

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

PRINTED: 03/24/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 470003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 03/11/2011
NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HOSPITAL OF VERMONT			STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT 05401	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS A full hospital survey was completed on March 8-11, 2011. In conjunction with the survey, four facility reports and one complaint were included for investigation. An Immediate Jeopardy situation was determined to exist based on the hospital's failure to prevent the use of unnecessary force resulting in injury, the use of prohibited weapons and restraints in response to patient behaviors, and for not assuring the immediate availability of emergency power for surgical procedure rooms in outpatient clinics. The Immediacy component of the Immediate Jeopardy situation was abated on 3/10/11 at 6:30 PM when the hospital assured all prohibited weapons and restraints were removed from Security staff and stated no further use of the weapons and restraint device will be allowed. The Immediacy component of the Immediate Jeopardy situation was abated on 3/11/11 at 1:30 PM when the hospital assured emergency lighting was being immediately installed in identified outpatient surgical procedure rooms. Note: As a result of the full hospital survey, and two complaint investigations to assess compliance with the Federal Conditions of Participation for Acute Care Hospitals, the hospital was determined not to be in compliance with the Conditions of Participation for: Patient Rights; Governing Body; Compliance with Federal State and Local Laws; and Surgical Services	A 000		
A 020	482.11 COMPLIANCE WITH LAWS Compliance with Federal, State and Local Laws	A 020	SEE ATTACHED PLAN OF CORRECTION	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *[Signature]* TITLE VP Quality (X6) DATE 4-5-11

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

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A 020	Continued From page 1 This CONDITION is not met as evidenced by: Based on staff interview and record review, the hospital failed to ensure compliance with Vermont State Statutes to include Bill of Rights or Hospital Patients and the 2006 Edition of VT Fire and Building Safety Codes. Findings include: Vermont State Statutes Title 18: Health Chapter 42: Bill of Rights For Hospital Patients Section 1852 (a) (1) The patient has the right to considerate and respectful care at all times and under all circumstances with recognition of his or her personal dignity. 1. Based on record review and staff interview the hospital failed to assure that each patient had the right to make informed decisions about their care and were treated with dignity and respect in 1 applicable record reviewed. (Patient #8) Findings include: Per record review, Patient #8, who was voluntarily admitted to Shepardson 6 inpatient psychiatric unit due to psychosis, requested Lunesta (medication for insomnia) during the evening shift on 1/18/11. Nursing notes on 1/18/11 at 8:35 PM stated "Pt requested Lunesta but when given it spit it right out. Nurses made multiple unsuccessful attempts to get pt to take Lunesta, pt continued to spit pill out and spit/spill chocolate milk on self and others. Pt continued to express that she wanted the medication, yet was unable to take it..." Per review of the hospital's internal investigation, one nurse held the medication in Patient #8's mouth while 2 other nurses physically held the patient's arm and head in an effort to force the patient to take the medication. Patient	A 020	SEE ATTACHED PLAN OF CORRECTION	4/12/11	
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A 020	Continued From page 2 #8 refused the medication. Per interview with Nurse #1 on 3/9/11 at 11:30 AM, three nurses were placed on administrative leave as the result of this event and staff education was provided which included the use of involuntary/emergency medication and restraint.	A 020	SEE ATTACHED PLAN OF CORRECTION	4-12-11	
A 043	2. Per interview with the Assistant Fire Marshal on 3/11/11 at 2:30 pm, the hospital began laboratory functions at an outpatient facility on 3/7/11 without first obtaining an occupancy permit in violation of 2006 Edition of VT Fire and Building Safety Code: 20 VSA Chapter 73. 482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on observations, staff interviews and record review conducted throughout the days of survey, the Governing Body failed to ensure protection and promotion of Patient Rights based on the hospital's failure to prevent the use of unnecessary force resulting in injury and the use of prohibited weapons and restraints in response to patient behaviors. The Governing Body failed to ensure the safety of patients by failing to equip outpatient facilities, were surgical procedures are performed, with required emergency lighting.	A 043	SEE ATTACHED PLAN OF CORRECTION 4/20/11 Aogo POC Accepted Deletato	4/26/11	
A 115	Refer to Tags: A-0154, A-702 462.13 PATIENT RIGHTS	A 115	SEE ATTACHED PLAN OF CORRECTION SEE ATTACHED PLAN OF CORRECTION	3/10/11 5/3/11	

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A 115	Continued From page 3 A hospital must protect and promote each patient's rights.	A 115		
A 121	This CONDITION is not met as evidenced by: Based on record review and staff interview, the Condition of Participation for Patient's Rights was not met based on the hospital's failure to prevent the use of unnecessary force resulting in injury and the use of prohibited weapons and restraints in response to patient behaviors. Refer to A-0154 482.13(a)(2)(i) PATIENT RIGHTS: GRIEVANCE PROCEDURES. (At a minimum:) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital. This STANDARD is not met as evidenced by: Based upon review of information provided to patients/families at the time of admission and interview, the facility failed to provide sufficient information that clearly articulated the facilities complaint and grievance process. Evidence includes the following: On 3/9/11 at approximately 2:00 PM, an interview was conducted with Manager of Patient & Family Advocacy related to the complaint and grievance process at the facility. At this time, a packet of information was reviewed which was confirmed to be the information presented to patients/families at the time of admission which was titled, "Guide for Inpatients". The packet contained additional information including patient rights and responsibilities.	A 121	SEE ATTACHED PLAN OF CORRECTION 4/20/11 POC Accepted Wallerstein	3/10/11 5/3/11
			SEE ATTACHED PLAN OF CORRECTION 4/20/11 POC Accepted Wallerstein A 401	4/26/11

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A 121	Continued From page 4 Form #017773P dated 1/25/10 was identified during the interview as to where patients/families could find information about the complaint and grievance process. The only information in the notice pertaining to filing a complaint and/or grievance was: "If you have any questions or complaints about your stay, please contact our Office of Patient and Family Advocacy. They will listen to your concerns and work with you to address them." The form provided the name of the hospital, address and phone number but no contact person. Also provided were Vermont agencies for additional assistance with other concerns.	A 121			
	Review of the "Guide for Inpatients" on page 11 read, "We encourage direct feedback to any staff at the time a concern arises. In addition, a specific review process is offered through our Office of Patient and Family Advocacy. This process includes appropriate investigation and resolution at the point of service and/or referral to our Grievance Committee for review and written response. For more information, contact our Office of Patient and Family Advocacy.		SEE ATTACHED PLAN OF CORRECTION	4/26/11	
A 131	Neither document clearly explained how a complaint or grievance could be filed including time frames and expectations. The interview confirmed that the information reviewed was how the patient was informed about their right to file a complaint or grievance 482.13(b)(2) PATIENT RIGHTS: INFORMED CONSENT The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.	A 131	SEE ATTACHED PLAN OF CORRECTION	4/12/11	

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A 131	Continued From page 5 The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This STANDARD is not met as evidenced by: Based on record review and staff interview the hospital failed to assure that each patient had the right to make informed decisions about their care and were treated with dignity and respect in 1 applicable record reviewed. (Patient #8) Findings include: 1. Per record review, Patient #8, who was voluntarily admitted to Shepardson 6 inpatient psychiatric unit due to psychosis, requested Lunesta (medication for insomnia) during the evening shift on 1/18/11. Nursing notes on 1/18/11 at 8:35 PM stated "Pt requested Lunesta but when given it spit it right out. Nurses made multiple unsuccessful attempts to get pt to take Lunesta, pt continued to spit pill out and spit/spill chocolate milk on self and others. Pt continued to express that she wanted the medication, yet was unable to take it..." Per review of the hospital's internal investigation, one nurse held the medication in Patient #8's mouth while 2 other nurses physically held the patient's arm and head in an effort to force the patient to take the medication. Patient #8 refused the medication. Per interview with Nurse #1 on 3/9/11 at 11:30 AM, three nurses were placed on administrative leave as the result of this event and staff education was provided which included the use of	A 131	SEE ATTACHED Plan of Correction	4/2/11	

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A 131 A 143	Continued From page 6 involuntary/emergency medication and restraint. 482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY	A 131 A 143	A-131 POE Accepted 4/20/11 J. Peterson		
A 144	The patient has the right to personal privacy. This STANDARD is not met as evidenced by: Based on observation and confirmed by interview, the facility failed to assure personal privacy for patients on one medical unit. Findings include; Based on observations from 3/8/11 through 3/10/11, medical records posted with the first and last names of patients were fully visible and legible from approximately 18 inches away from where they were stored at the nursing station. Per interview on 3/8/11 at 10:45 AM, the Nurse Manager of the unit confirmed that "patients and visitors are allowed in [the] area". Per interview on 3/10/11, a staff person who works behind the nursing station stated that "occasionally people come to the nursing station via the front". 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on observations and staff interview the hospital failed to provide an environment that would ensure safety and well being for all patients on the inpatient psychiatric units. Findings include: 1. On 3/9/11 at approximately 9:15 AM a tour was conducted on Shepardson 3 Psychiatric Unit. Five handwashing sinks with goose neck type faucets which were potentially lovable devices, were	A 144	SEE ATTACHED Plan of Correction A-143 4/20/11 J. Peterson	3/11/11	4/13/11

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A 154	<p>Continued From page 8 staff to restrain patients.</p> <p>1. Per record review, Patient #7, admitted voluntarily due to suicidal ideation and opiate withdrawal, became verbally and physically agitated yelling, slamming the door and throwing items in his/her room' on 1/24/11 after being told h/she couldn't leave the hospital. Constant observation was initiated at 2:09 PM. Nursing notes described Patient #7 as "... currently sitting in room and in behavioral control (although tense). Awaiting crisis team to evaluate." Patient #7 was later described as sitting on the toilet 'staring blankly and mute' while crisis met with family members. Following the emergency evaluation, Patient #7 was described as "frate banging his head on the wall stating "I'm going to kill myself." Patient #7 refused to transfer to the locked inpatient psychiatric unit 'without a fight'. Nursing notes stated "given the volatility of the situation and potential for harm I call a Code 8."</p> <p>Per interview on 3/9/11 at approximately 9:10 AM, Nurse # 1 stated "... h/she wanted to leave... furious h/she couldn't leave.. nurse sounded the panic button.. h/she was sitting on the toilet and threatened to harm staff... Security applied plastic wrist restraints after placing h/her on the floor on stomach..security picked h/her up and placed in wheelchair...3 or 4 security personnel present .. complained of arm hurting when restraint put on wrist... patient struggling during wrist restraint application... we told h/her to stop struggling but h/she wouldn't." Per record review, Patient #7 had a surgical procedure in 2002 on the right upper arm.</p> <p>Per review of the 1/24/11 Security Services Incident Report, security personnel responded to</p>	A 154	<p>SEE ATTACHED Plan of Correction</p>	<p>3/10/11 4/22/11</p>	

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A 154	Continued From page 9 the Code 8 and stood by while nursing and medical staff spoke to Patient #7 about his options. Patient #7 said h/she would rather hurt staff and go to jail than go to Shepardson 6" (locked inpatient psychiatric unit). Patient #7 refused to take oral medication or move from the toilet. The report stated " The patient was fully clothed and after several minutes the patient was advised that if h/she did not move we would be forced to move h/her. The patient continued to refuse and it was decided to then attempt to direct the patient into the wheelchair. However, as soon as contact was made with the patient then started to resist and was placed down on the floor. The area was very small and the patient was aggressively resisting so it was decided to place the patient into ASP disposable restraint." Per interview on 3/10/11 at 11:30 AM with Security Officer #1 and Security Officer #2, a total of four security officers and other patient support personnel responded to the Code 8. Security Officer #1 said he was informed that Patient #7 needed to be transferred to Shepardson 6 but h/she was refusing to go. Security Officer #1 said nursing and medical personnel were trying to convince Patient #7 to walk to the unit, but Patient #7 was verbally threatening stating h/she "would rather hurt staff and go to jail than go to Shepardson 6." Security Officer #1 described Patient #7 as dressed and seated on the toilet with fists clenched but no attempts were made to strike out. Security Officer #1 said he made the decision to place Patient #7 in the MOAB (Management of Aggressive Behavior) prone control position to avoid injury to his staff. (Patient placed on abdomen with each arm extended and secured at the shoulder and wrist with the wrists bent upward.) Four security	A 154	SEE ATTACHED Plan of Correction	3/16/11 5/3/11

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A 164	Continued From page 10 officers were used for the "take down" per Security Officer #1. Security Officer #1 said Patient #7 was yelling "no restraints" stating h/she had a "bad right elbow." Security Officer #2 said he had to back into the shower due to space constraints. An ASP Trifold Restraint was applied which restrained Patient #7's hands behind his/her back. " H/she was told not to resist but h/she continued to resist. h/she was twisting around." Security Officer #1 said after restraining Patient #7 h/she was "dragged" the length of h/her room to the wheelchair in the hallway and lifted into the chair. Patient #7 was transported, by four security officers, in wrist restraints and while holding his lower legs since h/she was trying to block movement of the wheelchair. Once arriving on Shepardson 6 and being led into seclusion, the plastic wrist restraints were removed by a device known as a 'Scarab cutter' used by security staff since the device cannot be removed with scissors. When Patient #7 refused to accept medication, Security Officer #1 said three security officers held Patient #7 down, with one on each arm and one holding h/her legs while the nurse administered injectable medications. Nursing notes on 1/24/11 stated the physician was aware of Patient #7's complaints of shoulder pain. On 1/27/11, nursing notes for Patient #7 stated "... c/o chest pain/sharp: 6/10 pain rating, pain has been present since when awoke in middle of the night last night." On 1/29/11, the physician ordered a chest x-ray. The inpatient psychiatry discharge summary dated 1/31/11 stated "On 1/29 a chest x-ray was obtained after pain continued, and showed a non-displaced rib fracture, possibly sustained during his struggle and restraint on Shepardson 3 at the time of transfer, for which no specific intervention was	A 164	SEE ATTACHED Plan of Correction	3/16/11 4/29/11	

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A 154	Continued From page 11 required." Per Interview on 3/9/11, Nurse #1 stated "the fracture probably occurred during or as the result of the restraint." Based on record review and staff interview, although Patient #7 was verbally threatening and agitated, h/she was not combative when the use of force was implemented. 2. Per review of Security Services Incident Reports, the form listed a selection of interventions including "FAHC Handcuffs and FAHC Mace". During interview on 3/10/11 at 11:30 AM, Security Officer #1 confirmed that ASP Trifold Restraints and pepper spray were carried by security personnel. Security Officer #1 said " It (pepper spray) would be the last resort. it's been used once in my 5 and 1/2 years.. it was used on a patient who weighed about 300 pounds who was using karate kicks and punches." The Vice President of Hospital Services provided documentation on 3/11/11 at 2:10 PM concerning the use of pepper spray at Patient #17 which occurred on 2/6/2008. A. Per review of Security Services Incident Report dated 2/6/2008, pepper spray was used on Patient #17 on Shepardson 6, the locked inpatient psychiatric unit. Per documentation in the report, Patient #17 was "acting out.. walked past the nurse's station several times and performed several martial arts stances towards staff.. made an impression of a gun and made the impression of shooting us.. Security proceeded to the hallway where h/she took off his socks clenched h/her fist and took up a defensive stance towards staff. ... refused several commands to calm down and come with security towards the seclusion room.. became combative with staff and had to be placed on the floor to control him and prevent	A 154	SEE ATTACHED Plan of Correction	3/10/11 5/3/11

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A 154	<p>Continued From page 12</p> <p>h/her from harming staff..picked up off the floor and taken to the seclusion room .. began to kick door.. nursing staff went to the nurse's station.. to get medications...security personnel verbally... commanded h/her to back away from the door..charged with clenched fists and was pushing S/O (security officer) out of the room.. continued to be combative.. Security staff and this officer deployed OC, (Oleoresin Capsicum) spraying 1 second burst in face.. "</p> <p>B. Per review of Security Services Incident Report and record review, Patient #16, who was admitted on 9/14/10 to the cardiac unit attempted to leave the hospital to smoke during the evening shift. Nursing notes stated "nurse and charge nurse went with Pt to 1st floor where he tried to exit the building. A transport member prevented h/her from exiting and the pt became violent striking out at anyone that attempted to stop h/her. Code 8 called and security restrained the pt." When security responded, one of the security officers observed the patient and two staff members involved in a 'struggle.' The report by security stated "...The patient at one point was in a standing position when I ordered the patient to lay on the ground or I would spray h/her (Patient #16). I pulled my OC (pepper spray) out and aimed it... I chose not to use the OC.. on seeing the OC canister h/she (Patient #16) appeared to pass out and go to the floor... h/she began to move around on the floor as if to appear to have a seizure... Staff holding the patient let go and I instructed them that the patient appeared to be faking. Staff again held the patient.. the patient was held to the floor on h/her back..I instructed staff to roll h/her (Patient #16) on stomach. ASP restraints were applied for his/her protection as well as staff. " Per interview on 3/11/11 at 1:50</p>	A 154	SEE ATTACHED PLAN of Correction	3/10/11 5/3/11	

