05.</p>	<p><b># 15-18 Response:</b></p> <ol style="list-style-type: none"> <li>Revised the Fluid/Blanket Warming Cabinet policy based in accordance with Manufacturer guidelines to specify which items may be safely stored.</li> <li>The ED nursing staff was re-educated about the code cart check policy.</li> <li>All OCMC departments with code carts have been re-educated about the code cart check policy.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Warming Cabinet temperature logs will be audited by the Nurse Managers daily.</li> <li>The Nurse Managers shall audit date/time/discard of fluids in the Warming Cabinet daily.</li> </ol> <p>Code cart logs will be audited by the Nurse Managers daily.</p>	<p>Nursing Director</p>	<p>April 30, 2005</p>
<p>The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (3) and/or (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).</p> <p>19. Patient #3, an adolescent male, was admitted to the Emergency Department (ED) on 1/10/04 at 5:25 PM following a motor vehicle accident. The patient needed to</p>	<p><b># 19 Response:</b></p> <p>Corrective action accomplished by convening peer review within 24 hrs of 1/10/04 MVA case involving Patient #3. All disciplines involved in the patient's care participated with the goal to analyze and correct pertinent ED systems issues. Actions implemented to prevent recurrence include:</p> <ol style="list-style-type: none"> <li>Guidelines adopted to establish time standards for reading and communicating radiological findings. This time standard and all other processes below apply to all patients that present with critical/life threatening illness or injuries</li> </ol>	<p>Medical Director, ED</p>	<p>May 4, 2005</p>

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<p>be extricated from the car. The patient was examined on arrival at CCMC and was described as having a tender lower chest, complaining of back pain, the right leg was externally rotated, abdomen was described as rigid and tender to palpation. Documentation in the medical record identified that at 5:51 PM a portable chest and pelvic x-rays were obtained and at 5:52 PM portable c-spine films were obtained. Documentation further noted that at 6:15 PM the surgical attending was at the patient's bedside and at 6:13 PM the orthopedic resident was also at the bedside.</p> <p>At 6:25 PM a CT of the abdomen was obtained which was followed shortly thereafter with additional x-rays of the right hip, leg and pelvis. A review of the radiology requisition/preliminary interpretation report identified that although the portable chest, pelvis and c-spine films had been taken at 5:51 and 5:52 PM, respectively, the chest and c-spine films were not presented to Acute Care Hospital #2 radiology until 7:30 PM. The pelvis film was not presented at this time. Documentation by the Acute Care Hospital #2 Radiology Department identified that a review of the chest x-ray identified a widened mediastinum with a questionable aortic arch injury. Once the CCMC ED physicians were made aware of this finding, the patient was then taken for a CT Scan of the chest at 8:25 PM. Documentation in the medical record identified that once the CT had been completed, the patient then was moved back to the trauma room. The patient complained of shortness of breath and his B/P deteriorated. The patient subsequently went into cardiac arrest and the code was called at 10:06 PM.</p> <p>Documentation was lacking in the medical record to reflect that a physician assessment of available data was performed in the ED during the period of 5:51 PM upon completion of the portable chest x-ray until 7:30 PM when the film was presented to radiology, at Acute Care Hospital #2 for review. Following this review, emergent interventions were not implemented in response to the radiological review but instead additional diagnostic testing was initiated.</p> <p>Facility policy entitled ED Radiology Exams and dated 9/24/04 identifies after performing the requested exam the tech returns the film and insert to the ED and places it on the counter in front of the ED radiology view box. The ED physician reads the film and writes his/her</p>	<p>upon assessment or re-assessment in the CCMC Emergency Department (ED)</p> <ul style="list-style-type: none"> <li>• Biased time from patient's initial radiograph to time of the unofficial read by ED Attending will be ≤ 15 minutes.</li> </ul> <p>2. Specific procedures were established to standardize communication between ED attending and radiologist for critically ill or injured patients.</p> <ul style="list-style-type: none"> <li>• Radiology Tech returns developed films directly to the responsible ED attending, who reviews films.</li> <li>• Direct 'ring down' phone installed at CCMC ED and Hartford Hospital radiology to create immediate link between ED attending and Radiologist to be accessed when clinically indicated.</li> <li>• Processes implemented for CCMC staff to hand carry clinically indicated films to radiology and return read films to ED Attending.</li> </ul> <p>3. All physician and nursing staff in the ED and Radiology were educated on the revised policy.</p> <p>4. ED physicians and nursing staff will sign an acknowledgment that they have read and understand the policy and will comply with the policy, including all care and documentation requirements.</p> <p>5. Physician performance issues related to the care of patient # 3 were addressed and corrective actions taken.</p> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>1. In the course of treatment of patients, the ED attending will monitor compliance with time standards for reading and communicating radiological findings for all patients meeting criteria (critically ill/immediate life-threatening illness or injury). Discrepancies will be reported to the Medical Director, ED for review and corrective action, if required.</li> <li>2. Twenty ED records per month will be audited by BD, Medical Director for compliance with clinical indicators related to timeliness and quality of care. ED Medical Director will institute any necessary corrective action and if warranted, will make recommendations to the Medical Staff office for further consideration and action.</li> </ol>	<p>Chief Medical Officer</p> <p>Medical Director, ED</p>	<p>May 4, 2005</p> <p>May 4, 2005</p>

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<p>interpretation on the form, and signs the form including printed name and date and time. The ED physician places the film in the file on the ED main counter for delivery to Acute Care Hospital #2's Radiology.                      This policy did not, however, address time frames for the readings, delivery and/or reporting of radiology interpretations.</p>			
<p>The following is a violation of the Connecticut General Statutes Section 127n-2C.</p> <p>20. The facility failed to submit to the Department a corrective action plan relative to an adverse event which occurred in the ED on 11/10/04 and which was subsequently reviewed under Peer Review.</p>	<p># 20 Response:</p> <ol style="list-style-type: none"> <li>Initial case review did not identify this as an Adverse Event per State of Connecticut definitions.</li> <li>CT DPH Adverse Event Reporting Criteria have been reviewed by Risk Manager, CMO, and VP for Patient Care and HR Services to assure compliance with criteria.</li> <li>Entire Executive management team retrained on reporting criteria.</li> <li>Risk Manager will institute an independent review of all potentially reportable events with QI Consultant and Executive Management Member to validate reporting decision.</li> <li>All potential Adverse Events will be reviewed as indicated according to State reporting criteria.</li> </ol> <p>Monitoring:</p> <ol style="list-style-type: none"> <li>Risk Manager will review all potentially reportable adverse outcomes with Chief Medical Officer to assure appropriate reporting.</li> </ol>	<p>Risk Manager</p>	<p>April 30, 2005</p>
<p>The following is violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and (c) Nursing Service (1) and/or (i) General (6).</p> <p>21. Patient #1 was admitted to the hospital on 7/14/04 with a diagnosis of "short term syndrome." Review of the clinical record identified that Patient #1 received physical therapy throughout the hospitalization and was assessed as incapable of rolling, sitting or standing independently. Interviews with RN #1 on 2/23/05 and PCA #2 on 2/22/05 identified that on 2/19/05, RN #1 and PCA #2 provided care for Patient #1 between 7:30 PM and 8:35 PM. At the conclusion of the care, Patient #1 was placed in the center of the crib, on her back with rolled blankets at her sides and the crib rails in a raised position. At approximately 8:43 PM, eight minutes later, RN #1 identified that Patient #1 was crying and she went to the room to investigate. On entering the room, RN #1 observed Patient #1 on the floor, lying face down,</p>	<p># 21 Response:</p> <ol style="list-style-type: none"> <li>Guidelines developed and implemented 2/23/05 to clarify staff responsibilities regarding enforcement of the hospital's Visitor Policy. The staff was educated on the guidelines and re-educated on the policy in staff meetings.</li> <li>Guidelines specify that parents are responsible for the supervision of their children at all times, and that staff members will return unsupervised children to the parent/guardian. Repeated occurrences may result in the parent being asked to remove the child from the hospital.</li> <li>Guidelines have been posted prominently in public areas of the hospital.</li> </ol> <p>Monitoring:                      Each Manager of an inpatient Med/Surg unit and the daily Resource Nurse will monitor compliance on unit rounds.</p>	<p>Vice President for Patient Care and HR Services</p>	<p>March 21, 2005</p>

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<p>approximately 5-7 feet from the crib, bleeding from the head and/or face. RN #1 initiated an emergency code, the patient was intubated, resuscitated and transferred to the pediatric intensive care unit. A neurosurgical consult was obtained on 2/20/05 that identified Patient #1 had sustained a left temporal fracture extending to the external auditory canal, a comminuted left parietal/occipital fracture with fragment, had blood in the ventricles and multiple areas of hemorrhage and/or contusion. Patient #1 subsequently expired on 2/25/05. Interview with RN #1 on 2/23/05 identified that she saw Person #1 standing near Patient #1's bedroom when she discovered Patient #1 on the floor. Person #1 was a seven (7) year old visitor of Patient #2. Although staff identified that they had periodically redirected Person #1 back to Person #2's room, Person #1 continued to walk around on the unit unattended. Additional interviews with Facility Administration identified that it was their belief that the seven (7) year old visitor was responsible for the injuries sustained by Patient #7. The hospital policy for visitors identified that an adult must accompany children under the age of twelve (12) at all times. None of the staff interviewed noted that they had addressed the problem with Person #1's parents.</p>			

04/27/2005

Accepted  
GJM  
11/5/04



November, 5, 2004

Ann Marie Montemerlo, RN  
Supervising Nurse Consultant  
Division of Health Systems Regulations  
Department of Public Health  
410 Capital Avenue  
Hartford, CT 06134

Dear Ann Marie:

Enclosed is Connecticut Children's Medical Center's response to your letter of October 27, 2004. Please let us know if you have any questions or concerns. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Barbara J. Murphy".

Barbara J. Murphy  
Vice President, Patient Care & Human Resource Services

## **APPENDIX**

# Violation #3

## **Risk of Flight Assessment Process Meeting**

**October 1, 2004**

**2 PM – 3 PM**

**Conference Room C**

**ATTENDANCE:** Beth Cannon, Theresa Hendricksen, Mary Ellen Mooney, Ann Taylor, Patricia McIntosh, Bill Agostinucci, Barbara Murphy, Leigh Cowels, Lori Notowitz, Trish Farmer, Erica Siddell

### **Requirements:**

1. Any patient who fits risk criteria and/or has DCF involvement.
2. The risk assessment must be documented even if there is no risk of flight.
3. The risk assessment must be completed within 24 hours of admission.
4. Results of assessment must be documented on the care plan

### **Additional Process Steps:**

1. The Manager of CFSS will forward her "risk assessment" list to the appropriate Nurse Manager so those patient's charts may be audited.
2. RNs will be instructed to notify the social worker immediately for any patient admitted where there is a patient and/or family history of DCF involvement.

**CONNECTICUT CHILDREN'S MEDICAL CENTER**  
**Corrective Action Plan**

**For**

**Department of Public Health Visit:  
 September 28, 29 30, 2004**

<b>Violation #</b>	<b>Corrective Action Plan</b>	<b>Resolution/Responsible Person</b>	<b>Effective Date</b>
1. Section 19-13-D4a (b) Administration (2) and/or (d) Medical records (3)	Documentation issue reviewed on 9/30/04 by manager with staff person involved. Chart audits for Endoscopy are comprehensive and address vital signs with feedback to individuals based on audit.	Surgeon in Chief Manager, PACU	10/1/04
2. Section 19-13-D4a (d) Medical records, (3) and/or (e) Nursing service (1)	Unit Manager reminded all staff of importance of stating a goal on the care plan for each identified issue requiring intervention, and provided them with an example of an effective goal for the identified patient. Care plans are included in concurrent chart audits.	Manager, M/S 7	10/1/04
3. Section 19-13-D4a (d) Medical records, (3) and/or (e) Nursing service (1)	Meeting held on 10/1/04 with nurse managers, director, and risk management to clarify risk assessment process, timelines, and need to include all patients with DCF involvement. RNS instructed to notify Social Worker immediately, including weekends and holidays, when patient admitted who meets these criteria. Social worker will document results of assessment on care plan. (Please see minutes in appendix)	Director, Med Surg Units Manager, Child & Family Support	October 1, 2004
4. Section 19-13-D4a (b) Administration (2) and/or (i) General (6)	Clinical and Support staff leadership have collaborated and developed revised policy clearly articulating each discipline's responsibility in assuring appropriate temperature maintenance. Policy to be implemented 11/10/04 following leadership education. (Please see Appendix for policy)	Director, Med Surg Units Manager, General Support	November 10, 2004

<p>5. Section 19-13-D4a (b) Administration (2) and/or (i) General (6)</p>	<p>Manager of unit removed all blood collection tubes from treatment rooms, re-educated staff that IV carts are the proper location for these, and instituted weekly checks by a Patient Care Assistant to insure that they are not stored there.</p>	<p>Manager, Med Surg- 7</p>	<p>October 11, 2004</p>
<p>6. Section 19-13-D4a (c) Medical staff (4)(A) and/or (d) Medical Record (2)</p>	<p>Surgeon-in-Chief has reviewed requirements for a complete H&amp;P and review of systems prior to procedure with each GI physician. He reminded them that their charts would be regularly reviewed, with individual follow up if any issues are present.</p>	<p>Surgeon in Chief Manager, PACU</p>	<p>November 4, 2004</p>
<p>7. Section 19-13-D4a (e) Nursing Service (1) and/or (g) Pharmacy (2)</p>	<p>Director immediately reviewed appropriate controlled drug count procedure with radiology RNs. Log reviewed daily to assure audit completed with two nurses beginning 10/1/04. New form introduced 11/1/04 to facilitate documentation of double signatures at beginning and end of shift. (Please see Appendix for example)</p>	<p>Director, Clinical &amp; Family support Serv. Manager, Radiology</p>	<p>October 1, 2004 (New form November 1, 2004)</p>
<p>8. Section 46a0153 (1)</p>	<p>ED Manager educated staff on need to specifically identify (on restraint log) behaviors requiring initiation of restraints. More specific documentation initiated 10/15/04, and new forms requiring specific description of the issue were put into service on 11/1/04 (please see Appendix for form)</p>	<p>Manager, ED</p>	<p>October 15, 2004 (New form November 1, 2004)</p>

CONNECTICUT CHILDREN'S MEDICAL CENTER

Hospital Operations

**Title: Refrigerator Alarm Policy**

Purpose: To ensure that Medications, formulas and Pantry Standards are stored in a safe and appropriate environment.

**Medication Refrigerators:**

1. Medication refrigerators are to be kept at temperatures between 34-46° F (2-8° C). Each refrigerator and freezer (when appropriate) is equipped with a digital sensor that audibly alarms when the refrigerator's internal temperature is out of the appropriately set range.
2. Staff is directed to notify the pharmacy when they detect a thermometer alarming between the hours of 7:00am to 10:00 pm. Upon notification, a pharmacy employee will be dispatched to investigate the alarm cause and assess product integrity. The pharmacy extension number is 5-9935
3. If the Medication refrigerator alarm is detected after 10 pm.
  - Staff is directed to check the internal temperature of the refrigerator to verify the temperature reading on the digital sensor.
  - If a failure to maintain appropriate temperature is identified, unit staff must transfer the product to one of the other medication refrigerators in the area
  - Leave a voice mail message with the pharmacy for immediate follow up at 7am
  - Call 5-team to notify them of a repair need for the refrigerator unit.
4. Pharmacy staff will verify correct temperature settings and unit functionality of all medication refrigerator alarms weekly or as needed on a specific unit basis.

**Formula Refrigerators/Freezers**

1. Formula refrigerators are to be kept at temperatures between 33-40° F and Freezers are to be kept at temperatures between -4 to 14. Each refrigerator and freezer is equipped with a digital sensor that audibly alarms when the refrigerator's internal temperature is out of the appropriately set range.
2. Staff is directed to notify the Diet Technician when they detect a thermometer alarming between the hours of 7:00am to 6:00 pm. Upon notification, a Diet Technician will be dispatched to investigate the alarm cause and product integrity. The Diet Technician's pager number 220-3896 or extension 5-8759.
3. If the formula refrigerator or freezer alarm is detected after 6 pm, the following steps should be taken:
  - Staff is directed to check the internal temperature of the refrigerator to verify the temperature reading on the digital sensor.
  - If the refrigerator unit is failing to maintain the appropriate temperature, unit staff must transfer the formula product to one of the other refrigerators in the area

- Leave a voice mail message with the Diet Tech office, 5-8759 for immediate follow up at 7am
  - Call 5-team to notify them of a repair need for the refrigerator unit.
4. Nutrition staff will verify correct temperature settings and unit functionality of all formula refrigerator alarms weekly or more frequently on a unit specific basis.

### **Pantry Refrigerators:**

1. Formula refrigerators are to be kept at temperatures between 33-40° F and Freezers are to be kept at temperatures between -4 to 14.
2. Environmental Services Staff will monitor pantry refrigerator and freezer temperatures and will manually record temperatures daily on our temperature log sheet.
3. Should the temperature of a refrigerator or freezer be observed to be out of range between the hours of 5:30am to 8:00pm, the staff member is directed to call the kitchen to notify them of the issue. The kitchen will dispatch a representative to the area to investigate the cause of the problem, evaluate the integrity of the stored product and to determine if any other action is necessary. (i.e. 5-team is to be called if the refrigerator is in need of repair).
4. If the refrigerator fails after 8:00. Staff is to transfer food product into another refrigerator on the unit for safe keeping, the Kitchen is to be notified by leaving a voice mail on the Production Manager's telephone, extension 5-9015, and 5-team must be called to be notified of the repair need.

Departments that do not operate 7 days a week have Digital Alarming Sensors placed on all their refrigeration equipment. Should a staff member come in to hear a sensor alarming, the "history" function on the alarm should be viewed to determine whether or not a temperature variance occurred while the department was closed. A staff member should be assigned to check the alarm as soon as the department reopens and sign a log indicating that no alarm conditions occurred while the department was closed.

It is the responsibility of all staff to check refrigerator temperatures every time the refrigerators are used. If a unit is not working, products should be moved to a working refrigerator.



Violation #7

**\*COTROLLED DRUG CHANGE OF SHIFT AUDIT  
Key Record**

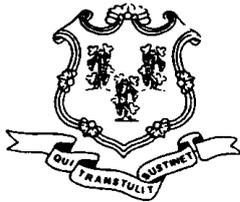
NURSING UNIT Radiology

MONTH Nov. YEAR 04

Day	Licensed Practitioners Start-of-Shift Count		Licensed Practitioners End-of-Shift Count	
1	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
2	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

\*Two signatures required if any C II control drugs counted.





# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

October 27, 2004

Larry Gold, President and CEO  
Connecticut Children's Medical Center  
282 Washington Street  
Hartford, CT 06106

Dear Mr. Gold:

Unannounced visits were made to Connecticut Children's Medical Center on September 28, 29 and 30, 2004 by representatives of the Division of Health Systems Regulation for the purpose of conducting a full survey at the request of CMS, follow-up to a statement of deficiencies for a survey completed on August 24, 2004 and follow-up to a violation letter dated September 2, 2004.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by November 10, 2004 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please address each violation with a prospective plan of correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Respectfully,

Ann Marie Montemerlo, RN  
Supervising Nurse Consultant  
Division of Health Systems Regulation

AMM:zsj

cc: Director of Nurses  
vlctcmedctr.doc



Phone:

Telephone Device for the Deaf: (860) 509-7191

410 Capitol Avenue - MS # \_\_\_\_\_

P. O. Box 340208 Hartford, CT 06134

DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

the hospital did have a clinician on-call for patients admitted during off hours and on weekends.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (d) Medical records (3) and/or (e) Nursing service (1).

4. During tours of MS 8 and PICU on 9/28/04, refrigerator temperatures were noted to be outside established parameters. The MS 8 "family pantry" refrigerator was noted to have an internal temperature of 51 degrees, as displayed on the digital thermometer. The refrigerator contained milk, milk products, and other food items belonging to patients and their families. The thermometer's temperature parameters were set at between 50 and 86 degrees. There was no mechanism in place for the purpose of monitoring refrigerator temperatures. Interview with the nurse manager identified that they rely on the digital thermometer's alarm to alert staff to temperatures outside the normal ranges. Hospital policy identified that refrigerator temperatures were to be maintained between 33 and 40 degrees. Further, during a tour of the PICU on 9/28/04, the refrigerator's digital thermometer was observed set within the hospital's parameters, however, the alarm was not in the "on" position.
5. Tour of the seventh floor treatment rooms on 9/29/04 identified that there were outdated blood collection tubes. Tour of both treatment rooms indicated that there were red top and green top blood collection tubes that had expired on 11/03, 7/04 and 8/04.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).

6. Patient #48 underwent a colonoscopy on 9/27/04. A review of the medical record with the Director of Peri-operative Services reflected that although the patient received a pre-procedure assessment on 9/27/04, the "review of systems" and/or "current H & P in medical record" was blank. A review of the facility policy for Sedation and Analgesia reflected that the credentialed physician ordering the sedation must perform a thorough health examination including a review of systems prior to administration of the sedation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (c) Medical staff (4)(A) and/or (d) Medical record (2).

FACILITY: Connecticut Children's Medical Center

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DATES OF VISITS: September 28, 29 and 30, 2004

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

7. A review of the controlled drug log located in the Fluoroscopy Area of the Radiology Department reflected that the daily count of controlled drugs utilized in the area was completed by one registered nurse for the month of September 2004. During interview, the pharmacist stated that the failure to complete the daily controlled drug audit with two nurses was an oversight.

The above is a violation of the Regulation of Connecticut State Agencies Section 19-13-D4a (e) Nursing service (1) and/or (g) Pharmacy (2).

8. A review of the Emergency Department log for Behavioral Restraints through 9/28/04 reflected a failure to document identified behavior that warranted the use of four point restraints. Facility documentation reflected that "danger to self and others" was most often the explanation for use of four point restraints. During interview the Manager of the Emergency Department stated that staff categorized the type of behavior rather than specific behaviors requiring the restraint.

The above is a violation of the General Statutes of Connecticut Section 46a-153 (1).

*PAC accepted 4/28/05 AMM JMW JDL/AMM*

**Exhibit E**

Connecticut Children's Medical Center  
 282 Washington Street  
 Hartford, Connecticut 06106

**Response to Department of Public Health Findings: Feb. 25, 2005-March 31, 2005**

Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p><b>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (DVA) and/or (2) and/or (1) Diagnostic and Therapeutic facilities and/or (1) General (6).</b></p> <ol style="list-style-type: none"> <li>Connecticut Children's Medical Center (CCMC) was unable to provide a written and executed contract with Acute Care Hospital #2 for the reading of x-rays by Acute Care Hospital #2 during periods when CCMC's radiologist was unavailable (e.g. off shift and/or weekend hours and/or holidays). The hospital policy lacked expected time frames for either initial or radiology interpretation, a communication process between the radiologist and the ED physician and lacked an identified process for emergent and/or trauma readings.</li> </ol>	<p><b>#1 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC will enter into a written Medical Imaging Services Agreement with Jefferson X-Ray by April 30, 2005 for the provision of medical imaging services to CCMC 24/7, including quality assurance and compliance with all applicable CCMC policies.</li> <li>CCMC policies regarding off hours medical imaging services have been revised to provide an improved system of communication during "off hours" and to clarify each staff member's role. Procedures were modified to assure that a radiologist interpretation is available when clinically indicated, including a procedure for emergent readings (within 30 minutes of time film taken). Hospital-based physicians and appropriate clinical staff will be trained on the revised policies.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Medical directors and department managers will implement and track hospital-based physician and appropriate clinical staff education on policy changes through training rosters.</li> <li>The Director, Clinical Services, on a weekly basis, will audit compliance with processes for ordering, completing and interpreting x-rays as described in CCMC policies. Findings will be forwarded to the Medical Directors of the ED and Radiology for review and corrective action.</li> <li>Fifty per cent of after hours x-rays that are sent for interpretation to Hartford Hospital Radiology will be audited on a weekly basis by the Director, Clinical Services for concordance with CCMC Attending Radiologist second read of radiograph. Discrepancies will be reported to the Medical Director of Radiology for review and corrective action.</li> </ol>	<p>Director, Clinical Services</p>	<p>April 30, 2005  May 4, 2005</p>

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Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>2. The facility failed to develop and/or maintain an executed contract and/or a written protocol for the joint Acute Care Hospital #2/CCMC system for pediatric trauma care. There is in place at this time at least an oral agreement with Acute Care Hospital #2. CCMC is not currently classified as a level 1 trauma facility in accordance with American College of Surgeons (ACS) accreditation and Public Health Code Section 19a-177-4(a).</p>	<p><b># 2 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC ED staff have been re-educated on the federal and state requirements for appropriate assessment, stabilization, and transfer of patients who require treatment and/or services not available at CCMC, including CCMC's Interhospital Transfer Guidelines.</li> <li>CCMC ED staff have been re-educated regarding CCMC's lack of status as a designated "trauma center" and the requirements of the Connecticut trauma regulations, including that patients assessed in the field as requiring services of a designated trauma center should not be transported to CCMC. In addition, education included explaining that patients presenting to the CCMC ED who meet field triage criteria for care at a trauma center are stabilized and transferred in accordance with EMTALA.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Attending physician will appropriately supervise and evaluate resident performance during care and documentation. Evaluation will be reflected in resident performance reviews.</li> <li>Twenty ED records per month will be audited for compliance with clinical indicators related to timeliness and quality of care. ED Medical Director will institute any necessary corrective action and if warranted, will make recommendations to the Medical Staff office for further consideration and action.</li> </ol>	<p>Medical Director, ED</p>	<p>April 30, 2005</p>
<p>3. Patient #4 arrived in CCMC's ED at 1:50 PM from another Acute Care Facility where it was determined that the patient's hematocrit level was 18 (normal 32.0% to 43.8%). Patient #4 was evaluated in the ED and a diagnosis of resolving cerebrovascular accident (CVA) was determined and plans to provide an exchange transfusion were initiated. The Blood Bank Supervisor identified that the 100 ml bag of PRBC was completed and available to be picked up at 5:15 PM. The Blood Bank Supervisor further identified that the 140 ml bag of PRBC was available at 5:50 PM. Facility documentation identified that both bags of blood were released to CCMC</p>	<p><b># 3 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC and Acute Care Hospital #2 have agreed to the following:                     <ol style="list-style-type: none"> <li>To institute processes for communication and documentation of when blood products are ready for pick-up</li> <li>CCMC policy on Blood Products Administration has been modified to require CCMC employees to document date and time for pick-up. Staff has been educated on the revised policy.</li> </ol> </li> <li>An addendum to the existing contract will be executed to document the agreement referred to</li> </ol>	<p>Nursing Director</p>	<p>April 30, 2005</p>