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A 154	Continued From page 13 PM, the Vice President of Hospital Services confirmed that the pepper spray container was directed at Patient #16 but was not used by security. Per record review, Patient #16 was admitted to the cardiology for recurrent chest pain and LOC (loss of consciousness) episodes. A neurology consult note stated that Patient #16 had seven episodes of loss of consciousness on 9/14/10 prior to the above event.	A 154	SEE ATTACHED PLAN OF CORRECTION 3-10-11	3-10-11 4/27/11
A 214	482.13(g) PATIENT RIGHTS: SECLUSION OR RESTRAINT Death Reporting Requirements: Hospitals must report deaths associated with the use of seclusion or restraint. (1) The hospital must report the following information to CMS: Each death that occurs while a patient is in restraint or seclusion. Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for	A 214	4/20/11 Per Accepted Correction SEE ATTACHED PLAN OF CORRECTION	4-26-11

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A 214	Continued From page 14 prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.	A 214			
	<p>(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.</p> <p>(3) Staff must document in the patient's medical record the date and time the death was reported to CMS.</p> <p>This STANDARD is not met as evidenced by: Based upon document review and interview, the facility failed to report timely deaths associated with restraint or seclusion for 5 of 5 records reviewed. (Patients # 49, 50, 51, 52 and 53). Evidence includes the following.</p> <p>The Regulatory Advisor for Fletcher Allen was interviewed on 3/10/11 at 2:30 PM regarding the facility process for death reporting relative to restraint and/or seclusion use. It was reported that the facility uses clinical auditors who review and look for the mandated CMS parameters required to be reported. The CMS form is completed, faxed and entered into the medical record.</p> <p>Record review revealed that Patient # 49 died within 24 hours of the removal of restraint on 1/19/2011. The death was reported to CMS on 1/31/2011. Patient # 50 died on 2/14/11 and the death was reported to CMS on 2/24/11. Patient # 51 died on 2/15/11 and the death was reported to CMS on 3/10/11. Patient # 52 died on 2/14/11 and the death was</p>		<p>SEE ATTACHED Plan of Correction</p>	4-26-11	

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A 214	Continued From page 15 reported to CMS on 3/10/11. Patient # 53 died on 2/4/11 and the death was reported to CMS on 2/14/11. When asked to produce other death reporting actions to CMS, staff confirmed that the facility did not follow the the reporting requirement for other deaths as well.	A 214	<p>4/20/11 POC Accepted M. J. [Signature]</p> <p>SEE ATTACHED Plan of Correction</p>	
A 267	<p>482.21(a)(2) QAPI QUALITY INDICATORS</p> <p>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the hospital failed to track adverse patient events related to the use of ASP Trifold restraints and pepper spray used by security personnel in 3 of 3 records reviewed. (Pl # 7, 16, 17) Findings include:</p> <p>Per review of security reports, record review and staff interview, hospital security personnel were equipped to use 'ASP Trifold Restraints' (used as handcuffs) and Oleoresin Capsicum (pepper spray) which are prohibited for use by hospital staff to restrain patients.</p> <p>1. Per record review, Patient #7, admitted voluntarily due to suicidal ideation and opiate withdrawal, became verbally and physically agitated yelling, slamming the door and throwing items in his/her room' on 1/24/11 after being told h/she couldn't leave the hospital. Constant observation was initiated at 2:09 PM. Nursing notes described Patient #7 as "... currently sitting in room and in behavioral control (although</p>	A 267		4/27/11

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A 267	Continued From page 16 tense). Awaiting crisis team to evaluate.." Patient #7 was later described as sitting on the toilet 'staring blankly and mute' while crisis met with family members. Following the emergency..... evaluation, Patient #7 was described as "irate banging his head on the wall stating "I'm going to kill myself." Patient #7 refused to transfer to the locked inpatient psychiatric unit 'without a fight'. Nursing notes stated "given the volatility of the situation and potential for harm I call a Code 8." Per interview on 3/9/11 at approximately 9:10 AM, Nurse # 1 stated "... h/she wanted to leave... furious h/she couldn't leave.. nurse sounded the panic button.. h/she was sitting on the toilet and threatened to harm staff... Security applied plastic wrist restraints after placing h/her on the floor on stomach.. security picked h/her up and placed in wheelchair.. 3 or 4 security personnel present .. complained of arm hurting when restraint put on wrist... patient struggling during wrist restraint application... we told h/her to stop struggling but h/she wouldn't." Per record review, Patient #7 had a surgical procedure in 2002 on the right upper arm. Per review of the 1/24/11 Security Services Incident Report, security personnel responded to the Code 8 and stood by while nursing and medical staff spoke to Patient #7 about his options. Patient #7 said h/she would rather hurt staff and go to jail than go to Shepardson 6" (locked inpatient psychiatric unit). Patient #7 refused to take oral medication or move from the toilet. The report stated " The patient was fully clothed and after several minutes the patient was advised that if h/she did not move we would be forced to move h/her. The patient continued to refuse and it was decided to then attempt to direct	A 267	SEE ATTACHED Plan of Correction	4-27-11	

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A 267	Continued From page 17 the patient into the wheelchair. However, as soon as contact was made with the patient then started to resist and was placed down on the floor. The area was very small and the patient was aggressively resisting so it was decided to place the patient into ASP disposable restraint." Per Interview on 3/10/11 at 11:30 AM with Security Officer #1 and Security Officer #2, a total of four security officers and other patient support personnel responded to the Code 8. Security Officer #1 said he was informed that Patient #7 needed to be transferred to Shepardson 6 but h/she was refusing to go. Security Officer #1 said nursing and medical personnel were trying to convince Patient #7 to walk to the unit, but Patient #7 was verbally threatening stating h/she "would rather hurt staff and go to jail than go to Shepardson 6." Security Officer #1 described Patient #7 as dressed and seated on the toilet with fists clenched but no attempts were made to strike out. Security Officer #1 said he made the decision to place Patient #7 in the MOAB (Management of Aggressive Behavior) prone control position to avoid injury to his staff. (Patient placed on abdomen with each arm extended and secured at the shoulder and wrist with the wrists bent upward.) Four security officers were used for the "take down" per Security Officer #1. Security Officer #1 said Patient #7 was yelling "no restraints" stating h/she had a "bad right elbow." Security Officer #2 said he had to back into the shower due to space constraints. An ASP Trifold Restraint was applied which restrained Patient #7's hands behind his/her back. " H/she was told not to resist but h/she continued to resist. h/she was twisting around." Security Officer #1 said after restraining Patient #7 h/she was "dragged" the length of	A 267	SEE ATTACHED Plan of Correction	4-27-11

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A 267	<p>Continued From page 18</p> <p>h/her room to the wheelchair in the hallway and lifted into the chair. Patient #7 was transported, by four security officers, in wrist restraints and while holding his lower legs since h/she was trying to block movement of the wheelchair. Once arriving on Shepardson 6 and being led into seclusion, the plastic wrist restraints were removed by a device known as a 'Scarab cutter' used by security staff since the device cannot be removed with scissors. When Patient #7 refused to accept medication, Security Officer #1 said three security officers held Patient #7 down, with one on each arm and one holding h/her legs while the nurse administered injectable medications. Nursing notes on 1/24/11 stated the physician was aware of Patient #7's complaints of shoulder pain.</p> <p>On 1/27/11, nursing notes for Patient #7 stated "c/o chest pain/sharp: 6/10 pain rating, pain has been present since when awoke in middle of the night last night." On 1/29/11, the physician ordered a chest x-ray. The Inpatient psychiatry discharge summary dated 1/31/11 stated "On 1/29 a chest x-ray was obtained after pain continued, and showed a non-displaced rib fracture, possibly sustained during his struggle and restraint on Shepardson 3 at the time of transfer, for which no specific intervention was required." Per Interview on 3/8/11, Nurse #1 stated "the fracture probably occurred during or as the result of the restraint." Based on record review and staff interview, although Patient #7 was verbally threatening and agitated, h/she was not combative when the use of force was implemented.</p> <p>2. Per review of Security Services Incident Reports, the form listed a selection of interventions including "FAHC Handcuffs and</p>	A 267	SEE ATTACHED Plan of Correction	4/27/11

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A 267	Continued From page 19 FAHC Mace'. During interview on 3/10/11 at 11:30 AM, Security Officer #1 confirmed that ASP Trifold Restraints and pepper spray were carried by security personnel. Security Officer #1 said "It (pepper spray) would be the last resort. It's been used once in my 5 and 1/2 years.. It was used on a patient who weighed about 300 pounds who was using karate kicks and punches." The Vice President of Hospital Services provided documentation on 3/11/11 at 2:10 PM concerning the use of pepper spray at Patient #17 which occurred on 2/6/2008. A. Per review of Security Services Incident Report dated 2/6/2008, pepper spray was used on Patient #17 on Shepardson 6, the locked inpatient psychiatric unit. Per documentation in the report, Patient #17 was "acting out.. walked past the nurse's station several times and performed several martial arts stances towards staff.. made an impression of a gun and made the impression of shooting us.. Security proceeded to the hallway where h/she took off his socks clenched h/her fist and took up a defensive stance towards staff. .. refused several commands to calm down and come with security towards the seclusion room.. became combative with staff and had to be placed on the floor to control him and prevent h/her from harming staff..picked up off the floor and taken to the seclusion room .. began to kick door.. nursing staff went to the nurse's station.. to get medications.. security personnel verbally commanded h/her to back away from the door..charged with clenched fists and was pushing S/O (security officer) out of the room.. continued to be combative.. Security staff and this officer deployed OC, (Oleoresin Capsicum) spraying 1 second burst in face.. "	A 267	See ATTACHED Plan of Correction	4-27-11	

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A 267	Continued From page 20 B. Per review of Security Services Incident Report and record review, Patient #16, who was admitted on 9/14/10 to the cardiac unit attempted to leave the hospital to smoke during the evening shift. Nursing notes stated "nurse and charge nurse went with Pt to 1st floor where he tried to exit the building. A transport member prevented h/her from exiting and the pt became violent striking out at anyone that attempted to stop h/her. Code 8 called and security restrained the pt." When security responded, one of the security officers observed the patient and two staff members involved in a 'struggle.' The report by security stated "...The patient at one point was in a standing position when I ordered the patient to lay on the ground or I would spray h/her (Patient #16). I pulled my OC (pepper spray) out and aimed it... I chose not to use the OC.. on seeing the OC canister h/she (Patient #16) appeared to pass out and go to the floor... h/she began to move around on the floor as if to appear to have a seizure... Staff holding the patient let go and I instructed them that the patient appeared to be faking. Staff again held the patient.. the patient was held to the floor on h/her back.. I instructed staff to roll h/her (Patient #16) on stomach. ASP restraints were applied for his/her protection as well as staff." Per interview on 3/11/11 at 1:50 PM, the Vice President of Hospital Services confirmed that the pepper spray container was directed at Patient #16 but was not used by security. Per record review, Patient #16 was admitted to the cardiology for recurrent chest pain and LOC (loss of consciousness) episodes. A neurology consult note stated that Patient #16 had seven episodes of loss of consciousness on 9/14/10 prior to the above event. 4. During the afternoon of 3/10/11 when	A 267	SEE ATTACHED Plan of Correction	4-27-11	

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A 267	Continued From page 21 surveyors informed the hospital of the immediate jeopardy related to the use of ASP Trifold restraints and pepper spray, the Vice President of Quality and Operational Effectiveness was not aware that ASP Trifold restraints and pepper spray were being used by security personnel. During review of the hospital's Quality program on 3/11/11 at 11:05 AM, the Director of Patient Safety stated that no changes were implemented related to the use of ASP Trifold restraints following their use on Patient #7 on 1/24/11. Per interview on 3/11/11 at 2:08 PM, the Vice President of Hospital Services stated "we looked at the regulations and thought it (pepper spray) was okay... it was used for safety and not for therapeutic reasons."	A 267	SEE ATTACHED Plan of Correction <i>A 267 4/29/11 POC Accepted J. [Signature]</i>	4-29-11	
A 395	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on observations, record review and staff interview, the hospital failed to evaluate the use of side rails for 1 applicable record reviewed. (Patient # 3) Findings include: 1. Observations during a tour of Shepardson 6 on 3/8/11 at 11:00 AM with Nurse #1, side rails were observed on patient beds. Nurse #1 confirmed that all beds have four side rails. Nurse #1 further stated that staff don't use the side rails as restraints and patients can elevate the side rails if they choose to. Nurse #1 further stated "for a geriatric patient we might put up the top half rail but it's not considered a restraint." On 3/8/11 at 1:45 PM, Patient #3 was observed in	A 395	SEE ATTACHED Plan of Correction	4/4/11	

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A 395	Continued From page 22 bed with two half- rails elevated at the head of the bed. Per record review, although Patient #3 was identified as being at high risk for falls, there was no assessment related to the use of side rails. Per interview on 3/8/11 at 4:10 PM and 3/9/11 at 9:10 AM, Nurse #1 confirmed that half-rails were used for Patient #3. Nurse #1 said the side rails were not used as restraints and possibly were used to access the call system, but staff were concerned about Patient #3's behavior and risk for falls. Nurse #1 stated "we could improve.. maybe other areas of the hospital use an assessment we could use." 2. During the initial tour of the Shepardson 3 Unit on 3/8/11 at approximately 10:30 AM; and on 3/10/11 at approximately 9:15 AM, the following rooms were observed to be equipped with 4 side rails: Rooms 332, 333, 311, 323 On 3/10/11 at approximately 9:30 AM on Shepardson 3, Nurse #4 indicated when Housekeeping prepared the room for admission; the 2 upper rails were left in the raised position. H/she added, the patients then decided if they wanted them up or down. Nurse #4 also said patients had an assessment for Fall Risk that was completed daily and included side rails; however, there were no individualized or specific assessments for the use of side rails.	A 395		
A 396	482.23(b)(4) NURSING CARE PLAN The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to ensure that nursing staff developed a nursing care plan for 2 of 3	A 396	SEE ATTACHED Plan of Correction A-395 4/20/11 Poc Accepted D. [Signature] SEE ATTACHED Plan of Correction	4/14/11 4-12-11

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A 398	Continued From page 23 patients (#26; and #27), and failed to ensure a care plan included the use of a C-PAP (continuous positive airway pressure) machine for one patient (#28). The findings include: 1. Patient #26 was admitted to the Shepardson 3 Psychiatric Unit on 3/6/11 with diagnoses which included Suicide Ideation, Depression (Chronic), Substance Abuse, Dissociative Identity disorder, Bulimia, and Family Conflict. Review of the Interdisciplinary Treatment Plan dated 3/7/11 identified Problems as; Depressive Symptoms; Suicidal Ideations with plan; Relationship Problems; and Substance Dependence (THC - tetrahydrocannabinol, the major psychoactive chemical compound in cannabis). The section for Psychological Interventions was not completed. The last page of the Care Plan was only signed by the Therapist on 3/6/11. Observation of the Shepardson 3 Unit on 3/8/11 at approximately 10:30AM upon entrance to the unit, found the normally unlocked exit door to be locked. Interview with the Psychiatrist following the tour, revealed the locked status was due to a patient who had been attempting to leave the unit. The Psychiatrist explained he/she did not feel there was therapeutic benefit for this patient to be transferred to the Shepardson 6 Psychiatric Unit, which was locked at all times. Interview with Nurse #4 on 3/9/11 at approximately 10:00AM revealed the Care Plan did not indicate Patient #26 was a flight risk. There was no revision to reflect the specific problem, or interventions to be implemented.	A 396	SEE ATTACHED Plan of Correction	4-12-11	

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A 396	Continued From page 24 2. Patient #27 was admitted to the Shepardson 3 Psychiatric Unit on 3/2/11 to 3/6/11 with diagnoses which included Suicide Ideation, Cervical Pain, History of ETOH (alcohol), Migraine, and Mood Disorders. Review of the Interdisciplinary Treatment Plan dated 3/3/11 identified Problems as: Suicidal Risk. The section for Psychological interventions was not completed. The last page of the Care Plan was not signed by the Therapist. Interview with Nurse #4 on 3/9/11 at approximately 9:40AM revealed the Interdisciplinary Care Plan should be completed within 24 hours of admission. 3. Patient #28 was admitted to Shepardson 3 Psychiatric Unit on 2/16/11 with diagnoses which included Severe Anxiety, Depression, Hypertension, and Hyperlipidemia. Treatment to include ECT (Electroconvulsive therapy). Review of the Pre-Admission Referral Summary dated 2/16/11 indicated the patient had a C-PAP (continuous positive airway pressure machine) for apnea. Review of the Interdisciplinary Treatment Plan dated 2/17/11 did not include a reference to the use of a C-PAP machine. Review of the Inpatient Psychiatry Treatment Plan Update dated 2/24/11 revealed a Physician, Social Worker, and Therapist signature; however, there was no signature for Nursing. On 3/10/11, an interview with Nurse #3 on Shepardson 3 at approximately 9:30AM revealed Pt. #28 did not use a CPAP machine.	A 396	SEE ATTACHED PLAN OF CORRECTION A396 4/20/11 pac accepted J. DeLatorre	4-12-11	
A 438	482.24(b) FORM AND RETENTION OF RECORDS The hospital must maintain a medical record for each inpatient and outpatient. Medical records	A 438	SEE ATTACHED PLAN OF CORRECTION	3-10-11	

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A 438	Continued From page 25 must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. This STANDARD is not met as evidenced by: Based on observation and staff interview the hospital failed to ensure that all medical records were properly stored in a location that protected them from potential fire and/or water damage. Findings include: During a tour on 3/7/11 at 3:16 PM improper storage of medical records was observed at an off campus medical records location. Active patient records were observed stored on metal shelves, however in several locations multiple records were stored without protection on top of metal shelves throughout the storage area with some stacks heights to be from 6 to 15 inches sitting in close proximity to sprinkler heads. If the sprinkler heads were prompted to disperse water, the improperly stored records would be in direct contact with water as it was expelled from the sprinkler heads and subject to destruction. The observation was confirmed by the Director for Health Information Management at the time of the tour.	A 438	SEE ATTACHED Plan of Correction A 438 4/20/11 POC Accepted Collection	3/10/11	
A 620	482.28(a)(1) DIRECTOR OF DIETARY SERVICES The hospital must have a full-time employee who- (i) Serves as director of the food and dietetic services; (ii) Is responsible for daily management of the	A 620	SEE ATTACHED Plan of Correction	4-26-11	

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A 620	Continued From page 26 dietary services; and (iii) Is qualified by experience or training. This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, the Director of Nutrition Services failed to assure that dietary staff implemented the policy for monitoring of refrigeration temperatures in accordance with safe food handling practices. Findings include: Per observation during a tour of the kitchen and dietary areas with the Director of Nutrition Services and other dietary staff on 3/8/11 commencing at 10:10 AM, refrigeration temperatures and/or temperature logs revealed multiple days when temperatures exceeded the safe range for storage of perishable foods and there was no evidence of actions taken. Out of range temperatures were recorded daily for freezer #1 for all of February and daily in March, with ranges from 14 - 24 degrees F (Fahrenheit). The thermometer stated that the temperature for freezer #1 was 25.8 degrees during the tour. There were also multiple days when logs for kitchen refrigerators #2, 4, 10 & 13 were out of range at 40 - 44 degrees F for the early AM temperature check. Logs for reach-in refrigerators in the Harvest Cafe revealed multiple days when temperatures were out of range at 40 - 41 degrees. Per review, the hospital's P/P "Cooler/Freezer Temperature Chart Standards for Nutrition Services" stated "If a cooler or freezer temperature is out of compliance, (at or below 39 degrees F for coolers and at or below 0 degrees for freezers) it will be reported immediately to the supervisor/lead on duty.(T?) the designated staff will take the following course of action and	A 620	SEE ATTACHED Plan of Correction	4-26-11	

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A 620	Continued From page 27 document by number in the column on the form and circle the cooler or freezer which is out of compliance." The out of range temperatures were not circled on the logs reviewed and there was no evidence of any remedial action taken per the policy. These omissions were confirmed during interview with the Director of Nutrition Services on the afternoon of 3/8/11 after policy review.	A 620	<i>4/20/11 POC Accepted C. Robertson</i>		
A 701	482.41(a) MAINTENANCE OF PHYSICAL PLANT The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This STANDARD is not met as evidenced by: Based on observation and interview, the hospital failed to ensure the environment was maintained in a safe manner. Findings include: Per observations made during the physical environment tour on 3/8/11 and 3/9/11 there were loose hand rails in the following locations: 1. Outside the labor and delivery lounge 2. Across from room 4-143 in the west pavilion 3. Between rooms 489-490 on Baird 4 4. Between rooms 574-575 on Shepardson 5 The above observations were confirmed by the facility Quality Assurance representative accompanying the surveyor at the time of the observations.	A 701	<i>A 620</i> <i>SEE ATTACHED Plan of Correction</i>	<i>4-1-11</i>	
A 702	482.41(a)(1) EMERGENCY POWER AND LIGHTING There must be emergency power and lighting in at least the operating, recovery, intensive care,	A 702	<i>4/20/11 POC Accepted C. Robertson</i> <i>SEE ATTACHED Plan of Correction</i>	<i>4-14-11</i>	

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A 702	Continued From page 28 and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.	A 702		
A 724	This STANDARD is not met as evidenced by: Based on observation and staff interview, the hospital failed to ensure emergency lighting was available at all outpatient offices where surgical procedures are performed. Findings include: Per observation of one outpatient clinic on 3/11/11, it was observed that although there is a system to illuminate the hallways in case of a power outage, only flashlights and glow sticks are available to illuminate the procedure rooms in case of a power outage. Per review of billing codes for March 1, 2011 through March 10, 2011, surgical procedures are performed in the two procedure rooms at the outpatient clinic. Per interview on 3/11/11, at approximately 9:45 AM, one clinical staff person stated that if the lights go out "we have flashlights in the rooms". Per interview, a second clinical staff person stated that if the lights went out during a procedure, staff would "make sure the flashlights were on so they could finish the procedure". 482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by: Based on observation and confirmed by interview, the hospital failed to assure laminate hoods in the pharmacy were maintained in an acceptable level of quality and safety. Findings include:	A 724	SEE ATTACHED Plan of Correction A 702 p/c Accepted SEE ATTACHED Plan of Correction	4-14-11 3-30-11

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A 724	Continued From page 29 Based on observation on 3/9/11 at 1:30 PM of the main pharmacy area, two of four laminate hoods where IV solutions are prepared had discolored and degraded paint on the outsides of the preparation area. The identified areas were tacky to the touch and although degraded to the frame in several pinpoint areas, did not appear to flake off the frame. Per interview at 1:50 PM on 3/9/11, Pharmacist # 1 confirmed that the areas were indeed degraded.	A 724	SEE ATTACHED Plan of Correction	3-30-11
A 749	482.42(a)(1) INFECTION CONTROL OFFICER RESPONSIBILITIES The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, hospital staff failed to adhere to aseptic technique during 2 applicable observations of treatment/care provision; failed to ensure consistent monitoring of temperatures and relative humidity was conducted and monitored in Central Sterile Processing; and failed to ensure equipment in disrepair was not used in the operating rooms. Findings include: 1. Per observation of set up procedures for a hemodialysis machine on the Medical Intensive Care Unit (MICU) on 3/8/11 at 3:25 PM, the Hemodialysis Technician (HD) attached the blood chamber for the CRIT-LINE to the Optiflux dialyzer with the same gloves used to move the trash can closer to the dialysis machine. The contamination of the dialyzer/set up was	A 749	SEE ATTACHED Plan of Correction <i>Azay Pte Accepted Correction</i>	4/26/11

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A 749	Continued From page 30 Immediately confirmed with the HD and the Director of Renal/Transplant Services. After the observation, the equipment was disposed of and a new set-up was initiated.	A 749		
	2. Per observation, on the afternoon of 3/8/11, Nurse #2 failed to maintain proper infection control and hand hygiene technique during a dressing change procedure. After sanitizing his/her hands and donning clean gloves, the nurse touched his/her face mask, adjusting the fit over the nose and contaminating the glove, and then proceeded to remove the dressing covering the catheter insertion site on the neck of Patient #40. During interview, immediately following the procedure, Nurse # stated s/he did not recall touching his/her mask during the process of changing the dressing. Per review the facility's policy titled Hemodialysis Vascular Access: Central Venous Catheter (CVC) Care and Maintenance, dated October 2010, identifies the procedure for CVC Site Assessment and Care which include; don mask and gown, perform hand hygiene and don gloves, proceed to open sterile supply packages and remove the dressing, '(be careful to avoid contaminating the insertion site)'		SEE ATTACHED Plan of Correction	4-26-11
	3. During Environment of Care Safety Audits, which includes staff from the Infection Control department, surveillance of the Central Sterile Process (CSR): (the department within the hospital that processes, issues, and controls professional supplies and equipment, both sterile and nonsterile, for some or all patient-care areas of the facility) failed to identify the lack of policy and process for the ongoing monitoring of temperatures and relative humidity in all CSR locations. Per national standards developed by AAMI (Association for the Advancement of		SEE ATTACHED Plan of Correction	4-26-11

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A 749	Continued From page 31 Medical Instrumentation) hospitals are expected to monitor and maintain temperatures and relative humidity within recommended levels in all locations associated with Central Sterile Reprocessing (CSR) to include decontamination, preparation & packing and sterile storage. Monitoring and maintaining temperatures and relative humidity at specific parameters is recommended to prevent microbial and bacterial growth in packaged sterilized material and instruments. Per Centers for Disease Control (CDC) and Health Care Infection Control Practice Advisory Committee (HICPAC) Guidelines for Environmental Infection Control in Health-Care Facilities 2003 states "...Relative humidity levels >60%, in addition to being perceived as uncomfortable, promote fungal growth.." During a tour of CSR on 3/9/11 at 1:50 PM a review of the hospital's monitoring process for temperature and humidity control was reviewed. Per observations of a Dickson humidity and temperature chart recorder in the sterile stores area, the temperature reading was 69 degrees Fahrenheit (F) and the relative humidity was 15.2. (Per AAMI guidelines ST79 2006 3.3.65 relative humidity in sterile storage is not to exceed 70% and in other CSR locations humidity should be kept between 30-60 %. Optimal temperatures is 75 degrees F in sterile storage; 68 - 73 degree F in preparation & packing; and 60-65 degrees F in decontamination area) . When asked how the relative humidity and temperature levels were monitored the Director of CSR confirmed the only process presently was for staff to remove the graft chart from the monitoring device weekly, replace with a new graft sheet and place the completed graft chart in a notebook. No daily monitoring and/or review policy existed to assess	A 749	SEE ATTACHED Plan of Correction	4/26/11	

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A 749	Continued From page 32 if relative humidity and temperature levels met recommended parameters in all 3 locations within CSR that have Dickson humidity and temperature monitoring devices. Recommend parameters were not made available to staff for monitoring temperatures and relative humidity nor was a process developed for notification if a problem was identified. In addition, the lack of monitoring and review of relative humidity and temperatures also was performed at the Fanny Allen outpatient surgical location. This deficient practice was also confirmed on 3/10/11 at 8:30 AM by the Director of CSR.	A 749	SEE ATTACHED Plan of Correction	4/26/11
A 940	4. Staff in the peri-operative area failed to adhere to infection control standards when an operating room table extension with torn and cracked vinyl was not removed from use. On the morning of 3/9/11 while touring the operative suite area, staff were observed preparing an operating room for the next surgical case. Utilizing the table extension with several breaks in the integrity of the vinyl surface compromised effective disinfection of the surfaces. In an addition, 2 other operating rooms table extension were noted to be stored on the floor in the operating room. These observations were confirmed by the interlm nurse manager for Surgical Services to be breaches in infection control practices and a potential compromise of patient safety. 482.51 SURGICAL SERVICES If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.	A 940	SEE ATTACHED Plan of Correction A-749 4/20/11 D. DeTosch	4-26-11

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A 940	Continued From page 33 This CONDITION is not met as evidenced by: Based on observations, staff interview and record review the Condition of Participation: Surgical Services was not met as evidenced by the hospitals failure to monitor temperature and humidity levels in the Central Sterile Processing locations; failure to ensure access to the operative and recovery area is limited to authorized individuals and failure to provide emergency lighting in out patient areas where surgical procedures are conducted. Findings include: 1. Per national standards developed by AAMI (Association for the Advancement of medical Instruments) hospitals are expected to monitor and maintain temperatures and relative humidity within recommended levels in all locations associated with Central Sterile Reprocessing (CSR) to include decontamination, preparation & packing and sterile storage. Monitoring and maintaining temperatures and relative humidity at specific parameters is recommended to prevent microbial and bacterial growth in packaged sterilized material and instruments. During a tour of CSR on 3/9/11 at 1:50 PM a review of the hospital's monitoring process for temperature and humidity control was reviewed. Per observations of a Dickson humidity and temperature chart recorder in the sterile stores area of CSR the temperature reading was 69 degrees Fahrenheit (F) and the relative humidity was 15.2. (Per AAMI guidelines ST79 2006 3.3.65 relative humidity in sterile storage is not to exceed 70% and in other CSR locations humidity should be kept between 30-60 %. Optimal temperatures is 75 degrees F in sterile storage; 68 - 73 degree F in preparation & packing; and 60-65 degrees F in	A 940	SEE ATTACHED Plan of Correction	4/26/11	

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A 940	Continued From page 34 decontamination area.) When asked how the relative humidity and temperature levels were monitored, the Director of CSR confirmed the only process presently was for staff to remove the graft-chart-from-the-monitoring-device-weekly-... replace with a new graft sheet and place the completed graft chart in a notebook. No daily monitoring and/or review policy existed to assess if relative humidity and temperature levels met recommended parameters in all 3 locations within CSR that have Dickson humidity and temperature monitoring devices. Recommended parameters were not made available to staff for monitoring temperatures and relative humidity nor was a process developed for notification if a problem was identified. In addition, the lack of monitoring and review of relative humidity and temperatures also was noted to exist at the Fanny Allen outpatient surgical location. This deficient practice was also confirmed on 3/10/11 at 8:30 AM by the Director of CSR.	A 940	SEE ATTACHED Plan of Correction	4/26/11
	2. During a tour on the morning of 3/9/11 with the Director of Peri-Operative Services the McClure entrance to the peri-operative area was observed to be unsecured creating potential access to the operative suites and recovery areas by unauthorized individuals. Although all other entrances to the peri-operative area are secured requiring employee ID badge authorization to access the area, the McClure entrance is not equipped with a badge ID monitoring system. An unauthorized individual can press the automatic door opener, travel down a corridor where stretchers and equipment are stored and enter into the operative suites area which is also not secured. In addition, both the McClure peri-operative door entrance and the entrance leading directly into the operating suites are not		SEE ATTACHED Plan of Correction	5/1/11 4/7/11

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 470003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 03/11/2011
NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HOSPITAL OF VERMONT			STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT 05401	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 940	Continued From page 35 distinctly marked either on the floor or doors warning unauthorized individuals are not permitted to enter. These observations were confirmed by the Director of Peri-Operative services at the time of the tour.	A 940		
A1005	3. Per observation of one outpatient clinic on 3/11/11, it was observed that although there is a system to illuminate the hallways in case of a power outage, only flashlights and glow sticks are available to illuminate the procedure rooms in case of a power outage. Per review of billing codes for March 1, 2011 through March 10, 2011, surgical procedures are performed in the two procedure rooms at the outpatient clinic. Per interview on 3/11/11, at approximately 9:45 AM, one clinical staff person stated that if the lights go out "we have flashlights in the rooms". Per interview, a second clinical staff person stated that if the lights went out during a procedure, staff would "make sure the flashlights were on so they could finish the procedure". 482.52(b)(3) OUTPATIENT POST-ANESTHESIA EVALUATION [The policies must ensure that the following are provided for each patient] A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The post-anesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures, which have been approved by the medical staff and which reflect current standards of anesthesia care.	A1005	SEE ATTACHED Plan of Correction A 940 4/14/11 PAC Acceptable Correction SEE ATTACHED Plan of Correction	4/14/11 4/26/11

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

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A1005	Continued From page 36 This STANDARD is not met as evidenced by: Based upon record review and interview, the facility failed to document complete post anesthesia evaluations. A review of 7 patients who had received anesthesia services revealed documentation by the individual qualified to administer anesthesia did not contain qualitative elements that addressed their recovery from anesthesia and in 1 of 7 applicable anesthesia evaluations, the written evaluations were mostly identical. (Patient #28) Evidence includes the following: 1. Record review for Patient #28 revealed a procedure requiring general anesthesia was ordered initially twice a week on 2/12/11 and increased to three times a week on 3/1/11. On 2/18/11, the first procedure was conducted. The post anesthesia evaluation conducted on 2/18/11 read: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". There was no qualitative data that indicated what "acceptable mental status" was nor "stable respiratory function or the type of anesthesia that was administered. On 2/21/11, the post anesthesia evaluation read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete	A1006	SEE ATTACHED Plan of Correction	4/20/11