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<p>staff from the blood bank at 5:56 PM. Review of the CCMC's nursing policy with relation to communication between the Acute Care Hospital #2 Blood Bank and CCMC's nursing units lacked specific direction for communication between the two entities. Review of the clinical record identified that RN #1 initiated the blood transfusion (100 ml of PBRCs) at 6:20 PM (more than one hour after the first aliquot of blood was available).</p>	<p>above by April 30, 2005. Compliance will be monitored by ongoing medical record reviews of patients receiving blood products.</p> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>All blood products issued over a period of 10 consecutive days will be audited for documentation of pick-up time and administration time.</li> <li>Thereafter, for the next 6 months, on one day per week, the records of patients who received blood will be audited for documentation of pick-up time and administration time.</li> </ol>		
<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-94a (b) Administration (2) and/or (c) Medical staff (3) and/or (4)(C) and/or (d) Medical records (3).</p> <ol style="list-style-type: none"> <li>CCMC was unable to provide evidence that Radiology Services were reviewed for performance quality. Review of the Patient Safety Committee Minutes dated July 15, 2004, identified that radiology communication problems had occurred on off-shift hours and weekends when services were to have been provided to CCMC by Acute Care Hospital #2. As a result of this concern and as part of a plan of correction that was to be implemented as a result of a CMS complaint validation survey concluded on 8/24/04, an x-ray interpretation tracking quality monitor form was implemented in the Emergency Department in September 2004. Evidence of follow-up to correct system discrepancies failed to be identified in the quality minutes reviewed. The hospital identified problems with the radiology process post-death of Patient #3 in November 2004 and proposed a policy and procedure to address the processes for radiology film interpretation. As of 3/9/05, the hospital had not implemented the plan. The following records lacked appropriate documentation per policy:                      Patient #20's Radiology Requisition/Preliminary Interpretation Report                      Patient #22's Radiology Requisition/Preliminary Interpretation Report                      Patient #30's Radiology Requisition/Preliminary</li> </ol>	<p><b># 4-10 Response:</b></p> <ol style="list-style-type: none"> <li>The issues related to the ED/Radiology exam process were reviewed for performance quality by the Performance Improvement Committee (PIC) at a meeting on April 7, 2005.</li> <li>The hospital PIC directed that the Medical Director of Radiology collect data on the status of all after hours radiology examinations, including those from the ED. After hours radiology performance will be compared to clinical indicators including timeliness of "wet" (emergent) readings of after-hours radiological studies and concordance between such readings of Radiology residents and the subsequent interpretations of Radiology attending physicians. These data are to be reported to the PIC on a monthly basis starting May 2005.</li> <li>Policies and procedures were revised to ensure timely and accurate processing and interpretation of after hours radiological studies including:                         <ul style="list-style-type: none"> <li>Processing of physician orders shall require accurate date, time and signature</li> <li>The radiology tech will secure any missing MD data before proceeding with the x-ray</li> <li>Transmission of a radiology interpretation to CCMC shall require documentation of the radiologist interpretation, and his/her signature, date and time.</li> </ul> </li> <li>Radiology residents were re-educated on requirements for the policy on April 17, 2005. New residents will be trained on the CCMC policy.</li> </ol>	<p>Chief Medical Officer</p>	<p>April 7, 2005</p> <p>April 30, 2005</p>

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**Regulations**

Regulations	Response/Action Plan	Responsible Individuals	Expected Completion
<p>Interpretation Report</p> <p>6. Patient #34's Radiology Requisition/Preliminary Interpretation Report</p> <p>7. Patient #40's Radiology Requisition/Preliminary Interpretation Report</p> <p>8. Patient #42's Radiology Requisition/Preliminary Interpretation Report</p>	<p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Results of audits for compliance with off-hours radiology policies will be reported each month for the next 6 months at the PIC starting May 2005</li> <li>Performance data for off-hours radiology readings will be reported each month for the next 6 months at the PIC starting May 2005.</li> <li>The PIC will report on these indicators quarterly to the Board Quality Improvement Committee starting May 2005.</li> </ol>	<p>Chief Medical Officer</p>	<p>May 5, 2005</p> <p>May 25, 2005</p>
<p>The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (f) Diagnostic and Therapeutic facilities.</p> <p>11. Patient #4 had a medical history that included sickle cell disease. Review of the Transport Program Triage Sheet dated 3/13/04 identified that Patient #4 presented to a Community Hospital Emergency Department with headache, facial droop, left sided weakness and ptosis of the right eye. A CT Scan of the head was performed and a diagnosis of stroke was documented. The triage sheet further identified that the patient had a hematocrit level of 18 (normal hematocrit 32.0 % to 43.8%). At 12:55 PM, MD #4 accepted the transfer of this patient who subsequently arrived to CCMC at 1:50 PM. Patient #4 was immediately assessed and designated a level two (2) triage level. At approximately 2:15 PM-2:30 PM, the plan was to proceed with a full exchange transfusion. IV access placement occurred at 3:30 PM and a type and cross specimen obtained at 3:45 PM. The Blood Bank Supervisor identified that the first bag of PRBC was available to be picked up at 5:15 PM. According to facility documentation, both units of blood were released to CCMC staff from the Acute Care Hospital's Blood Bank staff at 5:56 PM. The facility was unable to provide documentation that the nursing unit was notified that the first aliquot of blood was ready at 5:15 PM. Review of the clinical record with RN #3 on 3/10/05 identified that she initiated the blood transfusion (100 ml's of PBRC's) at 6:20 PM.</p>	<p><b># 11 Response:</b></p> <ol style="list-style-type: none"> <li>CCMC and Acute Care Hospital #2 have agreed to the following:                     <ol style="list-style-type: none"> <li>To institute processes for communication and documentation of when blood products are ready for pick-up</li> <li>CCMC policy on Blood Products Administration has been modified to require CCMC employees to document date and time for pick-up. Staff has been educated on the revised policy.</li> </ol> </li> <li>An addendum to the existing contract will be executed to document the agreement referred to above by April 30, 2005. Compliance will be monitored by ongoing medical record reviews of patients receiving blood products.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>All blood products issued over a period of 10 consecutive days will be audited for documentation of pick-up time and administration time.</li> <li>Thereafter, for the next 6 months, on one day per week, the records of patients who received blood will be audited for documentation of pick-up time and administration time.</li> </ol> <p><b># 11 Response:</b></p> <ol style="list-style-type: none"> <li>Sickle cell disease guidelines for acute complications and emergent complications and emergency care were reviewed to ensure compliance with current standards of the New England Pediatric Sickle Cell Consortium (NEPSCC).</li> <li>Guidelines were distributed to the Emergency Department in 2003. Updated guidelines were distributed in September 2004</li> <li>Inservice education on the revised guidelines was</li> </ol>	<p>Nursing Director</p> <p>Medical Director, Hematology/Oncology</p>	<p>April 30, 2005</p> <p>September 30, 2004</p>

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<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (g) Pharmacy (4) and/or (i) General (6).</p>	<p>completed for Emergency Department physicians and nurses last fall, 2004.</p> <p>4. Pediatric residents received a reference guide on the assessment and management of the patient with sickle cell disease in September 2004.</p> <p>5. Training will be presented to all new Pediatric residents annually, and Medical Staff and Nursing training will be updated and documented annually to assure understanding of updated sickle cell disease guidelines.</p> <p>Monitoring:                      1. Guidelines will be reviewed at least once a year by the CCMC Hematology-Oncology Care Committee to ensure appropriateness and compliance with NEPSCC standards.                      2. The records of 5 patients with Sickle Cell Disease are audited on a monthly basis for timeliness of care and compliance with standards. Feedback is provided to the appropriate providers.</p>	<p>Nursing Director</p>	<p>April 30, 2005</p>
<p>12. During a tour of Operating Room (OR) #3 on the morning of 3/8/05, multiple medication carts including the heart cart were observed unlocked and unattended. Interview with the Manager of the OR identified that the carts were utilized during an emergency in the Pediatric Intensive Care Unit on the morning of 3/8/05 and were not relocked.</p>	<p># 12-14 Response:                      1. Members of the Department of Anesthesia were educated about keeping drugs, syringes and anesthetics in locked carts when the drugs and carts were not attended. Individuals signed a sheet stating they understand and will comply with this requirement.                      2. Liquid Inhalant anesthetics have been placed in the locked anesthesia cart.                      3. The lock on the refrigerator in the ED Room 1 is in place.                      4. All clinical staff will be re-educated about proper storage and securing of medications and needles/syringes.</p> <p>Monitoring:                      1. Cart lock logs will be monitored daily                      2. Refrigerator locks will be monitored daily.                      Storage areas including carts will be monitored on all inpatient units weekly.</p>		
<p>13. During a tour of the cardiac cath lab on the morning of 3/8/05, liquid inhalant anesthetics were observed on the anesthesia machine that was unlocked and unattended.</p>			
<p>14. Observations during tour of the Emergency Department on 3/12/05 at approximately 5:15 PM identified that the medication refrigerator in the trauma room was unlocked. The refrigerator contained intravenous atropine, epinephrine, and other injectable medications. Interview with the Charge Nurse identified that the refrigerator was capable of locking.</p>			