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A1005	Continued From page 37 score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". On 2/25/11, the post-anesthesia evaluation read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". On 3/2, 3/4, 3/7, 3/9/11, the post anesthesia evaluations all read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". During an interview with the Health Care Service Director in the afternoon of 3/9/11, the documentation of the post anesthesia evaluations were discussed. The "canned" language is a choice in the electronic system that the provider has an option to choose. The anesthesia providers discuss and confer with clinical staff in PACU (Post Anesthesia Care Unit) and use the clinical signs documented by PACU staff. If no issues, they choose from the drop down menu the canned language as noted above. It was confirmed that looking directly at the post anesthesia evaluations, clinical indicators are not present but the system could be changed so that	A1005	SEE ATTACHED Plan of Correction	4/26/11

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A1005	Continued From page 38 all applicable clinical elements to measure anesthesia recovery could be included in their system.	A1005	1005 4/20/11 POC Accepted <i>[Signature]</i>	
A1104	482.55(a)(3) EMERGENCY SERVICES POLICIES [If emergency services are provided at the hospital --] (3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff. This STANDARD is not met as evidenced by: Based on staff interview and record review the facility failed to establish policies and procedures governing the provision of medical care by Physician Assistant (PA) in the ED (Emergency Department). Findings include: Per record review, Patient #55, who had been recently diagnosed with GBM (Glioblastoma multiforme, a type of brain cancer), was hospitalized for a period of 3 weeks duration for treatment of complex medical issues, including: Pneumocystis carinii pneumonia, septic shock, DVT (Deep Vein Thrombosis) of the left leg as well as bilateral Pulmonary Emboli (blockage of arteries in the lungs) and Atrial Fibrillation (condition related to heart rhythm). The patient received anticoagulant medication as part of their treatment, and was discharged from the hospital on 6/15/10. Patient #55 presented to the ED just 3 days later, on 6/18/10, complaining of left leg pain, and, despite the available information from the recent hospitalization regarding the patient's medical history, the PA did not consult with the supervising Attending physician and failed to conduct any diagnostic studies when assessing	A1104		
			SEE ATTACHED Plan of CORRECTION	3/24/11

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A1104	Continued From page 39 the patient's medical condition. Patient #55 was diagnosed, at that time, with Sciatica (related to irritation of the sciatic nerve) and discharged back to a SNF (Skilled Nursing Facility). Patient # returned to the ED, again, 3 days later, on 6/21/10, with ongoing pain, and the ED physician, who provided the patient's care at that time identified that the patient had a "complex medical hx (history) for GBM and chemo...." and included lab and diagnostic imaging studies as part of the assessment. The lab studies identified a significant drop in blood levels requiring blood transfusion, and a CT of the pelvis revealed retroperitoneal bleed (bleeding internally into the membrane that lines the abdominal cavity in the area of the lower back), and the patient was subsequently readmitted to the hospital for treatment. Per interview, at 9:50 AM on 3/10/11, the Medical Clinical Leader, responsible for the oversight of quality of care provided in the ED, stated that, although there is a supervising Attending physician available in the ED at all times, there was no formal process in place for assuring ongoing/continuing assessment of the medical care provided by PAs, and no policy or guidelines that clearly defined when a PA would be required to consult the Attending physician regarding medical care of ED patients. The Clinical Leader stated there is an expectation that a PA will consult with the Attending physician when a patient presents with a "complex" case, however that determination is left solely to the individual PA's judgment. S/he also stated that although there is an expectation that PAs will consult the Attending if they are considering use of advanced imaging studies, particularly CT or MRI, there is no policy or protocol to assure consistency of that practice. In addition, the Clinical Leader stated	A1104	<i>SEE ATTACHED Plan of CORRECTION</i>	3/24/11

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A1104	Continued From page 40 that the process for conducting ongoing assessment of medical care provided by PAs in the ED includes: a requirement to attend at least 50% of the monthly Quality Meetings where case reviews is conducted; and an informal process of review of PA records, conducted by the Clinical Leader, on those PAs with whom he works, during clinical shifts that s/he is scheduled as a supervising Attending. S/he further stated that they are currently in the process of developing policies and procedures for assuring ongoing/continuing assessment of medical care provided by PAs to ED patients.	A1104	SEE ATTACHED Plan of Correction A 1104 4/20/11 Poc [Signature]	3/24/11	

A 000 INITIAL COMMENTS

A full hospital survey was completed on March 8-11, 2011. In conjunction with the survey, four facility reports and one complaint-were-included for investigation.

An Immediate Jeopardy situation was determined to exist based on the hospital's failure to prevent the use of unnecessary force resulting in injury, the use of prohibited weapons and restraints in response to patient behaviors, and for not assuring the immediate availability of emergency power for surgical procedure rooms in outpatient clinics.

The Immediacy component of the Immediate Jeopardy situation was abated on 3/10/11 at 6:30 PM when the hospital assured all prohibited weapons and restraints were removed from Security staff and stated no further use of the weapons and restraint device will be allowed. The Immediacy component of the Immediate Jeopardy situation was abated on 3/11/11 at 1:30 PM when the hospital assured emergency lighting was being immediately installed in identified outpatient surgical procedure rooms.

Note: As a result of the full hospital survey, and two complaint investigations to assess compliance with the Federal Conditions of Participation for Acute Care Hospitals, the hospital was determined not to be in compliance with the Conditions of Participation for: Patient Rights; Governing Body; Compliance with Federal State and Local Laws; and Surgical Services

A020 482.11 COMPLIANCE WITH LAWS: Compliance with Federal, State and Local Laws

This CONDITION is not met as evidenced by: Based on staff interview and record review, the hospital failed to ensure compliance with Vermont State Statutes to include Bill of Rights or Hospital Patients and the 2006 Edition of VT Fire and Building Safety Codes.

Vermont State Statutes Title 18: Health

Chapter 42: Bill of Rights for Hospital Patients Section 1852 (a)(1)the patient has the right to considerate and respectful care at all times and under all circumstances with recognition of his or her personal dignity.

1. Based on record review and staff interview the hospital failed to assure that each patient had the right to make informed decisions about their care and were treated with dignity and respect in 1 applicable record reviewed. (Patient #8) Findings include:

Per record review, Patient #8, who was voluntarily admitted to Shepardson 6 Inpatient Psychiatric unit due to psychosis, requested Lunesta (medication for insomnia) during the evening shift on 1/18/11. Nursing notes on 1/18/11 at 8:35 PM stated "Pt requested Lunesta but when given it spit it right out. Nurses made multiple unsuccessful attempts to get pt to take Lunesta, pt continued to spit pill out and spit/spill chocolate milk on self and others. Pt continued to express that she wanted the medication, yet was unable to take it.... Per review of the hospital's internal investigation, one nurse held the medication in Patient #8's mouth while 2 other nurses physically held the patient's arm and head in an effort to force the patient to take the medication. Patient #8 refused the medication.

Per interview with Nurse #1 on 3/9/11 at 11:30 AM,-three nurses were placed on administrative leave as a result of this event and staff education was provided which included the use of involuntary/emergency medication and restraint.

Per interview with the Assistant Fire Marshal on 3/11/11 at 2:30 pm, the hospital began laboratory functions at an outpatient facility on 3/7/11 without first obtaining an occupancy permit in violation of 2006 Edition of VT Fire and Building Safety Code: 20 VSA Chapter 73.

Fletcher Allen Plan of Correction

An internal review was completed at the time of the incident. Based on this review, staff directly involved with the incident was placed on administrative leave. The Nurse Manager of Psychiatry units reeducated staff on the established Fletcher Allen policies entitled: "Emergency Medications" and "Restraint and Seclusion Behavioral Health Care." This education was completed with staff prior to the next scheduled shift in January 2011. These actions were taken prior to the full hospital survey conducted on 3/8-11/2011.

Content related to the Fletcher Allen policies entitled: "Emergency Medications" and "Restraint and Seclusion Behavioral Health Care" will be reinforced by the Nurse Educator and included as part of the psychiatry unit's "Education Days." The education will be completed by 4/12/2011. As part of the performance improvement process the Nurse Manager of Psychiatry reviews all emergency medications and restraint/seclusion use for compliance with policy with feedback to staff. Emergency medications and restraint/seclusion cases are also reviewed at the Psychiatry Quality Committee.

Regarding the survey finding, "beginning laboratory functions at an outpatient facility on 3/7/2011 without first obtaining an occupancy permit in violation of 2006 Edition of VT Fire and Building Safety Code: 20 VSA Chapter," it is important to note that the state agency which is accountable of review and issuance of the final inspection conducted the final inspection of the outpatient facility laboratory location on 3/7/11. Documentation was due from the Department of Labor and Industries by 4/1/2011 but as of the writing of this POC, has not yet been received.

In an effort to improve internal tracking of final inspections this item has been added to Fletcher Allen's "Project Close Out" checklist which will be completed by the Facilities Project Manager and forwarded to the Director of Facilities Planning and Development going forward. 4/20/11

A-020 P.O.C. Accepted.
Ol Olson

A 043 482.12 GOVERNING BODY

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body:

This CONDITION is not met as evidenced by: Based on observations, staff interviews and record review conducted throughout the days of survey, the Governing Body failed to ensure protection and promotion of Patient Rights based on the hospital's failure to prevent the use of unnecessary force resulting in injury and the use of prohibited weapons and restraints in response to patient behaviors. The Governing Body failed to ensure the safety of patients by failing to equip outpatient facilities, where surgical procedures are performed, with required emergency lighting.

Fletcher Allen Plan of Correction

The Chief Medical Officer reviewed Fletcher Allen's leadership responsibility and oversight for ensuring the protection and promotion of patient rights, ensuring the safety of patients in our outpatient facilities, in addition to reviewing the recent survey findings with the governing body at the 4/12/2011 Board of Trustees meeting. The Quality and Ethics Committee of the Board of Trustees will be informed by the Vice President of the Jeffords Institute for Quality of recent survey activity, findings and plans of correction for the 3/8-3/11/2011 survey activity at their next scheduled meeting on 5/16/2011.

Effective immediately on 3/10/2011 the use of Oleoresin Capsicum (OC) and ASP Trifold restraint devices by Fletcher Allen Health Care Security Officers has been discontinued. This change was communicated to security staff by the Director of Security at 4:55PM, 03/10/11. OC and Trifold restraint devices were collected by each shift supervisor prior to the beginning of each shift and delivered to the office of the Vice President of Hospital Services. Each officer has signed a copy of the email notification as verification of this change in policy. Existing supply locations of these devices were surveyed by the shift supervisor and any remaining stock was removed and secured. The supply chain sources of these devices to Fletcher Allen Health Care have been terminated as of 3/10/2011.

As of 5/3/2011, The Director of Purchasing will ensure that there is always a review of purchase requests for restraint products and ensure that comparison of the restraint products on the purchase requests is made against the approved restraint devices outlines in the Fletcher Allen Restraint Policies and catalogued in the item master of the Materials Management Information System. Any restraint order being placed that does not conform to the devices listed in the policies and/or catalogued in the item master of the Materials Management Information System will be reviewed by the Vice Presidents

The "Security Incident Report" which is used to document physical interventions by Fletcher Allen Security Officers will be revised to include a "Response Debrief." A debrief will be conducted by Security Officers following a response to a Code 8. The debrief will include the members of the clinical team in addition to the security team. The debrief form now includes a prompt for the team to file a SAFE report in the event of an injury. The "Security Incident Report" will be forwarded to the Manager of Security who will review for compliance with deployment of security related interventions. Cases requiring a second level review (those that result in injury, altercation or that the team has identified opportunity for improvement) will be forwarded to the Director of Security and the Vice President of Hospital Services.

Trended reports related to security responses will continue to be reviewed as part of the security management report made to the Environment of Care (EOC) Committee and the Restraint Committee. The EOC Committee is comprised of a multidisciplinary team. It is chaired by the Vice President of Hospital Services and includes but is not limited to representatives from Security, Supply Chain, Nursing, Infection Control, Patient Safety and Regulatory. The Restraint Committee is comprised the Managers of from Security, Regulatory, Emergency Department, Medical Surgical and Rehabilitation. Any identified areas of improvement will be feedback to the areas leadership for action. These reports are part of Fletcher Allen's integrated performance improvement process.

The Response Debrief tool and revised process will be implemented on 4/8/2011. The revised process will be presented at the 4/27/2011 EOC Committee meeting for approval.

The Environment of Care (EOC) Committee and the Restraint Committee report out to the Standards of Operation Committee, chaired by the Chief Medical Officer. The contents of the reports are shared at the Organization's Quality Council Committee.

In addition to the "Security Incident Report" The Institute for Quality Regulatory Team reviews all code 8's that result in restraint for compliance with policies and procedures. Case reviews now a standing agenda item on the Restraint Committee Meeting.

The Nursing Directors will communicate electronically to their nursing managers the new Security Response Debriefing process by 4/22/2011. Also highlighted will be the practices outlined in the Fletcher Allen Restraint Policies titled: Restraints for Medical, Surgical and Behavioral Health Indications on Non-Psychiatric Units and Restraint and Seclusion: Behavioral Health/Psychiatric Emergency. Included in the electronic communication will be the approved restraint types defined by the Fletcher Allen Policy. The new Security Response Debriefing process and approved restraint types will be communicated to staff via April 2011 Notes on Nursing.

The Vice President of Hospital Services communicated electronically on April 18, 2011 to the security team the acceptable restraint devices as outlined in the Fletcher Allen Restraint Policy titled: Restraint for Medical, Surgical and Behavioral Health Indications on Non Psychiatric Units, and Restraint and seclusion: behavioral health/psychiatric emergency. A thorough review of the revised Code 8 Debrief Protocol was conducted by the Director of Security at the April 12, 2011 staff meeting. A communication on the change was sent to Security Staff on April 6, 2011. Also reinforced at the staff meeting was the use of the Burlington Police Department as a resource in the event that extra support is needed.

An evaluation as to the appropriateness of installing additional battery pack lighting has been conducted by the Vice President for Medical Group Operations. Based on the completed evaluation, the Vice President for Hospital Services will oversee the addition of lighting to identified areas. A purchase order for the lighting and installation was placed

on 3/19/2011 and the work will be complete by 4/14/2011. Inspection, testing and maintenance shall be performed by Facilities Management in compliance with NFPA 101.7.9.3. This will be scheduled via the Facilities Management work order system. To ensure the placement of appropriate emergency lighting, the evaluation as to the need for emergency lighting has been added to the facility design guidelines and site activation process.

A-043 P.O.C. Accepted
Oleoresin Capsicum

Refer to Tags: A-0154, A-702
A 115 482.13 PATIENT RIGHTS

A hospital must protect and promote each patient's rights.

This CONDITION is not met as evidenced by: Based on record review and staff interview, the Condition of Participation for Patient's Rights was not met based on the hospital's failure to prevent the use of unnecessary force resulting in injury and the use of prohibited weapons and restraints in response to patient behaviors.

Fletcher Allen Plan of Correction

Effective immediately on 3/10/2011 the use of Oleoresin Capsicum (OC) and ASP Trifold restraint devices by Fletcher Allen Health Care Security Officers has been discontinued. This change was communicated to security staff by the Director of Security at 4:55PM, 03/10/11. OC and Trifold restraint devices were collected by each shift supervisor prior to the beginning of each shift and delivered to the office of the Vice President of Hospital Services. Each officer has signed a copy of the email notification as verification of this change in policy. Existing supply locations of these devices were surveyed by the shift supervisor and any remaining stock was removed and secured. The supply chain sources of these devices to Fletcher Allen Health Care have been terminated as of 3/10/2011.

As of 5/3/2011, The Director of Purchasing will ensure that there is always a review of purchase requests for restraint products and ensure that comparison of the restraint products on the purchase requests is made against the approved restraint devices outlines in the Fletcher Allen Restraint Policies and catalogued in the item master of the Materials Management Information System. Any restraint order being placed that does not conform to the devices listed in the policies and/or catalogued in the item master of the Materials Management Information System will be reviewed by the Vice Presidents

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Trended reports related to security responses will continue to be reviewed as part of the security management report made to the Environment of Care (EOC) Committee and the Restraint Committee. The EOC Committee is comprised of a multidisciplinary team. It is chaired by the Vice President of Hospital Services and includes but is not limited to representatives from Security, Supply Chain, Nursing, Infection Control, Patient Safety and Regulatory. The Restraint Committee is comprised the Managers of from Security, Regulatory, Emergency Department, Medical Surgical and Rehabilitation. Any identified areas of improvement will be feedback to the areas leadership for action. These reports are part of Fletcher Allen's integrated performance improvement process.

The Response Debrief tool and revised process will be implemented on 4/8/2011. The revised process will be presented at the 4/27/2011 EOC Committee meeting for approval.

The Environment of Care (EOC) Committee and the Restraint Committee report out to the Standards of Operation Committee, chaired by the Chief Medical Officer. The contents of the reports are shared at the Organization's Quality Council Committee.

In addition to the "Security Incident Report" The Institute for Quality Regulatory Team reviews all code 8's that result in restraint for compliance with policies and procedures. Case reviews now a standing agenda item on the Restraint Subcommittee Meeting

The Nursing Directors will communicate via email to their nursing managers the new Security Response Debriefing process by 4/22/2011. Also highlighted will be the practices outlined in the Fletcher Allen Restraint Policies titled: Restraints for Medical, Surgical and Behavioral Health Indications on Non-Psychiatric Units and Restraint and Seclusion: Behavioral Health/Psychiatric Emergency. Included in the electronic communication will be the approved restraint types defined by the Fletcher Allen Policy. The new Security Response Debriefing process and approved restraint types will be communicated to staff via April 2011 Notes on Nursing.

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In addition to the above POC, Fletcher Allen has formally responded to these findings in the IJ immediate plan submitted to the Division of Licensing and Protection dated 3/29/2011, a copy of which is provided for your reference labeled Attachment "A".

AIS 4/20/11 P.O.C. Accepted [Signature]

Refer to A-0154

A 121 482.13(a)(2)(i) PATIENT RIGHTS: GRIEVANCE PROCEDURES

[At a minimum:]

The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

This STANDARD is not met as evidenced by: Based upon review of information provided to patients/families at the time of admission and interview, the facility failed to provide sufficient information that clearly articulated the facilities complaint and grievance process. Evidence includes the following:

On 3/9/11 at approximately 2:00 PM, an interview was conducted with Manager of Patient & Family Advocacy related to the complaint and grievance process at the facility. At this time, a packet of information was reviewed which was confirmed to be the information presented to patients/families at the time of admission which was titled, "Guide for Inpatients". The packet contained additional information including patient rights and responsibilities.

Form #017773P dated 1/25/10 was identified during the interview as to where patients/families could find information about the complaint and grievance process. The only information in the notice pertaining to filing a complaint and/or grievance was: "If you have any questions or complaints about your stay, please contact our Office of Patient and Family Advocacy. They will listen to your concerns and work with you to address them." The form provided the name of the hospital, address and phone number but no contact person. Also provided were Vermont agencies for additional assistance with other concerns. Review of the "Guide for Inpatients" on page 11 read, "We encourage direct feedback to any staff at the time a concern arises. In addition, a specific review process is offered through our Office of Patient and Family Advocacy. This process includes appropriate investigation and resolution at the point of service and/or referral to our Grievance Committee for review and written response. For more information, contact our Office of Patient and Family Advocacy. Neither document clearly explained how a complaint or grievance could be filed

including time frames and expectations. The interview confirmed that the information reviewed was how the patient was informed about their right to file a complaint or grievance

Fletcher Allen Plan of Correction

A query was sent to the University Health System Consortium (UHC) for copies of grievance practices and policies used by other academic organizations. These responses were taken into consideration when reviewing and modifying the Fletcher Allen process. The Fletcher Allen "Guide for Inpatients" will be modified to include an insert that articulates the complaint and grievance process. A draft of the insert has been approved by the Vice President of the Institute for Quality and will be implemented by April 26th. As part of the monitoring process, Volunteer Ambassadors will visit newly admitted patients and verify receipt of the "Guide for Inpatients" and the inclusion of the insert. Opportunities for improvement will be forwarded to the Manager of the Office of Patient and Family Advocacy for action, action plans will be incorporated into Fletcher Allen's performance improvement process.

A 121 5/20/11 P.O.C. Accepted [Signature]

A 131 482.13(b)(2) PATIENT RIGHTS: INFORMED CONSENT

The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

This STANDARD is not met as evidenced by: Based on record review and staff interview the hospital failed to assure that each patient had the right to make informed decisions about their care and were treated with dignity and respect in 1 applicable record reviewed. (Patient #8) Findings include:

1. Per record review, Patient #8, who was voluntarily admitted to Shepardson 6 inpatient psychiatric unit due to psychosis, requested Lunesta (medication for insomnia) during the evening shift on 1/18/11. Nursing notes on 1/18/11 at 8:35 PM stated "Pt requested Lunesta but when given it spit it right out. Nurses made multiple unsuccessful attempts to get pt to take Lunesta, pt continued to spit pill out and spit/spill chocolate milk on self and others. Pt continued to express that she wanted the medication, yet was unable to take it" Per review of the hospital's internal investigation, one nurse held the medication in Patient #8's mouth while 2 other nurses physically held the patient's arm and head in an effort to force the patient to take the medication. Patient #8 refused the medication. Per interview with Nurse #1 on 3/9/11 at 11:30 AM, three nurses were placed on administrative leave as the result of this event and staff education was provided which included the use of involuntary/emergency medication and restraint.

Fletcher Allen Plan of Correction

An internal review was completed at the time of the incident. Based on this review, staff directly involved with the incident was placed on administrative leave. The Nurse Manager of Psychiatry reeducated staff on the established Fletcher Allen policies entitled: "Emergency Medications" and "Restraint and Seclusion Behavioral Health Care." This education was completed with staff prior to the next scheduled shift in January 2011. These actions were taken prior to the full hospital survey conducted on 3/8/2011.

Content related to the Fletcher Allen policies entitled: "Emergency Medications" and "Restraint and Seclusion Behavioral Health Care" will be reinforced by the Nurse Educator and included as part of the psychiatry unit's "Education Days." The education will be completed by 4/12/2011. As part of the performance improvement process the Nurse Manager of Psychiatry reviews all emergency medications and restraint/seclusion use for policy compliance with feedback to staff. Emergency medications and restraint/seclusion cases are also reviewed at the Psychiatry Quality Committee.

A 131 P.O.C. Accepted 4/20/11 [Signature]

A 143 482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY

The patient has the right to personal privacy.

This STANDARD is not met as evidenced by: Based on observation and confirmed by interview, the facility failed to assure personal privacy for patients on one medical unit. Findings include: Based on observations from 3/8/11 through 3/11/11, medical records posted with the first and last names of patients were fully visible and legible from approximately 18 inches away from where they were stored at the nursing station. Per interview on 3/8/11 at 10:45 AM, the Nurse Manager of the unit confirmed that "patients and visitors are allowed in [the] area". Per interview on 3/10/11, a staff person who works behind the nursing station stated that "occasionally people come to the nursing station via the front".

Fletcher Allen Plan of Correction

An audit of nursing units was completed by Nursing Directors on 3/11/2011 to ensure that patient identifiers were not visible to non healthcare individuals. The chart rack on the surgical unit identified during the survey was removed to avoid any possibility of names being visible. The audit of patient care areas and the action plan to correct the nursing unit, in which this was perceived as an issue, was completed and communicated to the survey team prior to the exit conference. Resolution of this issue was also communicated by the Vice President of the Institute for Quality to the survey team during the exit interview, prior to the end of the survey. As part of our internal "mock survey process" our regulatory team lead by the Regulatory Director will conduct surveys to review compliance with patient confidentiality. Mock survey results are communicated to the appropriate leadership and are included in Fletcher Allen's performance improvement process.

A143 - P.O.C. Accepted 4/20/11 *Or Odet Josh R*

A 144 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING

The patient has the right to receive care in a safe setting.

This STANDARD is not met as evidenced by: Based on observations and staff interview the hospital failed to provide an environment that would ensure safety and well being for all patients on the inpatient psychiatric units. Findings include:

1. *On 3/9/11 at approximately 9:15 AM a tour was conducted on Shepardson 3 Psychiatric Unit. Five hand washing sinks with goose neck type faucets which were potentially loopable devices, were observed in the following areas: 2 in the hallways near room 335 and outside the Activity room; in the tub room; in the Activity room; and in the Activity room/kitchen.*

2. *Based on observations of the two inpatient psychiatric units during survey, four sinks on Shepardson 6 located in the hallways had goose neck type faucets which were potentially loopable devices. During interview on 3/9/11 at 3:30 PM, Nurse #1 said the sinks were included for evaluation during safety rounds but no concerns had been identified.*

Fletcher Allen Plan of Correction

Non loopable faucets were ordered on 3/30/2011 with an expected delivery date of 4/4/2011. The planned completion date for installation is 4/13/2011. The "Environment of Care" team led by the Safety Specialist will continue to conduct Environmental Safety Rounds (ESR) every 6 months. Feedback regarding results of the ESR is communicated as appropriate to Fletcher Allen leadership for improvements.

A 154 482.13(e) USE OF RESTRAINT OR SECLUSION

Patient Rights: Restraint or Seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to

ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

This STANDARD is not met as evidenced by: Based on record review and staff interview, the hospital failed to prevent the use of unnecessary force resulting in injury and the use of prohibited weapons and restraints in response to patient behaviors in 3 of 3 records reviewed. (Pt. # 7, 16,17) Findings include:

Per review of security reports, record review and staff interview, hospital security personnel were equipped to use 'ASP Trifold Restraints' (used as handcuffs) and Oleoresin Capsicum (pepper spray) which are prohibited for use by hospital staff to restrain patients

- 1. Per record review, Patient #7, admitted voluntarily due to suicidal ideation and opiate withdrawal, became 'verbally and physically agitated yelling slamming the door and throwing items in his/her room' on 1/24/11 after being told h/she couldn't leave the hospital. Constant observation was initiated at 2/09 PM. Nursing notes described Patient #7 as "...currently sitting in room and in behavioral control (although tense). Awaiting crisis team to evaluate..." Patient #7 was later described as being sitting on the toilet 'staring blankly and mute' while crisis met with family members. Following the emergency evaluation, Patient #7 was described as "irate banging his head on the wall stating I'm going to kill myself." Patient #7 refused to transfer to the locked inpatient psychiatric unit 'without a fight'. Nursing notes stated "given the volatility of the situation and potential for harm I call a Code 8."*

Per interview on 3/9/11 at approximately 9:10 AM, Nurse #1 stated "...h/she wanted to leave... furious h/she couldn't leave.... nurse sounded the panic button...h/she was sitting on the toilet and threatened to harm staff... security applied plastic wrist restraints after placing h/she on the floor on stomach... security picked h/she up and placed in wheelchair... 3 or 4 security personnel present... complained of arm hurting when restraint put on wrist... patient struggling during wrist restraint application... we told h/her to stop struggling but h/she wouldn't." Per record review, Patient #7 had a surgical procedure in 2002 on the right upper arm.

Per review of the 1/24/11 security services incident report, security personnel responded to the code 8 and stood by while nursing and medical staff spoke to Patient #7 about his options. Patient #7 said h/she would rather hurt staff and go to jail than go to Shepardson 6" (locked inpatient psychiatric unit). Patient #7 refused to take oral medication or move from the toilet. The report stated "the patient was fully clothed and after several minutes the patient was advised that if h/she did not move we would be forced to move h/her. The patient continued to refuse and it was decided to then attempt to direct the patient into the wheelchair. However, as soon as contact was made with the patient then started to resist and was placed down on the floor. The area was very small and the patient was aggressively resisting so it was decided to place the patient into ASP disposable restraint."

Per interview on 3/10/11 at 11:30 AM with security officer #1 and security officer #2, a total of four security officers and other patient support personnel responded to the Code 8. Security officer #1 said he was informed that Patient #7 needed to be transferred to Shepardson 6 but h/she was refusing to go. Security officer #1 said nursing and medical personnel were trying to convince Patient #7 to walk to the unit, but Patient #7 was verbally threatening stating h/she "would rather hurt staff and go to jail than go to Shepardson 6." Security officer #1 described Patient #7 as dressed and seated on the toilet with fists clenched but no attempts were made to strike out. Security officer #1 said he made the decision to place Patient #7 in the MOAB (Management of Aggressive Behavior) prone control position to avoid injury to his staff. (Patient placed on abdomen with each arm extended and secured at the shoulder and wrist with the wrists bent upward.) Four security officers were used for the "take down" per security officer #1. Security officer #1 said Patient #7 was yelling "no restraints" state h/she had a "bad right elbow." Security officer #2 said he had to back into the shower due to space constraints. An ASP Trifold restraint was applied which restrained Patient #7's hand behind his/her back. H/she was told not to resist but h/she continued to resist... h/she was twisting around." Security officer #1 said after restraining Patient #7 h/she was "dragged" the length of h/her room to the wheelchair in the hallway and lifted into the chair. Once arriving on Shepardson 6 and being led into seclusion, the plastic wrist restraints were removed by a device known as a 'Scarab cutter' used by security staff since the device cannot be removed with scissors. When Patient #7 refused to accept medication, security officer #1 said three security officers

held Patient #7 down, with one on each arm and one holding g/her legs while the nurse administered injectable medications. Nursing notes on 1/24/11 stated the physician was aware of Patient #7's complaint of shoulder pain.

On 1/27/11, nursing notes for Patient #7 stated "...c/o chest pain/sharp: 6/10 pain rating, pain has been present since when awoke in middle of the night last night." On 1/29/11, the physician ordered a chest-x-ray. The inpatient psychiatry discharge summary dated 1/31/11 stated "On 1/29 chest x-ray was obtained after pain continued, and showed a non-displaced rib fracture, possibly sustained during his struggle and restraint on Shepardson 3 at the time of transfer, for which no specific intervention was required." Per interview on 3/9/11, Nurse #1 stated "that fracture probably occurred during or as the result of the restraint." Based on record review and staff interview, although Patient #7 was verbally threatening and agitated, h/she was not combative when the use of force was implemented.

2. Per review of security services incident reports, the form listed a selection of interventions, including "FAHC Handcuffs and FAHC Mace." During interview on 3/10/11 at 11:30 AM, security officer #1 said "it (pepper spray) would be the last resort... it's been used once in my 5 and ½ years.... It was used on a patient who weighed about 300 pounds who was using karate kicks and punches." The Vice President of Hospital Services provided documentation on 3/11/11 at 2:10 PM concerning the use of pepper spray at Patient #17 which occurred on 2/6/2008

A. Per review of security services incident report dated 2/6/08, pepper spray was used on Patient #17 on Shepardson 6, the locked inpatient psychiatric unit. Per documentation in the report, Patient #17 was "acting out...walked past the nurse's station several times and performed several marshal arts stances towards staff... make an impression of a gun and made the impression of shooting us. Security proceeded to the hallway where h/she took off his socks clenched h/her fist and took up a defensive stance towards staff... refused several commands to calm down and come with security towards the seclusion room... became combative with staff and had to be placed on the floor to control him and prevent h/her from harming staff... picked up off the floor and taken to the seclusion room... began to kick door, nursing staff went to the nurse's station...to get medications... security personnel verbally commanded h/her to back away from the door... charged with clenched fists and was pushing s/o (security officer) out of the room... continued to be combative.... Security staff and this officer deployed OC, (Oleoresin Capsicum) spraying 1 second burst in the face..."

B. Per review of security services incident report and record review, Patient #16, who was admitted on 9/14/10 to the cardiac unit attempted to leave the hospital to smoke during the evening shift. Nursing notes stated "nurse and charge nurse went with patient to 1st floor where he tried to exit the building. A transport member prevented h/her from exiting and the patient became violent striking out at anyone that attempted to stop h/her. Code 8 called and security restrained the patient/: When security responded, one of the security officers observed the patient and two staff members involved in a 'struggle.' The report by security stated "...the patient at one point was in a standing position when I ordered the patient to lay on the ground or I would spray h/her (patient #16). I pulled my OC (pepper spray) out and aimed it... I chose not to use the OC.... On seeing the OC canister h/she (patient #16) appeared to pass out and go to the floor... h/she began to move around on the floor as if to appear to have a seizure... Staff holding the patient let go and I instructed them to that patient appeared to be faking. Staff again held the patient... the patient was held to the floor on h/her back... I instructed staff to roll h/her (patient #16) on stomach. ASP restraints were applied for his/her protection as we as staff." Per interview on 3/11/11 at 1:50 PM, the Vice President of Hospital Services confirmed that the pepper spray container was directed at Patient #16 but was not used by security. Per record review, Patient #16 was admitted to the cardiology for recurrent chest pain and LOC (loss of consciousness) episodes. A neurology consult note stated that Patient #16 had seven episodes of loss of consciousness on 9/14/10 prior to the above event.