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<p>The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D-4a (b) Administration (2) and/or (f) General (6).</p> <p>15. During tour of the OR on 3/8/05, blanket warmers were observed to contain multiple types of fluid containers. Although rigid fluid containers were dated with date of discard, several fluid bags were undated. A review of the facility policy for the Fluid Warming Cabinet identified a lack of specific timing for fluids that were warmed, however, the warmer's temperature log identified bottles of fluid over 72 hours old were to be discarded.</p> <p>16. Observations during tour of the Emergency Department on 3/8/05 of the three code carts identified that the Code Cart Daily Check Log Sheets dated 1/05 through 3/8/05 lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily.</p> <p>17. Further observations during tour of the Emergency Department on 3/12/05 at 5:10 PM identified that the Code Cart Daily Check Log Sheets dated 3/12/05 for the three (3) code carts lacked documentation to reflect that the defibrillator function tests and the code cart checks were performed on 3/12/05.</p> <p>18. Observations during tour of the facility on 3/8/05, 3/09/05, 3/10/05 and 3/11/05 identified that the Code Cart Daily Check Log Sheets for Code Carts #18, #17, #16, #15, #13 and #7, lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily for the period of 11/01/04 through 3/11/05.</p>	<p><b># 15-18 Response:</b></p> <ol style="list-style-type: none"> <li>Revised the Fluid/Blanket Warming Cabinet policy based in accordance with Manufacturer guidelines to specify which items may be safely stored.</li> <li>The ED nursing staff was re-educated about the code cart check policy.</li> <li>All OCMC departments with code carts have been re-educated about the code cart check policy.</li> </ol> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>Warming Cabinet temperature logs will be audited by the Nurse Managers daily.</li> <li>The Nurse Managers shall audit date/time/discard of fluids in the Warming Cabinet daily.</li> </ol> <p>Code cart logs will be audited by the Nurse Managers daily.</p>	<p>Nursing Director</p>	<p>April 30, 2005</p>
<p>19. Patient #3, an adolescent male, was admitted to the Emergency Department (ED) on 11/10/04 at 5:25 PM following a motor vehicle accident. The patient needed to</p>	<p><b># 19 Response:</b></p> <p>Corrective action accomplished by convening peer review within 24 hrs of 11/10/04 MVA case involving Patient #3. All disciplines involved in the patient's care participated with the goal to analyze and correct pertinent ED systems issues. Actions implemented to prevent reoccurrence include:</p> <ol style="list-style-type: none"> <li>Guidelines adopted to establish time standards for reading and communicating radiological findings. This time standard and all other processes below apply to all patients that present with critical/life threatening illness or injuries</li> </ol>	<p>Medical Director, ED</p>	<p>May 4, 2005</p>

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<p>be extricated from the car. The patient was examined on arrival at CCMC and was described as having a tender lower chest, complaining of back pain, the right leg was externally rotated, abdomen was described as rigid and tender to palpation. Documentation in the medical record identified that at 5:51 PM a portable chest and pelvic x-rays were obtained and at 5:52 PM portable c-spine films were obtained. Documentation further noted that at 6:15 PM the surgical attending was at the patient's bedside and at 6:13 PM the orthopedic resident was also at the bedside.</p> <p>At 6:25 PM a CT of the abdomen was obtained which was followed shortly thereafter with additional x-rays of the right hip, leg and pelvis. A review of the radiology requisition/preliminary interpretation report identified that although the portable chest, pelvis and c-spine films had been taken at 5:51 and 5:52 PM, respectively, the chest and c-spine films were not presented to Acute Care Hospital #2 radiology until 7:30 PM. The pelvis film was not presented at this time. Documentation by the Acute Care Hospital #2 Radiology Department identified that a review of the chest x-ray identified a widened mediastinum with a questionable aortic arch injury. Once the CCMC ED physicians were made aware of this finding, the patient was then taken for a CT Scan of the chest at 8:25 PM. Documentation in the medical record identified that once the CT had been completed, the patient then was moved back to the trauma room. The patient complained of shortness of breath and his B/P deteriorated. The patient subsequently went into cardiac arrest and the code was called at 10:06 PM.</p> <p>Documentation was lacking in the medical record to reflect that a physician assessment of available data was performed in the ED during the period of 5:51 PM upon completion of the portable chest x-ray until 7:30 PM when the film was presented to radiology, at Acute Care Hospital #2 for review. Following this review, emergent interventions were not implemented in response to the radiological review but instead additional diagnostic testing was initiated.</p> <p>Facility policy entitled ED Radiology Exams and dated 9/24/04 identifies after performing the requested exam the tech returns the film and insert to the ED and places it on the counter in front of the ED radiology view box. The ED physician reads the film and writes his/her</p>	<p>upon assessment or re-assessment in the CCMC Emergency Department (ED)</p> <ul style="list-style-type: none"> <li>• Elapsed time from patient's initial radiograph to time of the unofficial read by ED Attending will be ≤ 15 minutes.</li> </ul> <p>2. Specific procedures were established to standardize communication between ED attending and radiologist for critically ill or injured patients.</p> <ul style="list-style-type: none"> <li>• Radiology Tech returns developed films directly to the responsible ED attending, who reviews films.</li> <li>• Direct 'ring down' phone installed at CCMC ED and Hartford Hospital radiology to create immediate link between ED attending and Radiologist to be accessed when clinically indicated.</li> <li>• Processes implemented for CCMC staff to hand carry clinically indicated films to radiology and return read films to ED Attending.</li> </ul> <p>3. All physician and nursing staff in the ED and Radiology were educated on the revised policy.</p> <p>4. ED physicians and nursing staff will sign an acknowledgment that they have read and understand the policy and will comply with the policy, including all care and documentation requirements.</p> <p>5. Physician performance issues related to the care of patient # 3 were addressed and corrective actions taken.</p> <p><b>Monitoring:</b></p> <ol style="list-style-type: none"> <li>1. In the course of treatment of patients, the ED attending will monitor compliance with time standards for reading and communicating radiological findings for all patients meeting criteria (critically ill/immediate life-threatening illness or injury). Discrepancies will be reported to the Medical Director, ED for review and corrective action, if required.</li> <li>2. Twenty ED records per month will be audited by ED, Medical Director for compliance with clinical indicators related to timeliness and quality of care. ED Medical Director will institute any necessary corrective action and if warranted, will make recommendations to the Medical Staff office for further consideration and action.</li> </ol>	<p>Chief Medical Officer</p> <p>Medical Director, ED</p>	<p>May 4, 2005</p> <p>May 4, 2005</p>

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<p>interpretation on the form, and signs the form including printed name and date and time. The ED physician places the film in the file on the ED main counter for delivery to Acute Care Hospital #2's Radiology. This policy did not, however, address time frames for the readings, delivery and/or reporting of radiology interpretations.</p>			
<p>The following is a violation of the Connecticut General Statutes Section 127n-2C.</p> <p>20. The facility failed to submit to the Department a corrective action plan relative to an adverse event which occurred in the ED on 11/10/04 and which was subsequently reviewed under Peer Review.</p>	<p># 20 Response: 1. Initial case review did not identify this as an Adverse Event per State of Connecticut definitions. 2. CT DPH Adverse Event Reporting Criteria have been reviewed by Risk Manager, CMO, and VP for Patient Care and HR Services to assure compliance with criteria. Entire Executive management team retained on reporting criteria. 3. Risk Manager will institute an independent review of all potentially reportable events with QI Consultant and Executive Management Member to validate reporting decision. 4. All potential Adverse Events will be reviewed as indicated according to State reporting criteria. Monitoring: 1. Risk Manager will review all potentially reportable adverse outcomes with Chief Medical Officer to assure appropriate reporting.</p>	Risk Manager	April 30, 2005
<p>The following is violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and (c) Nursing Service (1) and/or (i) General (6).</p> <p>21. Patient #1 was admitted to the hospital on 7/14/04 with a diagnosis of "short term syndrome." Review of the clinical record identified that Patient #1 received physical therapy throughout the hospitalization and was assessed as incapable of rolling, sitting or standing independently. Interviews with RN #1 on 2/23/05 and PCA #2 on 2/22/05 identified that on 2/19/05, RN #1 and PCA #2 provided care for Patient #1 between 7:30 PM and 8:35 PM. At the conclusion of the care, Patient #1 was placed in the center of the crib, on her back with rolled blankets at her sides and the crib rails in a raised position. At approximately 8:43 PM, eight minutes later, RN #1 identified that Patient #1 was crying and she went to the room to investigate. On entering the room, RN #1 observed Patient #1 on the floor, lying face down,</p>	<p># 21 Response: 1. Guidelines developed and implemented 2/23/05 to clarify staff responsibilities regarding enforcement of the hospital's Visitor Policy. The staff was educated on the guidelines and re-educated on the policy in staff meetings. 2. Guidelines specify that parents are responsible for the supervision of their children at all times, and that staff members will return unsupervised children to the parent/guardian. Repeated occurrences may result in the parent being asked to remove the child from the hospital. 3. Guidelines have been posted prominently in public areas of the hospital. Monitoring: Each Manager of an inpatient Med/Surg unit and the daily Resource Nurse will monitor compliance on unit rounds.</p>	Vice President for Patient Care and HR Services	March 21, 2005

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<p>approximately 5-7 feet from the crib, bleeding from the head and/or face. RN #1 initiated an emergency code, the patient was intubated, resuscitated and transferred to the pediatric intensive care unit. A neurosurgical consult was obtained on 2/20/05 that identified Patient #1 had sustained a left temporal fracture extending to the external auditory canal, a comminuted left parietal/occipital fracture with fragment, had blood in the ventricles and multiple areas of hemorrhage and/or contusion. Patient #1 subsequently expired on 2/25/05. Interview with RN #1 on 2/23/05 identified that she saw Person #1 standing near Patient #1's bedroom when she discovered Patient #1 on the floor. Person #1 was a seven (7) year old visitor of Patient #2. Although staff identified that they had periodically redirected Person #1 back to Person #2's room, Person #1 continued to walk around on the unit unattended. Additional interviews with Facility Administration identified that it was their belief that the seven (7) year old visitor was responsible for the injuries sustained by Patient #7. The hospital policy for visitors identified that an adult must accompany children under the age of twelve (12) at all times. None of the staff interviewed noted that they had addressed the problem with Person #1's parents.</p>			

04/27/2005



STATE OF CONNECTICUT  
DEPARTMENT OF PUBLIC HEALTH

April 11, 2005

Mr. Larry Gold, President and CEO  
Connecticut Children's Medical Center  
282 Washington Street  
Hartford, CT 06106

Dear Mr. Gold:

Unannounced visits were initiated on February 20, 2005 to Connecticut Children's Medical Center by representatives of the Division of Health Systems Regulation for the purpose of conducting multiple investigations and a full federal survey with additional information received through March 31, 2005.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for April 25, 2005 at 10:00 AM in the Division of Health Systems Regulation, Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

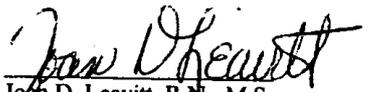
Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

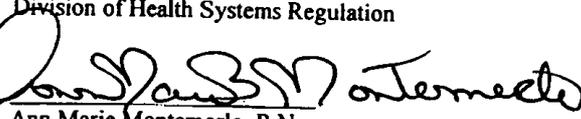
Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Sincerely,

  
John D. Leavitt, R.N., M.S.  
Public Health Services Manager  
Division of Health Systems Regulation

  
Ann Marie Montemerlo, R.N.  
Supervising Nurse Consultant  
Division of Health Systems regulations

JDL:AMM:zbj

- c. Director of Nurses  
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THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
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WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (1)(A) and/or (2) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).