Per interview on 3/11/11 at 2:08 PM, the Vice President of Hospital Services stated, "we looked at the regulations and thought it (pepper spray) was okay...it was used for safety and not for therapeutic reasons."

Fletcher Allen Plan of Correction

Effective immediately on 3/10/2011 the use of Oleoresin Capsicum (OC) and ASP Trifold restraint devices by Fletcher Allen Health Care Security Officers has been discontinued. This change was communicated to security staff by the

Director of Security at 4:55PM, 03/10/11. OC and Trifold restraint devices were collected by each shift supervisor prior to the beginning of each shift and delivered to the office of the Vice President of Hospital Services. Each officer has signed a copy of the email notification as verification of this change in policy. Existing supply locations of these devices were surveyed by the shift supervisor and any remaining stock was removed and secured. The supply chain sources of these devices to Fletcher Allen Health Care have been terminated as of 3/10/2011.

As of 5/3/2011, The Director of Purchasing will ensure that there is always a review of purchase requests for restraint products and ensure that comparison of the restraint products on the purchase requests is made against the approved restraint devices outlines in the Fletcher Allen Restraint Policies and catalogued in the item master of the Materials Management Information System. Any restraint order being placed that does not conform to the devices listed in the policies and/or catalogued in the item master of the Materials Management Information System will be reviewed by the Vice Presidents

The "Security Incident Report" which is used to document physical interventions by Fletcher Allen Security Officers will be revised to include a "Response Debrief." A debrief will be conducted by Security Officers following a response to a Code 8. The debrief will include the members of the clinical team in addition to the security team. The debrief form now includes a prompt for the team to file a SAFE report in the event of an injury. The "Security Incident Report" will be forwarded to the Manager of Security who will review for compliance with deployment of security related interventions. Cases requiring a second level review (those that result in injury, altercation or that the team has identified opportunity for improvement) will be forwarded to the Director of Security and the Vice President of Hospital Services.

Trended reports related to security responses will continue to be reviewed as part of the security management report made to the Environment of Care (EOC) Committee and the Restraint Committee. The EOC Committee is comprised of a multidisciplinary team. It is chaired by the Vice President of Hospital Services and includes but is not limited to representatives from Security, Supply Chain, Nursing, Infection Control, Patient Safety and Regulatory. The Restraint Committee is comprised the Managers of from Security, Regulatory, Emergency Department, Medical Surgical and Rehabilitation. Any identified areas of improvement will be feedback to the areas leadership for action. These reports are part of Fletcher Allen's integrated performance improvement process.

The Response Debrief tool and revised process will be implemented on 4/8/2011. The revised process will be presented at the 4/27/2011 EOC Committee meeting for approval.

The Environment of Care (EOC) Committee and the Restraint Committee report out to the Standards of Operation Committee, chaired by the Chief Medical Officer. The contents of the reports are shared at the Organization's Quality Council Committee.

In addition to the "Security Incident Report" The Institute for Quality Regulatory Team reviews all code 8's that result in restraint for compliance with policies and procedures. Case reviews now a standing agenda item on the Restraint Subcommittee Meeting

The Nursing Directors will communicate electronically to their nursing managers the new Security Response Debriefing process by 4/22/2011. Also highlighted will be the practices outlined in the Fletcher Allen Restraint Policies titled: Restraints for Medical, Surgical and Behavioral Health Indications on Non-Psychiatric Units and Restraint and Seclusion: Behavioral Health/Psychiatric Emergency. Included in the electronic communication will be the approved restraint types defined by the Fletcher Allen Policy. The new Security Response Debriefing process and approved restraint types will be communicated to staff via April 2011 Notes on Nursing.

The Vice President of Hospital Services communicated electronically on April 18, 2011 to the security team the acceptable restraint devices as outlined in the Fletcher Allen Restraint Policy titled: Restraint for Medical, Surgical and Behavioral Health Indications on Non Psychiatric Units, and restraint and seclusion: behavioral health/psychiatric emergency. A thorough review of the revised Code 8 debrief protocol was conducted by the Director of Security at the April 12, 2011 staff meeting. A communication on the change was sent to Security Staff on April 6, 2011. Also

reinforced at the staff meeting was the use of the Burlington Police Department as a resource in the event that extra support is needed.

In addition to the above POC, Fletcher Allen has responded to the findings in the IJ immediate plan submitted to the Division of Licensing and Protection dated 3/29/2011, a copy of which is provided for your reference labeled Attachment "A".

P.O.C. Accepted 4/20/11 De. Oortosh

A 214 482.13(g) PATIENT RIGHTS: SECLUSION OR RESTRAINT

Death Reporting Requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

- (1) *The hospital must report the following information to CMS:*
 - *Each death that occurs while a patient is in restraint or seclusion.*
 - *Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.*
 - *Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death: "Reasonable to assume" in this context includes, but is not limited to deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.*
- (2) *Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.*
- (3) *Staff must document in the patient's medical record the date and time the death was reported to CMS.*

This STANDARD is not met as evidenced by: Based upon document review and interview, that facility failed to report timely deaths associated with restraint or seclusion for 5 of 5 records reviewed. (Patients #49, 50, 51, 52 and 53). Evidence includes the following:

The Regulatory Advisor for Fletcher Allen was interviewed on 3/10/11 at 2:30 PM regarding the facility process for death reporting relative to restraint and/or seclusion use. It was reported that the facility uses clinical auditors who review and look for the mandated CMS parameters required to be reported. The CMS form is completed, faxed and entered into the medical record.

Record review revealed that Patient #49 died within 24 hours of removal of restraint on 1/19/11. The death was reported to CMS on 1/31/11.

Patient #50 died on 2/14/11 and the death was reported to CMS on 2/24/11

Patient # 51 died on 2/15/11 and the death was reported to CMS on 3/10/11

Patient #52 died on 2/14/11 and the death was reported to CMS on 3/10/11

Patient #53 died on 2/4/11 and the death was reported to CMS on 2/14/11

When asked to produce other death reporting actions to CMS, staff confirmed that the facility did not follow the reporting requirements for other deaths as well.

Fletcher Allen Plan of Correction

On 4/1/2011 the Regulatory Director reviewed the death reporting parameters specified by CMS 482.13 with Clinical Auditors in the Institute for Quality. The reporting process has been revised to meet the reporting timelines. Timeliness of reporting will be added as a performance measure for the mortality review process effective 4/26/2011.

A 267 482.(a)(2) QAPI Quality Indicators

The hospital must measure, analyze and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.

This STANDARD is not met as evidenced by: Based on record review and staff interview the hospital failed to track adverse patient events related to the use of ASP Trifold restrains and pepper spray used by security personnel in 3 of 3 records reviewed. (Pt # 7, 16, 17,) Findings include:

Per review of security reports, record review and staff interview, hospital security personnel were equipped to use 'ASP' Trifold Restraints' (used as handcuffs) and Oleoresin Capsicum (pepper spray) which are prohibited for use by hospital staff to restrain patients.

- 1. Per record review, Patient #7, admitted voluntarily due to suicidal ideation and opiate withdrawal, became 'verbally and physically agitated yelling, slamming the door and throwing items in his/her room' on 1/24/11 after being told h/she couldn't leave the hospital. Constant observation was initiated at 2:09 PM. Nursing notes described Patient #7 as "...currently sitting in room and behavioral control (although tense). Awaiting crisis team to evaluate..." Patient #7 was later described sitting on the toilet 'staring blankly and mute; while crisis met with family members. Following the emergency... evaluation, Patient #7 was described as "irate banging his head on the wall stating "I'm going to kill myself." Patient #7 refused to transfer to the locked inpatient psychiatric unit 'without a fight'. Nursing notes stated "given the volatility of the situation and potential for harm I call a Code 8*

Per interview on 3/9/11 at approximately 9:10 AM, Nurse #1 stated "...h/she wanted to leave... furious h/she couldn't leave.... nurse sounded the panic button...h/she was sitting on the toilet and threatened to harm staff... security applied plastic wrist restraints after placing h/she on the floor on stomach... security picked h/she up and placed in wheelchair... 3 or 4 security personnel present... complained of arm hurting when restraint put on wrist... patient struggling during wrist restraint application... we told h/her to stop struggling but h/she wouldn't." Per record review, Patient & had a surgical procedure in 2002 on the right upper arm.

Per review of the 1/24/11 security services incident report, security personnel responded to the code 8 and stood by while nursing and medical staff spoke to Patient #7 about his options. Patient #7 said h/she would rather hurt staff and go to jail than go to Shepardson 6" (locked inpatient psychiatric unit). Patient #7 refused to take oral medication or move from the toilet. The report stated "the patient was fully clothed and after several minutes the patient was advised that if h/she did not move we would be forced to move h/her. The patient continued to refuse and it was decided to then attempt to direct the patient into the wheelchair. However, as soon as contact was made with the patient then started to resist and was placed down on the floor. The area was very small and the patient was aggressively resisting so it was decided to place the patient into ASP disposable restraint."

Per interview on 3/10/11 at 11:30 AM with security officer #1 and security officer #2, a total of four security officers and other patient support personnel responded to the Code 8. Security officer #1 said he was informed that Patient #7 needed to be transferred to Shepardson 6 but h/she was refusing to go. Security officer #1 said nursing and medical personnel were trying to convince Patient #7 to walk to the unit, but Patient #7 was verbally threatening stating h/she "would rather hurt staff and go to jail than go to Shepardson 6." Security officer #1 described Patient #7 as dressed and seated on the toilet with fists clenched but no attempts were made to strike out. Security officer #1 said he made the decision to place Patient #7 in the MOAB (Management of Aggressive Behavior) prone control position to avoid injury to his staff. (Patient placed on abdomen with each arm extended and secured at the shoulder and wrist with the wrists bent upward.) Four security officers were used for the "take down" per security officer #1. Security officer #1 said Patient #7 was yelling "no restraints" state h/she had a "bad right elbow." Security officer #2 said he had to back into the shower due to space constraints. An ASP Trifold restraint was applied which restrained Patient #7's hand behind his/her back. H/she was told not to resist but h/she continued to resist... h/she was twisting around." Security officer #1 said after restraining Patient #7 h/she was "dragged" the length of h/her room to the wheelchair in the hallway and lifted into the chair. Once arriving on Shepardson 6 and being led into seclusion, the plastic wrist restraints were removed by a device known as a 'Scarab cutter' used by security staff since the device cannot be removed with scissors. When Patient #7 refused to accept medication, security officer #1 said three security officers

held Patient #7 down, with one on each arm and one holding g/her legs while the nurse administered injectable medications. Nursing notes on 1/24/11 stated the physician was aware of Patient #7's complaint of shoulder pain.

On 1/27/11, nursing notes for Patient #7 stated "...c/o chest pain/sharp: 6/10 pain rating, pain has been present since when awoke in middle of the nigh last night." On 1/29/11, the physician ordered a chest-x-ray. The inpatient psychiatry discharge summary dated 1/31/11 stated "On 1/29 chest x-ray was obtained after pain continued, and showed a non-displaced rib fracture, possibly sustained during his struggle and restraint on Shepardson 3 at the time of transfer, for which no specific intervention was required." Per interview on 3/9/11, Nurse #1 stated "that fracture probably occurred during or as the result of the restraint." Based on record review and staff interview, although Patient #7 was verbally threatening and agitated, h/she was not combative when the use of force was implemented.

2. Per review of security services incident reports, the form listed a selection of interventions, including "FAHC Handcuffs and FAHC Mace." During interview on 3/10/11 at 11:30 AM, security officer #1 said "it (pepper spray) would be the last resort... it's been used once in my 5 and 1/2 years.... It was used on a patient who weighed about 300 pounds who was using karate kicks and punches." The Vice President of Hospital Services provided documentation on 3/11/11 at 2:10 PM concerning the use of pepper spray at Patient #17 which occurred on 2/6/2008

C. Per review of security services incident report dated 2/6/08, pepper spray was used on Patient #17 on Shepardson 6, the locked inpatient psychiatric unit. Per documentation in the report, Patient #17 was "acting out...walked past the nurse's station several times and performed several marshal arts stances towards staff... make an impression of a gun and made the impression of shooting us. Security proceeded to the hallway where h/she took off his socks clenched h/her fist and took up a defensive stance towards staff... refused several commands to calm down and come with security towards the seclusion room... became combative with staff and had to be placed on the floor to control him and prevent h/her from harming staff... picked up off the floor and taken to the seclusion room... began to kick door, nursing staff went to the nurse's station...to get medications... security personnel verbally commanded h/her to back away from the door... charged with clenched fists and was pushing s/o (security officer) out of the room... continued to be combative.... Security staff and this officer deployed OC, (Oleoresin Capsicum) spraying 1 second burst in the face..."

D. Per review of security services incident report and record review, Patient #16, who was admitted on 9/14/10 to the cardiac unit attempted to leave the hospital to smoke during the evening shift. Nursing notes stated "nurse and charge nurse went with patient to I" floor where he tried to exit the building. A transport member prevented h/her from exiting and the patient became violent striking out at anyone that attempted to stop h/her. Code 8 called and security restrained the patient/: When security responded, one of the security officers observed the patient and two staff members involved in a 'struggle.' The report by security stated "...the patient at one point was in a standing position when I ordered the patient to lay on the ground or I would spray h/her (patient #16). I pulled my OC (pepper spray) out and aimed it... I chose not to use the OC.... On seeing the OC canister h/she (patient #16) appeared to pass out and go to the floor,,, h/she began to move around on the floor as if to appear to have a seizure... Staff holding the patient let go and I instructed them to that patient appeared to be faking. Staff again held the patient... the patient was held to the floor on h/her back... I instructed staff to roll h/her (patient #16) on stomach. ASP restraints were applied for his/her protection as we as staff." Per interview on 3/11/11 at 1:50 PM, the Vice President of Hospital Services confirmed that the pepper spray container was directed at Patient #16 but was not used by security. Per record review, Patient #16 was admitted to the cardiology for recurrent chest pain and LOC (loss of consciousness) episodes. A neurology consult note stated that Patient #16 had seven episodes of loss of consciousness on 9/14/10 prior to the above event.

During the afternoon of 3/10/11 when surveyors informed the hospital of the Immediate Jeopardy related to the use of ASP Trifold Restraints and pepper spray, the Vice President of Quality and Operational Effectiveness was not aware that ASP Trifold Restraints and pepper spray were being used by security personnel. During review of the hospital's Quality program on 3/11/11 at 11:05 AM, the Director of Patient Safety stated that no changes were implemented to the use of ASP Trifold restraints following their use on Patient #7 on 1/24/11. Per interview on 3/11/11 at 2:08 PM, with the Vice President of Hospital Services stated "we looked at the regulations and thought it (pepper spray) was okay.... It was used for safety and not for therapeutic reasons."

Fletcher Allen Plan of Correction

In reference to tracking of patient events related to security interventions the following actions have been taken:

The "Security Incident Report" which is used to document physical interventions by Fletcher Allen Security Officers will be revised to include a "Response Debrief." A debrief will be conducted by Security Officers following a response to a Code 8. The debrief will include the members of the clinical team in addition to the security team. The debrief form now includes a prompt for the team to file a SAFE report in the event of an injury. The "Security Incident Report" will be forwarded to the Manager of Security who will review for compliance with deployment of security related interventions. Cases requiring a second level review (those that result in injury, altercation or that the team has identified opportunity for improvement) will be forwarded to the Director of Security and the Vice President of Hospital Services.

Trended reports related to security responses will continue to be reviewed as part of the security management report made to the Environment of Care (EOC) Committee and the Restraint Committee. The EOC Committee is comprised of a multidisciplinary team. It is chaired by the Vice President of Hospital Services and includes but is not limited to representatives from Security, Supply Chain, Nursing, Infection Control, Patient Safety and Regulatory. The Restraint Subcommittee is comprised the Managers of from Security, Regulatory, Emergency Department, Medical Surgical and Rehabilitation. Any identified areas of improvement will be feedback to the areas leadership for action. These reports are part of Fletcher Allen's integrated performance improvement process.

The Response Debrief tool and revised process will be implemented on 4/8/2011. The revised process will be presented at the 4/27/2011 EOC Committee meeting for approval.

The Environment of Care (EOC) Committee and the Restraint Committee report out to the Standards of Operation Committee, chaired by the Chief Medical Officer. The contents of the reports are shared at the Organization's Quality Council Committee.

In addition to the "Security Incident Report" the Institute for Quality Regulatory Team reviews all code 8's that result in restraint for compliance with policies and procedures. Case reviews now a standing agenda item on the Restraint Committee Meeting

As of 5/3/2011, The Director of Purchasing will ensure that there is always a review of purchase requests for restraint products and ensure that comparison of the restraint products on the purchase requests is made against the approved restraint devices outlines in the Fletcher Allen Restraint Policies and catalogued in the item master of the Materials Management Information System. Any restraint order being placed that does not conform to the devices listed in the policies and/or catalogued in the item master of the Materials Management Information System will be reviewed by the Vice Presidents

The Nursing Directors will communicate electronically to their nursing managers the new Security Response Debriefing process by 4/22/2011. Also highlighted will be the practices outlined in the Fletcher Allen Restraint Policies titled: Restraints for Medical, Surgical and Behavioral Health Indications on Non-Psychiatric Units and Restraint and Seclusion: Behavioral Health/Psychiatric Emergency. Included in the electronic communication will be the approved restraint types defined by the Fletcher Allen Policy. The new Security Response Debriefing process and approved restraint types will be communicated to staff via April 2011 Notes on Nursing.

The Vice President of Hospital Services communicated electronically on April 18, 2011 to the security team the acceptable restraint devices as outlined in the Fletcher Allen Restraint Policy titled: Restraint for Medical, Surgical and Behavioral Health Indications on Non Psychiatric Units, and restraint and seclusion: behavioral health/psychiatric emergency. A thorough review of the revised Code 8 debrief protocol was conducted by the Director of Security at the April 12, 2011 staff meeting. A communication on the change was sent to Security Staff on April 6, 2011. Also reinforced at the staff meeting was the use of the Burlington Police Department as a resource in the event that extra support is needed.

A214 4/20/11
P.O.C. Qa. McIntosh, SW

A 395 482.23(b)(3) RN SUPERVISION OF NURSING CARE

A registered nurse must supervise and evaluate the nursing care for each patient.

This STANDARD is not met as evidenced by: Based on observations, record review and staff interview, the hospital failed to evaluate the use of side rails for 1 applicable record reviewed (Patient #3) Findings include:

- 1. Observations during a tour of Shepardson 6 on 3/8/11 at 11:00 AM with Nurse #1, side rails were observed on patient beds. Nurse #1 confirmed that all beds have four side rails, Nurse #1 further stated that staff don't use the side rails as restraints and patients can elevate the side rails if they choose to. Nurse #1 further stated "for a geriatric patient we might put up the top half rail but is not considered a restraint."*

On 3/8/11 at 1:45 PM, Patient #3 was observed in bed with two half-rails elevated at the head of the bed. Per record review, although Patient #3 was identified as being at high risk for falls, there was no assessment related to the use of side rails. Per interview on 3/8/11 at 4:10 PM and 3/9/11 at 9:10 AM, Nurse #1 confirmed that half-rails were used for Patient #3. Nurse #1 said the side rails were not used as restraints and possibly were used to access the call system, but staff were concerned about Patient #3's behavior and risk for falls. Nurse #1 state "we could improve... maybe other areas of the hospital use and assessment that we could use."

- 2. During the initial tour of the Shepardson 3 unit on 3/8/11 at approximately 10:30 AM; and on 3/10/11 at approximately 9:15 AM, the following rooms were observed to be equipped with 4 side rails: Rooms 332, 333, 311, 323. On 3/10/11 at approximately 9:30 AM on Shepardson 3, Nurse #4 indicated when Housekeeping prepared the room for admission; the 2 upper rails were left in the raised position. H/she added, the patient then decided if they wanted them up or down. Nurse #4 also said patients had an assessment for Fall Risk that was completed daily and included side rails; however, there were no individualized or specific assessments for the use of side rails.*

Fletcher Allen Plan of Correction

The inpatient Psychiatry nursing flow sheet was updated by the Nurse Manager to include assessment of side rails. On 3/25/2011, the Psychiatry Nurse Manger communicated the expectation that side rail assessment be included as part of the unit's nursing assessment. The Nurse Manager will review nursing documentation for compliance with side rail assessments and give feedback to staff as required, beginning 4/4/2011.

A 396 482/23 (b)(4) NURSING CARE PLAN

The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient.

This STANDARD is not met as evidenced by: Based on observations, record review and staff interview, the hospital failed to ensure that nursing staff developed a nursing care plan for 2 of 3 patients (#26 and #27), and failed to ensure a care plan included the use of C-PAP (continuous positive airway pressure) machine for one patient (#28). Findings include:

- 1. Patient #26 was admitted to the Shepardson 3 psychiatric unit o 3/6/11 with diagnoses which included Suicide Ideation, Depression (chronic), Substance Abuse, Dissociative Identity disorder, Bulimia and Family Conflict.*

Review of the Interdisciplinary Treatment Plan dated 3/7/11 identified problems as: depressive symptoms, suicidal ideations with plan; relationship problems, and substance dependence (THC - tetrahydrocannabinol, the major psychoactive compound in cannabis). The section for Psychological Interventions was not completed. The last page of the Care Plan was only signed by the Therapist on 3/6/11.

Observation on Shepardson 3 unit on 3/8/11 at approximately 10:30 AM upon entrance to the unit, found the normally unlocked exit door to be locked. Interview with the Psychiatrist following the tour, revealed the locked status was due to a patient who had been attempting to leave the unit. The Psychiatrist explained he/she did not there was a therapeutic benefit for this patient to be transferred to the Shepardson 6 unit, which was locked at all times.

Interview with Nurse #4 on 3/9/11 at approximately 10:00 AM revealed the Care Plan did not indicate Patient #26 was a flight risk. There was no revision to reflect the specific problem, or interventions to be implemented.

2. Patient #27 was admitted to Shepardson 3 Psychiatric unit on 3/2/11 to 3/8/11 with diagnoses which included Suicide Ideation, Cervical pain, History of ETOH (alcohol), Migraine and Mood Disorders.

Review of the Interdisciplinary Treatment Plan dated 3/3/11 identified Problems as: Suicidal Risk. The section for Psychological Interventions was not completed. The last page of the Care Plan was not signed by the Therapist. Interview with Nurse #4 on 3/9/11 at approximately 9:40 AM revealed the Interdisciplinary Care Plan should be completed within 24 hours of admission.

3. Patient #28 was admitted to Shepardson # Psychiatric Unit on 2/16/11 with diagnoses which included Severe Anxiety, Depression, Hypertension, and Hyperlipidemia. Treatment to included ECT (electroconvulsive therapy).

Review of the Pre-Admission Referral Summary dated 2/16/11 indicated the patient had a C-PAP (continuous positive airway pressure machine) for apnea. Review of the Interdisciplinary Treatment Plan dated 2/17/11 did not include a reference to the use of a C-PAP machine. Review of the Inpatient Psychiatry Treatment Plan update dated 2/24/11 revealed a Physician, Social Worker, and Therapist signature, however, there was o signature for Nursing. On 3/10/11, an interview with Nurse #3 on Shepardson 3 at approximately 9:30 AM revealed patient #28 did not use a CPAP machine.

Fletcher Allen Plan of Correction

Following the rules set forth in the "Local Coverage Determination (LCD) for Psychiatric Inpatient Hospitalization" (L29838), clinical staff will be educated on the completion of "Inpatient Psychiatry Multi-disciplinary Treatment Plans" and "Multi-disciplinary Treatment Plan Updates." The psychiatry Nurse Educator will reinforce the education provided on nursing care plans, utilization, documentation and the required updates by 4/12/2011. The Medical Director of inpatient Psychiatry will educate the providers on "Inpatient Psychiatry Multi-disciplinary Treatment Plans" and "Multi-disciplinary Treatment Plan Updates" by 4/12/2011. Daily audits of the "Multi-disciplinary Treatment Plan" (initial and updates) will be conducted by Activity Therapies with feedback to the Nurse Manager and Medical Director beginning 4/4/2011. Monthly care plans audits will be conducted an RN Clinical Auditors from the Institute for Quality with feedback to the Nurse Manager and Nurse Director.

4/10/11

A-395-P.O.C. Accepted *[Signature]*

A 438 482/24 (b) FORM AND RETENTION OF RECORDS

The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

This STANDARD is not met as evidenced by: Based on observation and staff interview the hospital failed to ensure that all medical records were properly stored in a location that protected them from potential fire and/or water damage. Findings include:

During a tour on 3/7/11 at 3:15 PM improper storage of medical records was observed at an off campus medical records location. Active patient records were observed stored on metal shelves, however in several locations multiple records were stored without protection on top of metal shelves throughout the storage area with some stacks heights to

be from 6 to 15 inches sitting in close proximity to sprinkler heads. If the sprinkler heads were prompted to disperse water, the improperly stored records would be in direct contact with water as it was expelled from the sprinkler heads and subject to destruction. The observation was confirmed by the Director for Health Information Management at the time of the tour.

Fletcher Allen Plan of Correction

The Director of Health Information Management removed the medical records that were stored on top of the metal shelves at the UHC location on 3/10/2011. This action was communicated to the survey team prior to the exit interview on 3/11/2011. The Environment of Care team led by the Safety Specialist will continue to conduct Environmental Safety Rounds (ESR) to access appropriateness of record storage. Feedback regarding results of the ESR is communicated as appropriate to Fletcher Allen leadership.

A 438 4/20/11 - POC Accepted Dr. Deetosh

A620 482.28(a)(1) DIRECTOR OF DIETARY SERVICES

The hospital must have a full-time employee who-

- (i) Serves as director of the food and dietetic services;
- (ii) Is responsible for daily management of the dietary services; and
- (iii) Is qualified by experience or training.

This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, the Director of Nutrition Services failed to assure that dietary staff implemented the policy for monitoring of refrigeration temperatures in accordance with safe food handling practices. Findings Include:

Per observation during a tour of the kitchen and dietary areas with the Director of Nutrition Services and other dietary staff on 3/8/11 commencing at 10:10 AM, refrigeration temperatures and/or temperature logs revealed multiple days when temperatures exceeded the safe range for storage of perishable foods and there was no evidence of actions taken. Out of range temperatures were recorded daily for freezer #1 for all of February and daily in March, with ranges from 14-24 degrees F (Fahrenheit). The thermometer stated that the temperature for freezer #1 was 25.8 degrees during the tour. There were also multiple days when logs for kitchen refrigerators #2, 4, 10 & 13 were out of range at 40 - 44 degrees F for the early AM temperature check. Logs for reach-in refrigerators in the Harvest Café revealed multiple days when temperatures were out of range at 40 - 41 degrees. Per review, the hospital's P/P "Cooler/Freezer Temperature Chart Standards for Nutrition Services" stated "If a cooler or freezer temperature is out of compliance, (at or below 39 degrees F for coolers and at or below 0 degrees for freezers) it will be reported immediately to the supervisor/lead on duty. (T?) the designated staff will take the following course of action and document by number in the column on the form and circle the cooler or freezer which is out of compliance". The out of range temperatures were not circled on the logs reviewed and there was no evidence of any remedial action taken per the policy. These omissions were confirmed during the interview with the Director of Nutrition Services on the afternoon of 3/8/11 after policy review.

Fletcher Allen Plan of Correction

The freezer referenced above was removed as requested by the Director of Nutrition Services on 3/11/2011, prior to the survey team's departure. Nutrition Policy "Nutr0004010" has been revised to clarify the process regarding documentation of corrective actions related to monitoring of refrigerator temperatures. The policy was reviewed with all nutrition supervisors and education regarding the process for entering electronic maintenance requests will be completed by the Director of Nutrition Services by 4/26/2011. The Environment of Care team led by the Safety Specialist will continue to conduct Environmental Safety Rounds (ESR). Feedback regarding results of the ESR is communicated as appropriate to Fletcher Allen leadership.

A701 482.41(a) MAINTENANCE OF PHYSICAL PLANT

A - 620 POC Accepted
Dr. Deetosh

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

This STANDARD is not met as evidenced by: Based on observation and interview; the hospital failed to ensure the environment was maintained in a safe manner. Findings include:

Per observations made during the physical environment tour on 3/8/11 and 3/9/11 there were loose hand rails in the following locations:

- 1. Outside the labor and delivery lounge*
- 2. Across from room 40143 in the west pavilion*
- 3. Between rooms 489-490 on Baird 4*
- 4. Between rooms 574-575 on Shepardson 5*

The above observations were confirmed by the facility Quality Assurance representative accompanying the surveyor at eh time of the observations.

Fletcher Allen Plan of Correction

The handrails referenced in the following locations have been secured:

- Outside the Labor and Delivery lounge
- Across from room 40143 in the West Pavilion
- Between rooms 489-490 on Baird 4
- Between rooms 574-575 on Shepardson 5

The Environment of Care team led by the Safety Specialist will continue to conduct Environmental Safety Rounds (ESR). Feedback regarding results of the ESR is communicated as appropriate to Fletcher Allen leadership

A-701-7-00. 4/20/11 *DeDeCato*

A702 482.41(a)(1) EMERGENCY POWER AND LIGHTING

There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

This STANDARD is not met as evidenced by: Based on observation and staff interview, the hospital failed to ensure emergency lighting was available at all outpatient offices where surgical procedures are performed. Findings include:

Per observation of one outpatient clinic on 3/11/11, it was observed that although there is a system to illuminate the hallways in case of a power outage, only flashlights and glow sticks are available to illuminate the procedure rooms in case of a power outage. Per review of billing codes for March 1, 2011 through March 10, 2011, surgical procedure are performed in the two procedure rooms at eh outpatient clinic. Per interview on 3/11/11, at approximately 9:45 AM, one clinical staff person stated that if the lights go out "we have flashlights in the rooms". Per interview, a second clinical staff person stated that if the lights went out during a procedure. Staff would "make sure the flashlights were on so they could finish the procedure".

Fletcher Allen Plan of Correction

An evaluation as to the appropriateness of installing additional battery pack lighting has been conducted by the Vice President for Medical Group Operations. Based on the completed evaluation, the Vice President for Hospital Services will oversee the addition of lighting to identified areas. A purchase order for the lighting and installation was placed on 3/19/2011 and the work will be complete by 4/14/2011. Inspection, testing and maintenance shall be performed by Facilities Management in compliance with NFPA 101.7.9.3. This will be scheduled via the Facilities Management work order system. To ensure the placement of appropriate emergency lighting, the evaluation as to the need for emergency lighting has been added to the facility design guidelines and site activation process.

A724 482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE

Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

This STANDARD is not met as evidenced by: Based on observation and confirmed by interview the hospital failed to assure laminate hoods in the pharmacy were maintained in an acceptable level of quality and safety. Findings include:

Based on observation on 3/9/11 at 1:30 PM of the main pharmacy area, two of four laminate hoods where IV solutions are prepared had discolored and degraded paint on the outsides of the preparation area. The identified areas were tacky to the touch and although degraded to the frame in several pinpoint areas, did not appear to flake off the frame. Per interview at 1:50 PM on 3/9/11, Pharmacist # 1 confirmed that the areas were indeed degraded.

Fletcher Allen Plan of Correction

Stainless steel cover plates were installed on the laminate hoods used for IV solution preparation on 3/30/2011. Inspections of hood surface integrity will be added to the bi-annual hood recertification process.