1. Connecticut Children's Medical Center (CCMC) was unable to provide a written and executed contract with Acute Care Hospital #2 for the reading of x-rays by Acute Care Hospital #2 during periods when CCMC's radiologist was unavailable (e.g. off shift and/or weekend hours and/or holidays). Interview with the DNS on 3/10/05 identified that CCMC did not have a contract delineating radiology services provided by Acute Care Hospital #2 on off-hours, weekends and holidays. A review of CCMC's policy for Emergency Department (ED) Radiology Exams approved in August 2004 for off-hours, weekends and holidays, indicated in part, that the CCMC ED physician reads the film and writes his/her interpretation on the form (the Radiology Request/Preliminary Interpretation form attached to the film's jacket). The ED physician then places the film in the upright file for delivery to Acute Care Hospital #2 Radiology by a CCMC radiology "runner" who brings the film to the radiology resident at Acute Care Hospital #2. The Acute Care Hospital #2 radiology resident reviews the film, writes a preliminary interpretation on the form and the "runner" brings the film back to CCMC and places it on the counter in front of the ED radiology view box for the CCMC ED attending to review. The policy lacked expected time frames for either initial or radiology interpretation, a communication process between the radiologist and the ED physician and lacked an identified process for emergent and/or trauma readings.
2. The facility failed to develop and/or maintain an executed contract and/or a written protocol for the joint Acute Care Hospital #2/CCMC system for pediatric trauma care. Interview with the CCMC Trauma Coordinator identified that although there is no single formal written document which outlines the shared program there are various documents which identify the various aspects of the program such as a Pediatric Surgeon Response Document and the Radiological Services Procedure. In addition to these documents, there is the joint monthly meeting of the Trauma Steering Committee. He added that the function of the Trauma Steering Committee is to review cases and set policy. A review of the Trauma Steering Committee meeting minutes for the period of 10/14/04 through 1/21/05 identified that shared services between CCMC and Acute Care Hospital #2 relative to the joint trauma program included pediatric nursing education at Acute Care Hospital #2, Acute Care Hospital #2 on-call lists for both trauma and neurosurgery physicians, back-up by Acute Care Hospital #2 for pediatric trauma and radiology services. Further review identified that as of the last meeting on 1/21/05 of the Trauma steering Committee identified an update was provided on the status of the joint trauma center's

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Memorandum of Understanding (MOU). Discussion was held on the status of the document and "how to expedite its completion." A review of the Trauma Program meeting minutes dated June 23, 2004 identified that it was agreed that for Acute Care Hospital #2/CCMC to function as a level 1 trauma center, a contractual administrative agreement that effectively makes them one administrative unit "should be developed." It was agreed that the best approach would be to develop a joint administrative agreement formalizing operating authority for CCMC.

Interview with the CCMC Director of Trauma Service on 3/9/05, identified that there is an "informal plan with Acute Care Hospital #2" relative to the trauma program. The Director stated that the program is an evolving trauma system with the goal to have CCMC classified as a level 1 trauma facility. There is a sharing of staff and programs. There is in place at this time at least an oral agreement with Acute Care Hospital #2. CCMC is not currently classified as a level 1 trauma facility in accordance with American College of Surgeons (ACS) accreditation and Public Health Code Section 19a-177-4(a).

3. Patient #4 arrived in CCMC's ED at 1:50 PM from another Acute Care Facility where it was determined that the patient's hematocrit level was 18 (normal 32.0% to 43.8%). Patient #4 was evaluated in the ED and a diagnosis of resolving cerebrovascular accident (CVA) was determined. Subsequent to consultation between MD #4 and MD #1 at approximately 2:15 to 2:30 PM on 3/13/04, plans to provide an exchange transfusion were initiated. Review of the ED record and interview with RN #3 identified that a type and screen was obtained at 3:45 PM. Review of facility documentation with the Acute Care Hospital #2 Blood Bank Supervisor on 3/8/05 identified that Patient #4 was entered into the blood bank system at 4:12 PM and processing of the type and screen was initiated. The medical record identified that Patient #4 was admitted to the Pediatric Intensive Care Unit (PICU) at 4:40 PM with treatment plans to include an exchange transfusion. Review of the exchange transfusion orders written at 4:45 PM directed the first 100 cubic centimeters (cc) of blood to run over a two hour period. Interview with the Blood Bank Supervisor identified that the order for the exchange transfusion was received in the blood bank at 5:11 PM, nearly one half hour after the order was written. The order requested that the Packed Red Blood Cells (PRBC) be split into two (2) aliquots (units) of 100 cc's and 140 cc's. The Blood Bank Supervisor identified that the 100 cc bag of PRBC was completed and available to be picked up at 5:15 PM. The Blood Bank Supervisor further identified that the 140 cc bag of PRBC was available at 5:50 PM. Facility documentation identified that both bags of blood were released to CCMC staff from the blood bank at 5:56 PM. The Blood Bank Supervisor identified that although it is the standard practice for blood bank staff to call the nursing unit when the first unit of blood is ready, Acute Care Hospital #2 was unable to provide

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documentation as to who called the CCMC nursing unit or the time the nursing unit was notified when the first aliquot of blood was ready at 5:15 PM. Review of Blood Bank policies failed to specify the procedure that Acute Care Hospital #2 Blood Bank staff would follow to alert nursing when the ordered blood product was available. Interview with CCMC's RN #1 on 3/10/05 identified that although the unit secretary would inform her as to when the blood product was available to be picked up from the blood bank, RN #1 was unable to identify when she was made aware that the blood was ready for pickup. Review of the CCMC's nursing policy with relation to communication between the Acute Care Hospital #2 Blood Bank and CCMC's nursing units lacked specific direction for communication between the two entities. Review of the clinical record identified that RN #1 initiated the blood transfusion (100 cc of PBRC's) at 6:20 PM (more than one hour after the first aliquot of blood was available).

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (c) Medical staff (3) and/or (4)(C) and/or (d) Medical records (3).

4. CCMC was unable to provide evidence that Radiology Services were reviewed for performance quality. A review of CCMC Board Quality Improvement Committee minutes from September 15, 2004 through February 16, 2005 and/or the Performance Improvement Committee minutes from August 8, 2004 through February 3, 2005 failed to identify that the hospital had reviewed the quality of services for Radiology. Review of the Patient Safety Committee Minutes dated July 15, 2004, identified that radiology communication problems had occurred on off-shift hours and weekends when services were to have been provided to CCMC by Acute Care Hospital #2. As a result of this concern and as part of a plan of correction that was to be implemented as a result of a CMS complaint validation survey concluded on 8/24/04, an x-ray interpretation tracking quality monitor form was implemented in the Emergency Department in September 2004. The tracking form identified the dates and times the radiology exam was requested, the date, time and interpretation of the emergency physician and the dates and times of the initial and final Acute Care Hospital #2 Radiology Department interpretation. Although the physician director of CCMC's ED reported in the September 20, 2004 minutes of the Patient Safety Committee that radiology interpretations were occurring in a timely manner, a review of the x-ray interpretation tracking quality monitor forms for October 2004 through February 2005 identified that items of information on the x-ray interpretation forms were not consistently completed. Evidence of follow-up to correct system discrepancies failed to be identified in the quality minutes reviewed. During interview, the physician director of the CCMC ED stated that although data had been collected, it had not been

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interpreted. A review of the facility's Performance Improvement Plan approved in May 2004 directed that the Board Quality Improvement Committee review reports regarding specific outcome indicators and provide feedback to the Performance Improvement Committee. The plan identified that setting of priorities included a review of problem-prone processes and unusual/sentinel events. The hospital identified problems with the radiology process post-death of Patient #3 in November 2004 and proposed a policy and procedure to address the processes for radiology film interpretation. As of 3/9/05, the hospital had not implemented the plan and per interview with the VP of Patient Care Services, physicians were in the process of being educated. Further, a review of the proposed Trauma Radiology During Off-Hours for Level One and Level Two Trauma Activations procedure failed to identify an expected time frame from the completion of the x-ray to the time of the Acute Care Hospital #2 radiology interpretation and from the time of the radiology interpretation to notification of the CCMC attending surgeon.

5. Review of Patient #20's Radiology Requisition/Preliminary Interpretation Report for the CT Scan performed on 3/12/05 lacked the date and time the exam was requested.
6. Review of Patient #22's Radiology Requisition/Preliminary Interpretation Report for the x-ray performed on 1/3/05 identified that the Radiology Attending interpretation was documented on 3/8/05. In addition, final x-ray report for the exam performed on 1/3/05 lacked the date and time the exam was interpreted by the attending radiologist. Review of the medical record and interview with the Attending Radiologist on 3/10/05 at 11:05 AM identified that on 3/8/05, the Radiology Manager requested him to complete the interpretation and that the interpretation should have been performed the day after the exam (1/4/05). The Attending Radiologist further identified that the final report for the exam performed on 1/3/05 was signed on 3/8/05 and that there was no documentation on the final report to reflect when the final report was interpreted.
7. Review of Patient #30's Radiology Requisition/Preliminary Interpretation Report for the exam performed on 1/12/05 lacked the time when the exam was requested and when the Emergency Department (ED) interpreted the exam. The Radiology Attending interpretation lacked the date and time the exam was interpreted. In addition, the cervical spine film final report performed on 1/12/05, the CT of the abdomen final report performed on 1/11/05, and the CT of the brain final report performed on 1/12/05 lacked the date and time the exams were interpreted by the radiologist.
8. Review of Patient #34's Radiology Requisition/Preliminary Interpretation Report for the x-rays performed 10/3/04 lacked the date and when the Emergency Department (ED) Interpreted the exam, lacked the time of the Radiology Residents and Radiology

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Attending interpretation of the exam and the time the Radiology Attending interpreted the exam. The CT Scan requested on 10/3/04 lacked the time requested.

9. Review of Patient #40's Radiology Requisition/Preliminary Interpretation Report for the CT Scan shunt series dated 3/12/05 lacked the time the exam was requested and the time of the Radiology Resident's interpretation.
10. Review of Patient #42's Radiology Requisition/Preliminary Interpretation Report for the CT Scan dated 3/12/05 lacked the time the exam was requested. The x-rays dated 3/12/05 lacked the time the exam was requested and lacked the date and time the ED Physician interpreted the exam. The ED Radiology Exams Policy identified that the requesting practitioner completes the section for the examination requested and patient history, including signature, printed name, date and time. For off hours, the CCMC ED physician reads the film and writes the interpretation on the form, and signs the form including printed name, date, and time. An Acute Care Hospital #2 Radiology Resident reviews the film, writes a preliminary interpretation on the form, and signs with a signature, printed name, and date and time. The Radiology Attending reads the film the next morning.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (f) Diagnostic and Therapeutic facilities.

11. Patient #4 had a medical history that included sickle cell disease. Review of the Transport Program Triage Sheet dated 3/13/04 with MD #4 (ED Attending) identified that Patient #4 presented to a Community Hospital Emergency Department with headache, facial droop, left sided weakness and ptosis of the right eye. A CT Scan of the head was performed and a diagnosis of stroke was documented. The triage sheet further identified that the patient had a hematocrit level of 18 (normal hematocrit 32.0 % to 43.8%). At 12:55 PM, MD #4 accepted the transfer of this patient who subsequently arrived to CCMC at 1:50 PM. Patient #4 was immediately assessed and designated a level two (2) triage level. According to the Triage Classifications Guidelines, a patient who is designated a level two (2) requires prompt medical attention, as an extended delay might be harmful to the patient and/or result in disability or loss of life. Review of the ED record with Physician's Assistant (PA) #1 on 3/16/05 identified that she evaluated the patient at 2:00 PM, documented that ptosis of the right eye was observed; otherwise, the patient's neurological symptoms had subsided. MD #1 (Hematologist) stated during interview on 3/11/05 that MD #4 (ED Attending) consulted with him while the patient was in the ED at approximately 2:15 PM-2:30 PM, with the plan to proceed with a full exchange transfusion. At 2:55 PM, PA #1 ordered a Blood Type and Cross. MD #4 stated during interview on 3/9/05 that although the patient's neurological deficits had resolved, symptoms could

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potentially reoccur, therefore, he requested Patient #4 be moved to Room #1 (close observation room) for close monitoring of the patient's status. MD #4 stated that Patient #4 was the sickest patient in the ED at this time and directed PA #1 to expedite her care. RN #3 identified during interview on 3/14/05 that she obtained the Type and Cross at 3:45 PM. Interview with the Director of Nurses on 3/11/05 identified that ED physicians utilize the New England Pediatric Sickle Cell Disease Consortium for Routine Health Care Maintenance of Pediatric Patients with Sickle Cell Disease. According to these guidelines, exchange transfusion therapy should be initiated as soon as possible in the event of a suspected stroke. Interventions based upon evaluation provided to Patient #4 since arrival to the ED at 1:50 PM included an order for blood type and cross at 2:55 PM, Tylenol at 2:45 PM for complaints of headache, IV access placement at 3:30 PM and a type and cross specimen obtained at 3:45 PM. MD #4's discharge diagnosis from the ED to the Pediatric Intensive Care Unit (PICU) included resolving cerebrovascular accident.

Review of facility documentation dated 3/14/04 identified that RN #4 had collected the type and screen and informed the Blood Bank that the patient would receive an exchange transfusion in the PICU. At 4:03 PM, the blood specimen was received by Acute Care Hospital #2's Laboratory, logged into Blood Bank specimen processing at 4:06 PM with the type and screen initiated at 4:12 PM. On 3/14/04 at 4:40 PM, Patient #4 was admitted to the PICU with an exchange transfusion order written at 4:45 PM that directed administration of Packed Red Blood Cells (PRBC) 100 cubic centimeters (cc) intravenously to run over two hours. Interview with the Blood Bank Supervisor at Acute Care Hospital #2 and documentation review identified that this order was received in the blood bank at 5:11 PM and required the PRBC's be split into two (2) aliquots of 100 cc's and 140 cc's. The Blood Bank Supervisor identified that the 100 cc bag of PRBC was available to be picked up at 5:15 PM. According to facility documentation, both units of blood were released to CCMC staff from the Acute Care Hospital's Blood Bank staff at 5:56 PM. The Blood Bank Supervisor identified that it is the standard practice for blood bank staff to call the nursing unit when the first unit of blood is ready. The facility was unable to provide documentation that the nursing unit was notified that the first aliquot of blood was ready at 5:15 PM. Review of the clinical record with RN #3 on 3/10/05 identified that she initiated the blood transfusion (100 cc's of PBRC's) at 6:20 PM. Interview with RN #1 failed to identify why the transfusion was not initiated from 5:15 PM (blood available) until 6:20 PM. According to Blood Diseases of Infancy and Childhood, Mosby, Seventh Edition, 1995, Chapter 12, pages 433-434:

"Cerebrovascular accidents are one of the most devastating complications of sickle cell disease. Immediate treatment of stroke includes intravenous hydration and general supportive care. Simple transfusion to achieve a hematocrit level of 30% to 34 % or exchange transfusion to reduce the Hb S to less than 30% should be

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undertaken as soon as possible." According to Nathan and Oski's Hematology of Infancy and Childhood, Sixth Edition, 2003, Volume 1, Chapter 19, Sick Cell Disease, page 807: "The standard approach to treating a patient with acute infarction is exchange transfusion."

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (g) Pharmacy (4) and/or (i) General (6).

12. During a tour of Operating Room (OR) #3 on the morning of 3/8/05, multiple medication carts including the heart cart were observed unlocked and unattended. Interview with the Manager of the OR identified that the carts were utilized during an emergency in the Pediatric Intensive Care Unit on the morning of 3/8/05 and were not relocked.
13. During a tour of the cardiac cath lab on the morning of 3/8/05, liquid inhalant anesthetics were observed on the anesthesia machine that was unlocked and unattended.
14. Observations during tour of the Emergency Department on 3/12/05 at approximately 5:15 PM identified that the medication refrigerator in the trauma room was unlocked. The refrigerator contained intravenous atropine, epinephrine, and other injectable medications. Interview with the Charge Nurse identified that the refrigerator was capable of locking.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (i) General (6).

15. During tour of the OR on 3/8/05, blanket warmers were observed to contain multiple types of fluid containers. Although rigid fluid containers were dated with date of discard, several fluid bags were undated. A review of the facility policy for the Fluid Warming Cabinet identified a lack of specific timing for fluids that were warmed, however, the warmer's temperature log identified bottles of fluid over 72 hours old were to be discarded. During interview the DNS stated that the policy was in flux secondary to the introduction of a new OR Manager who was introducing new policies.
16. Observations during tour of the Emergency Department on 3/8/05 of the three code carts identified that the Code Cart Daily Check Log Sheets dated 1/05 through 3/8/05 lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily. The Code Blue Code Cart Policy

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identified that the integrity of the contents of the code carts would be monitored on a daily basis and that the area manager who was responsible for the cart would assign a healthcare provider to assess the integrity of the numbered, tamper-evident locks and perform the Defibrillator Function Test. This individual would ascertain whether the locks were intact and would document that on the Code Cart Daily Check Log Sheet by recording the date and time, the lock numbers and their signature.