A-724 P.O.C Accepted ~ 4/20/11 - *OnleeTosh*

A 749 482.42(a)(1) INFECTION CONTROL OFFICER RESPONSIBILITIES

The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, hospital staff failed to adhere to aseptic technique during 2 applicable observations of treatment/care provision; failed to ensure consistent monitoring of temperatures and relative humidity was conducted and monitored in Central Sterile Processing; and failed to ensure equipment in disrepair was not used in the operating rooms. Findings include:

1. *Per observation of set up procedures for a hemodialysis machine on the Medical Intensive Care Unit (MICU) on 3/8/11 at 3:25 PM, the Hemodialysis Technician (HD) attached the blood chamber for the CRIT-LINE to the Optiflux dialyzer with the same gloves used to move the trash can closer to the dialysis machine. The contamination of the dialyzer/set up was immediately confirmed with the HD and the Director of Renal/Transplant Services. After the observation, the equipment was disposed of and a new set-up was initiated.*

2. *Per observation, on the afternoon of 3/8/11, Nurse #2 failed to maintain proper infection control and hand hygiene technique during a dressing change procedure. After sanitizing his/her hands and donning clean gloves, the nurse touched his/her face mask, adjusting the fit over the nose and contaminating the glove, and then proceeded to remove the dressing covering the catheter insertion site on the neck of Patient #40. During interview, immediately following the procedure, Nurse # stated s/he did not recall touching his/her mask during the process of changing the dressing. Per review the facility's policy titled Hemodialysis Vascular Access: Central Venous Catheter (CVC) Care and Maintenance, dated October 2010, identifies the procedure for CVC Site Assessment and Care which include; don mask and gown, perform hand hygiene and don gloves, proceed to open sterile supply packages and remove the dressing, '(be careful to avoid contaminating the insertion site)'.*

3. *During Environment of Care Safety Audits, which includes staff from the Infection Control department, surveillance of the Central Sterile Process (CSR): (the department within the hospital that processes, issues, and controls professional supplies and equipment, both sterile and non-sterile, for some or all patient-care areas of the facility) failed to identify the lack of policy and process for the ongoing monitoring of temperatures and relative humidity in all CSR locations. Per national standards developed by AAMI (Association for the Advancement of Medical Instrumentation) hospitals are expected to monitor and maintain temperatures and relative humidity within recommended levels in all locations associated with Central Sterile Reprocessing (CSR) to limit contamination, preparation & packing and sterile storage. Monitoring and maintaining temperatures and relative humidity at specific parameters is recommended to prevent microbial and bacterial growth in packaged sterilized material and*

instruments. Per Centers for Disease Control (CDC) and Health Care Infection Control Practice Advisory Committee (HICPAC) Guidelines for Environmental Infection Control in Health-Care Facilities 2003 states "... Relative humidity levels >60%, in addition to being perceived as uncomfortable, promote fungal growth .. " During a tour of CSR on 3/9/11 at 1:50 PM a review of the hospital's monitoring process for temperature and humidity control was reviewed. Per observations of a Dickson humidity and temperature chart recorder in the sterile stores area, the temperature reading was 69 degrees Fahrenheit (F) and the relative humidity was 15.2. (Per AAMI guidelines ST79 2006 3.3.65 relative humidity in sterile storage is not to exceed 70% and in other CSR locations humidity should be kept between 30-60 %. Optimal temperatures is 175 degrees F in sterile storage; 68 - 73 degree F in preparation & packing; and 60-65 degrees F in decontamination area). When asked how the relative humidity and temperature levels were monitored the Director of CSR confirmed the only process presently was for staff to remove the graft chart from the monitoring device weekly, replace with a new graft sheet and place the completed graft chart in a notebook. No daily monitoring and/or review policy existed to assess if relative humidity and temperature levels met recommended parameters in all 3 locations within CSR that have Dickson humidity and temperature monitoring devices. Recommend parameters were not made available to staff for monitoring temperatures and relative humidity nor was a process developed for notification if a problem was identified. In addition, the lack of monitoring and review of relative humidity and temperatures also was performed at the Fanny Allen outpatient surgical location. This deficient practice was also confirmed on 3/10/11 at 8:30 AM by the Director of CSR.

4. Staff in the peri-operative area failed to adhere to infection control standards when an operating room table extension with torn and cracked vinyl was not removed from use. On the morning of 3/9/11 while touring the operative suite area, staff were observed preparing an operating room for the next surgical case. Utilizing the table extension with several breaks in the integrity of the vinyl surface compromised effective disinfection of the surfaces. In an addition, 2 other operating rooms table extension were noted to be stored on the floor in the operating room. These observations were confirmed by the interim nurse manager for Surgical Services to be breaches in infection control practices and a potential compromise of patient safety.

Fletcher Allen Plan of Correction

The Fletcher Allen policies "RENL00074 and RENL009" were revised to clarify the section on aseptic technique. These revisions were completed by the Dialysis Assistant Nurse Manager and the Manager of Infection Prevention. The Assistant Nurse Manager will educate the acute dialysis unit staff on the revised policies and procedures by 4/26/2011. Fletcher Allen is participating in a CDC collaborative to reduce infections. The audit tool developed by this CDC collaborative will be used to monitor compliance with aseptic technique. The Infection Prevention team will perform aseptic technique audits during April 2011 and provide feedback to the Assistance Nurse Manager. In addition, the Assistance Nurse Manager will implement "peer" aseptic technique monitoring audits. The results will be reviewed monthly at staff meetings.

The policy entitled "Monitoring of Temperature and Relative Humidity in Central Reprocessing" was developed and implemented by the Central Sterile Reprocessing (CSR) Director on 3/11/2011. This policy outlines the ongoing monitoring, required documentation and required follow-up activity if the temperature and humidity exceed the acceptable ranges. CSR staff was educated to the policy by the Director of CSR on 4/1/2011. Compliance with the revised policy will be monitored weekly by the CSR Charge. Audits regarding compliance with the revised policy will be incorporated into Environmental Safety Rounds beginning 4/26/2011.

Vinyl Mattresses in Peri-operative Services were inspected by Managers and their designee on 3/31/2011. Mattresses in need of replacement were removed from service and replacements were ordered with an anticipated delivery date of 4/18/2011. The Peri-operative managers reviewed the importance of infection prevention using the appropriate policies. The importance of infection prevention and the role and responsibility to include mattress inspection and equipment handling was presented by the Nurse Manager /educator at the unit staff meeting on 4/14/2011. Peri-operative Managers will assess the integrity of mattresses and appropriate equipment handling in use in the Peri-operative setting as part of their daily rounding process

A 940 482.51 SURGICAL SERVICES

A-749-4/20/11
P.O.C. Accepted
J. Deet to SM

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

This CONDITION is not met as evidenced by: Based on observations, staff interview and record review the Condition of Participation: Surgical Services-was-not met as evidence by the hospitals failure to monitor temperature and humidity levels in the Central Sterile Processing locations; failure to ensure access to the operative and recovery area is limited to authorized individuals and failure to provide emergency lighting in out patient areas where surgical procedures are conducted. Findings include:

1. Per national standards developed by AAMI (Association for the Advancement of medical Instruments) hospitals are expected to monitor and maintain temperatures and relative humidity within recommended levels in all locations associated with Central Sterile Reprocessing (CSR) to include decontamination, preparation & packing and sterile storage. Monitoring and maintaining temperatures and relative humidity at specific parameters is recommended to prevent microbial and bacterial growth in packaged sterilized material and instruments. During a tour of CSR on 3/9/11 at 1:50 PM a review of the hospital's monitoring process for temperature and humidity control was reviewed. Per observations of a Dickson humidity and temperature chart recorder in the sterile stores area of CSR the temperature reading was 69 degrees Fahrenheit (F) and the relative humidity was 15.2. (Per AAMI guidelines ST79 2006 3.3.65 relative humidity in sterile storage is not to exceed 70% and in other CSR locations humidity should be kept between 30-60 %. Optimal temperatures is 75 degrees F in sterile storage; 68 - 73 degree F in preparation & packing; and 60-65 degrees F in decontamination area.) When asked how the relative humidity and temperature levels were monitored, the Director of CSR confirmed the only process presently was for staff to remove the graft chart from the monitoring device weekly, replace with a new graft sheet and place the completed graft chart in a notebook. No daily monitoring and/or review policy existed to assess if relative humidity and temperature levels met recommended parameters in all 3 locations within CSR that have Dickson humidity and temperature monitoring devices. Recommended parameters were not made available to staff for monitoring temperatures and relative humidity nor was a process developed for notification if a problem was identified. In addition, the lack of monitoring and review of relative humidity and temperatures also was noted to exist at the Fanny Allen outpatient surgical location. This deficient practice was also confirmed on 3/10/11 at 8:30 AM by the Director of CSR.

2. During a tour on the morning of 3/9/11 with the Director of Peri-Operative Services the McClure entrance to the peri-operative area was observed to be unsecured creating potential access to the operative suites and recovery areas by unauthorized individuals. Although all other entrances to the peri-operative area are secured requiring employee ID badge authorization to access the area, the McClure entrance is not equipped with a badge ID monitoring system. An unauthorized individual can press the automatic door opener, travel down a corridor where stretchers and equipment are stored and enter into the operative suites area which is also not secured. In addition, both the McClure peri-operative door entrance and the entrance leading directly into the operating suites are not distinctly marked either on the floor or doors warning unauthorized individuals are not permitted to enter. These observations were confirmed by the Director of Peri-Operative services at the time of the tour:

3. Per observation of one outpatient clinic on 3/11/11, it was observed that although there is a system to illuminate the hallways in case of a power outage, only flashlights and glow sticks are available to illuminate the procedure rooms in case of a power outage. Per review of billing codes for March 1, 2011 through March 10, 2011, surgical procedures are performed in the two procedure rooms at the outpatient clinic. Per interview on 3/11/11, at approximately 9:45 AM, one clinical staff person stated that if the lights go out "we have flashlights in the rooms". Per interview, a second clinical staff person stated that if the lights went out during a procedure, staff would "make sure the flashlights were on so they could finish the procedure".

Fletcher Allen Plan of Correction

The policy entitled "Monitoring of Temperature and Relative Humidity in Central Reprocessing" was developed and implemented by Central Sterile Reprocessing (CSR) Director on 3/11/2011. This policy outlines the ongoing monitoring, required documentation and required follow-up activity if the temperature and humidity exceed the acceptable ranges. CSR staff was educated to the policy by the Director of CSR on 4/1/2011. Compliance with the revised policy will be monitored weekly by the CSR Charge. Audits regarding compliance with the revised policy will be incorporated into Environmental Safety Rounds beginning 4/26/2011.

Regarding the security of the McClure Peri-operative door entrance, the Director of Security, Parking and Safety has identified a solution. Installation of an Operating Room door lock and door release system for this entrance is scheduled to occur on 5/1/2011. The Director of Facilities Management will ensure that appropriate signage distinctly marking the McClure Peri-operative door entrance and the entrance leading into the operative suites is installed by 4/7/2011.

An evaluation as to the appropriateness of installing additional battery pack lighting, has been conducted by the Vice President for Medical Group Operations. Based on the completed evaluation, the Vice President for Hospital Services will oversee the addition of lighting to identified areas. A purchase order for the lighting and installation was placed on 3/19/2011 and the work will be complete by 4/14/2011. Inspection, testing and maintenance shall be performed by Facilities Management in compliance with NFPA101.7.9.3. This will be scheduled via the Facilities Management work order system. To ensure the placement of appropriate emergency lighting, the evaluation as to the need for emergency lighting has been added to the facility design guidelines and site activation process.

4/20/11 Delect Intash P.O.C Accepted

A1005 482.52(b)(3) OUTPATIENT POST-ANESTHESIA EVALUATION
[The policies must ensure that the following are provided for each patient]

A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The post-anesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures, which have been approved by the medical staff and which reflect current standards of anesthesia care.

This STANDARD is not met as evidenced by: Based upon record review and interview, the facility failed to document complete post anesthesia-evaluations; A review of 7-patients who had received anesthesia services revealed documentation by the individual qualified to administer anesthesia did not contain qualitative elements that addressed their recovery from anesthesia and in 1 of 1 applicable anesthesia evaluations, the written evaluations were mostly identical. (Patient #28) Evidence includes the following:

1. Record review for Patient #28 revealed a procedure requiring general anesthesia was ordered initially twice a week on 2/12/11 and increased to three times a week on 3/1/11. On 2/18/11, the first procedure was conducted. The post anesthesia evaluation conducted on 2/18/11 read: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". There was no qualitative data that indicated what "acceptable mental status" was nor "stable respiratory function or the type of anesthesia that was administered. On 2/21/11, the post anesthesia evaluation read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, I postoperative events are documented below".

On-2/25/11, the post-anesthesia evaluation read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body

temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below".

On 3/2, 3/4, 3/7, 3/9/11, the post anesthesia evaluations all read as: "the patient has been evaluated, assessed and discharged from anesthesia care with stable cardiorespiratory function and acceptable mental status, pain management, body temperature, fluid balance, nausea/vomiting control and Aldrete score. Additional monitoring and assessment needs have been addresses. If present, postoperative events are documented below". During an interview with the Health Care Service Director in the afternoon of 3/9/11, the documentation of the post anesthesia evaluations were discussed. The "canned" language is a choice in the electronic system that the provider has an option to choose. The anesthesia providers discuss and confer with clinical staff in PACU (Post Anesthesia Care Unit) and use the clinical signs documented by PACU staff. If no issues, they choose from the drop down menu the canned language as noted above. It was confirmed that looking directly at the post anesthesia evaluations, clinical indicators are not present but the system could be changed so that all applicable clinical elements to measure anesthesia recovery could be included in their system.

Fletcher Allen Plan of Correction

The Chair of the Department of Anesthesia will ensure the inclusion of the following patient specific clinical information in the electronic health record (EHR): blood pressure, pulse, respirations, temperature, oxygen saturation, type of anesthesia administered, mental status and pain score. The Medical Director of Anesthesia will communicate the changes to the Department of Anesthesia by 4/26/2011. An RN from the Institute for Quality will conduct monthly chart audits to monitor compliance with completion of the post-anesthesia evaluation. Feedback regarding compliance will be forwarded to the Chair of the Department of Anesthesia for appropriate action.

A1005 - 4/20/11 P.B.C. *Q. O. O. J. T. O. S.*

A 1104 482.55(a)(3) EMERGENCY SERVICES POLICIES
[If emergency services are provided at the hospital--]

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff. This STANDARD is not met as evidenced by: Based on staff interview and record review the facility failed to establish policies and procedures governing the provision of medical care by Physician Assistant (PA) in the ED (Emergency Department). Findings include:

Per record review, Patient #55, who had been recently diagnosed with GBM (Glioblastoma multiforme, a type of brain cancer), was hospitalized for a period of 3 weeks duration for treatment of complex medical issues, including: Pneumocystis carinii pneumonia, septic shock, DVT (Deep Vein Thrombosis) of the left leg as well as bilateral Pulmonary Emboli (blockage of arteries in the lungs) and Atrial Fibrillation (condition related to heart rhythm). The patient received anticoagulant medication as part of their treatment, and was discharged from the hospital on 6/15/10. Patient #55 presented to the ED just 3 days later, on 6/18/10, complaining of left leg pain, and, despite the available information from the recent hospitalization regarding the patient's medical history, the PA did not consult with the supervising Attending physician and failed to conduct any diagnostic studies when assessing the patient's medical condition. Patient #55 was diagnosed, at that time, with Sciatica (related to irritation of the sciatic nerve) and discharged back to a SNF (Skilled Nursing Facility). Patient # returned to the ED, again, 3 days later, on 6/21/10, with ongoing pain, and the ED physician, who provided the patient's care at that time identified that the patient had a "complex medical hx (history) for GSM and chemo" and included lab and diagnostic imaging studies as part of the assessment. The lab studies identified a significant drop in blood levels requiring blood transfusion, and a CT of the pelvis revealed retroperitoneal bleed (bleeding internally into the membrane that lines the abdominal cavity in the area of the lower back), and the patient was subsequently readmitted to the hospital for treatment.

Per interview, at 9:50 AM on 3/10/11, the Medical Clinical Leader, responsible for the oversight of quality of care provided in the ED, stated that, although there is a supervising Attending Physician available in the ED at all times, there was no formal process in place for assuring ongoing/continuing assessment of the medical care provided by PAs, and no policy or guidelines that clearly defined when a PA would be required to consult the Attending physician regarding medical care of ED patients. The Clinical Leader stated there is an expectation that a PA will consult with

the Attending physician when a patient presents with a "complex" case, however that determination is left solely to the individual PA's judgment. S/he also stated that although there is an expectation that PAs will consult the Attending if they are considering use of advanced imaging studies, particularly CT or MRI, there is no policy or protocol to assure consistency of that practice. In addition, the Clinical Leader stated that the process for conducting ongoing assessment of medical care provided by PAs in the ED includes: a requirement to attend at least 50% of the monthly Quality Meetings where case review is conducted; and an informal process of review PA records, conducted by the Clinical Leader, on those PAs with whom he works, during clinical shifts that s/he is scheduled as a supervising Attending. S/he further stated that they are currently in the process of developing policies and procedures for assuring ongoing/continuing assessment of medical care provided by PAs to ED patients.

Fletcher Allen Plan of Correction

An Emergency Room Physician Assistant (PA) Scope of Practice and Delineation of Privileges document was updated on 3/24/2011 by the ED Medical Director to articulate attending oversight. Specifically, PA's are now required to present all triage level 3 patients to an Attending for consultation. The ED Medical Director updated the ED providers regarding the Scope of Practice changes on 3/24/2011. The Emergency Department "Ongoing Professional Practice Evaluation" (OPPE) process used to identify practice trends that impact the quality of care, has been updated to include PA evaluation criteria based on sample chart reviews. Criteria include appropriate diagnostic tests, completion of medical exam, documentation of pain at discharge, condition at discharge, final disposition and appropriateness of care are reviewed at the provider level. These criteria will be used for cases reviewed as part of the Emergency Department Quality Assurance process for cases that return within 72 hours of discharge.

A 1104. POC Accepted
DeDeeTash