17. Further observations during tour of the Emergency Department on 3/12/05 at 5:10 PM identified that the Code Cart Daily Check Log Sheets dated 3/12/05 for the three (3) code carts lacked documentation to reflect that the defibrillator function tests and the code cart checks were performed on 3/12/05. Interview with the Charge Nurse at 5:10 PM identified that the defibrillator and crash carts should be checked daily during the day shift. Further observations at 8:55 PM identified that the Code Cart Daily Check Log Sheets for 3/12/05 lacked documentation to reflect that the checks were performed after surveyor inquiry at 5:10 PM.
18. Observations during tour of the facility on 3/8/05, 3/09/05, 3/10/05 and 3/11/05 identified that the Code Cart Daily Check Log Sheets for Code Carts #18, #17, #16, #15, #13 and #7, lacked consistent documentation to reflect that the defibrillator function tests and/or the code cart checks were performed daily for the period of 11/01/04 through 3/11/05.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and/or (3) and/or (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (f) Diagnostic and Therapeutic facilities and/or (i) General (6).

19. Patient #3, an adolescent male, was admitted to the Emergency Department (ED) on 11/10/04 at 5:25 PM following a motor vehicle accident. The ambulance run form identified that the patient had been seated in the front passenger seat of a car which had been "t-boned" by an SUV at a high rate of speed causing a 2 foot intrusion of the right front passenger side. The patient needed to be extricated from the car. He was described by the paramedics as being cold, clammy, had a tender abdomen throughout all quadrants which radiated to the back, had pain in the right hip area and pelvic region with an outward rotation and shortening to the right leg. The patient was examined on arrival at CCMC and was described as having a tender lower chest, complaining of back pain, the right leg was externally rotated, abdomen was described as rigid and tender to palpation. The patient was groaning at this time. Two intravenous lines of Normal Saline (NS) were running at a rate of "open." Documentation in the medical record identified that at 5:51 PM a portable chest and pelvic x-rays were obtained and at 5:52 PM portable c-spine films were obtained.

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saw these films. MD #5 seeing Physician #12 in the patient's room with the patient, MD #5 did not speak to MD #12 about these films. Once MD #5 learned of the suspected aortic arch injury she thought that the child needed further evaluation and a CT chest scan was "set up to evaluate" the extent of injury.

Following the chest CT, the patient went to the orthopedic room because the orthopedists were anxious to set his leg. Shortly thereafter, the patient had a rapid decompensation. Documentation in the medical record was inconsistent with this interview in that it did not reflect the patient returning to the orthopedic room upon completion of the CT scan of the chest.

Interview with the Trauma Surgeon (MD #12) on 3/22/05 identified that he responded to an emergency page and was asked by the Trauma Coordinator to come to the ED and see a patient. When he arrived at the ED he saw Patient #3 and touched his belly, which seemed fine and not problematic from a surgical perspective. He also looked at the Abdominal CT Scan as it was being done and didn't see any problems. He directed the surgical resident (MD #11) to bring the other films to radiology but he himself did not view any of these other x-rays. He wrote a progress note confined only to his interpretation of the abdominal findings which was timed for 6:30 PM and he then went home with no plan to come back to see this patient. He did not recall if he discussed the case with the ED attending (MD #5) at any time.

Interview with the Pediatric Resident (MD #10) on 3/15/05 identified that she knew that the patient had received numerous x-rays and although she inquired of the surgical resident as to where the x-rays might be, no one knew. She added that the surgical resident (MD #11) told her that she had viewed the chest x-ray with the trauma surgeon, prior to the x-rays going to the radiologist at 7:30 and he felt that the aorta "looked a little rotated."

Interview with the Surgical Resident (MD #11) on 3/21/05, identified that she responded to a page and went to the trauma room in the ED. She assessed the patient for injuries and the only specific injury that she saw was the right femur. She then went to CT Scan and looked at the abdominal CT. Also present were MD #12 and MD #13. She then looked at the chest x-ray and stated she saw a "normal chest x-ray." She did not confer with anyone else upon reading this film. MD #12 left the ED and did not give any further directions regarding this patient. MD #13 was informed later that the patient had a transected thoracic aorta and paged MD #12 because he was not in the building. He instructed her to page the cardiothoracic service and to activate the OR; however, it was not clear if he meant the OR at Acute Care Hospital #2 or Connecticut Children's Medical Center.

Interview with the Acute Care Hospital #2 Radiology Resident on 3/15/05 identified that the first time she was apprised of the trauma case at the Hospital was when a physician, not involved in the care of Patient #3 called her and asked her if she had viewed the CT scan of the abdomen and pelvis. She added that he had also told her

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that he had looked at the films with the trauma surgeon and felt that they were okay. She did not agree with this and asked to see any other films that might have been taken. She also asked him why no one else had contacted her from the ED earlier. She then looked at the chest x-ray and saw a very abnormal mediastinum which was suggestive of an aortic arch injury. She consulted with the Acute Care Hospital #2 Pediatric Radiology Attending and he concurred. She did suggest further studies to include a chest CT which would be obtained at the discretion of the clinicians and should have been based on their assessment of the patient. She added that the only person that ever contacted her from the ED regarding the films again was the physician who was not involved in the case.

Interview with a paramedic who responded to the accident identified that she arrived on scene and it was clear that the patient needed to be extricated from the car, the car needed to be cut because the patient was pinned inside. The fire department began cutting off the roof of the car. The patient was pale and sweaty and two IV lines were initiated. The patient complained of pain in his abdomen and chest and also pain in his back upon breathing. She contacted C-Med for a patch to another hospital which was designated as a Trauma Level 1 Facility, and described the mechanism as high speed "t-bone" into passenger door with 2 foot invasion. She also described the condition of the patient. The paramedics were then told to transport to CCMC, which did not have a trauma designation. Upon arrival at the ED, she told the Trauma Coordinator, that in her opinion the patient should have gone to a level 1 trauma facility. He explained to her that CCMC had established an algorithm which was used in determining where the patient should go. Upon learning of the patient's death, the paramedic met with the Trauma Coordinator (TC) and was told that the patient had died from a "horrific injury which did not present in the usual manner." She informed the TC that her anger was based on the Hospital's slowness in responding to the emergency. He acknowledged that they are still "slow with trauma because it's new to them." Facility policy entitled ED Radiology Exams and dated 9/24/04 identifies after performing the requested exam the tech returns the film and insert to the ED and places it on the counter in front of the ED radiology view box. The ED physician reads the film and writes his/her interpretation on the form, and signs the form including printed name and date and time. The ED physician places the film in the upright file on the ED main counter for delivery to Acute Care Hospital #2's Radiology.

This policy did not, however, address time frames for the readings, delivery and/or reporting of radiology interpretations.

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The following is a violation of the Connecticut General Statutes Section 127n-2C.

20. The facility failed to submit to the Department a corrective action plan relative to an adverse event which occurred in the ED on 11/10/04 and which was subsequently reviewed under Peer Review.

The following is violation of the Regulations of Connecticut State Agencies Section 19-13-D4a (b) Administration (2) and (e) Nursing Service (1) and/or (i) General (6).

21. Patient #1 was admitted to the hospital on 7/14/04 with a diagnosis of "short term syndrome." Review of the clinical record and interview with Physical Therapist (PT) #1 on 2/23/05 identified that Patient #1 received physical therapy throughout the hospitalization and was assessed as incapable of rolling, sitting or standing independently. Interviews with RN #1 on 2/23/05 and PCA #2 on 2/22/05 identified that on 2/19/05, RN #1 and PCA #2 provided care for Patient #1 between 7:30 PM and 8:35 PM. At the conclusion of the care, Patient #1 was placed in the center of the crib, on her back with rolled blankets at her sides and the crib rails in a raised position. At approximately 8:43 PM, eight minutes later, RN #1 identified that Patient #1 was crying and she went to the room to investigate. On entering the room, RN #1 observed Patient #1 on the floor, lying face down, approximately 5-7 feet from the crib, bleeding from the head and/or face. RN #1 initiated an emergency code, the patient was intubated, resuscitated and transferred to the pediatric intensive care unit. A neurosurgical consult was obtained on 2/20/05 that identified Patient #1 had sustained a left temporal fracture extending to the external auditory canal, a comminuted left parietal/occipital fracture with fragment, had blood in the ventricles and multiple area of hemorrhage and/or contusion. Interviews with MD #1 on 2/20/05 and MD #2 on 2/22/05 identified that Patient #1's injuries were extensive, she remained in critical condition and her prognosis was poor. Patient #1 subsequently expired on 2/25/05. Interview with RN #1 on 2/23/05 identified that she saw Person #1 standing near Patient #1's bedroom when she discovered Patient #1 on the floor. Person #1 was a seven (7) year old visitor of Patient #2. Interview on 2/20/05, 2/22/05 and 2/23/05 with RNs #1, #2, #3 and PCAs #1, #2, #3 and the unit secretary revealed that Person #1 was repeatedly seen walking around the unit, unattended, on 2/18/05 and 2/19/05. Interview with PCA #3 on 2/23/05 identified that on 2/19/05 between 7:45 PM and 8:00 PM, he observed Person #1 standing in Patient #1's bedroom. Patient #1 was not in the room at the time and he instructed Person #1 to return to Patient #2's room. Although staff identified that they had periodically redirected Person #1 back to Person #2's room, Person #1 continued to walk around on the unit unattended. Additional interviews with Facility Administration identified that it was their belief that the seven (7) year old visitor was

**THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED**

responsible for the injuries sustained by Patient #7. The hospital policy for visitors identified that an adult must accompany children under the age of twelve (12) at all times. None of the staff interviewed noted that they had addressed the problem with Person #1's parents.