



AGENCY OF HUMAN SERVICES
DEPARTMENT OF DISABILITIES, AGING AND INDEPENDENT LIVING

Division of Licensing and Protection
103 South Main Street, Ladd Hall
Waterbury VT 05671-2306
<http://www.dail.vermont.gov>
Voice/TTY (802) 241-2345
To Report Adult Abuse: (800) 564-1612
Fax (802) 241-2358

February 22, 2011

Dr. Melinda Estes, Administrator
Fletcher Allen Hospital Of Vermont
111 Colchester Ave
Burlington, VT 05401

Provider ID #: 470003

Dear Dr. Estes:

The Division of Licensing and Protection completed a complaint investigation at your facility on January 13, 2011. The purpose of the survey was to determine if your facility met the conditions of participation for Acute Care Hospitals found in 42 CFR Part 482.

Following the survey, your facility submitted a Plan of Corrections (POC) which was found to be acceptable on February 18, 2011.

Sincerely,

A handwritten signature in black ink that reads "Suzanne E. Leavitt RN, MS". The signature is written in a cursive style.

Suzanne Leavitt, RN, MS
Assistant Director

cc: Carol Muzzy, Regulatory Director

Enclosure



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

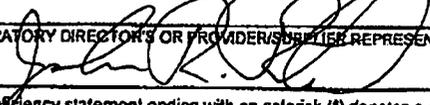
PRINTED: 01/28/2011
FORM APPROVED
OMB NO. 0938-0391

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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 01/13/2011 |
| NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HOSPITAL OF VERMONT | | | STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT 05401 | |
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| A 000 | INITIAL COMMENTS An unannounced on-site complaint investigation was conducted by the Division of Licensing and Protection on 12/20/10 - 12/21/10 and 1/11/11-1/13/11 as authorized by the Centers for Medicare and Medicaid Services, to review the Conditions of Participation for: Patient Rights, Quality Assurance, Medical Staff, Nursing Services, Medical Records, Surgical Services, Infection Control and Governing Body. The Conditions of Participation for: Governing Body and Medical Staff were not met. | A 000 | <i>Pl ampt 2. 18. 11 f. mcIntire / ST</i> | |
| 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 information obtained through staff interviews and record reviews, the hospital failed to ensure that accountability and responsibility for the qualifications, conduct, and oversight of an individual's clinical practice was reviewed by an appropriate privileging body or clinical department. | A 043 | <i>See ATTACHED PLAN OF Correction</i> | <i>2/8/2011</i> |
| A 049 | Refer to Tags: A-0049 and A- 0338 482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. | A 049 | <i>See ATTACHED PLAN OF Correction</i> | <i>2/8/2011</i> |

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

TITLE

(X6) DATE



Chief Medical Officer 2-8-11

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 049 Continued From page 1

A 049

This STANDARD is not met as evidenced by: Based upon staff interviews and record reviews, the hospital's Governing Body failed to ensure that the medical staff demonstrated accountability for the delineation of privileges for an individual who provides specialized care for patients who undergo cardiac procedures. Findings include:

Based on staff interview, it was confirmed that a job classification, a review of qualifications, and determination of responsibilities were not presented to the medical staff for credentialing, or to the Governing Body for approval, for an individual who has practiced as a member of a cardiac interventional team since 2003. For the past 7 years this individual, who is also an RN (RN #1), has not received a written evaluation, was not required to complete yearly mandatory competencies and has functioned without a job description in a role which the Governing Body was not aware existed.

Per interview on 1/12/11 at 11:00 AM, the Chief Medical Officer (CMO), who is responsible for the Institute of Quality as well as the Medical Staff, confirmed the Governing Body is "...extremely engaged in the credentialing process". The CMO also stated two members of the governing body attend every credentialing meeting, bringing all information back to the Governing Body for review and consideration prior to approval of any appointments or reappointments. The CMO confirmed the hospital medical staff are "...well aware" of the credentialing process and the Medical Bylaws. The Clinical Leader and/or Health Care Service Leader, also known as the Chair of a Department for each of the clinical services offered at the hospital, was identified by the CMO as the responsible person to ensure

See ATTACHED
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A 049

Continued From page 2

staff within their departments are privileged and/or have medical staff membership. At the time of this interview, the CMO stated the Governing Body was not aware of the issues related to RN #1, stating "...we missed this".

Per interview on 1/12/11 at 10:05 AM, the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but "...a little unusual because s/he's not a provider, not a physician and not an advanced practice nurse". The Chief of Cardiology also stated "If we did not have [RN #1] we would need to have 2 Electrophysiologists... due to the complex ablations which require 2 people to work very closely in tandem with each other". However, despite the lack of credentialing, this individual was provided the opportunity to perform and assist the attending physician in highly technical interventional cardiac catheter ablation for atrial fibrillation (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "...was not getting traditional oversight" for the clinical services s/he was specifically providing. In relation to the Governing Body's approval process and accountability of the medical staff to request a review for privileging RN #1, the Chief of Cardiology stated "...it had fallen within the cracks...". Per review, the Medical Staff Rules and Regulations, adopted 12/21/10, state "Health Care Service Leaders are responsible for ensuring that all members of the Medical Staff assigned to their service are subject to ongoing professional practice evaluations".

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A 049 Continued From page 3

Per interview on 1/12/11 at 8:55 AM, the Manager of Medical Staff Operations (who is designated by the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as an "Allied Health Care Professional" (referencing Article IX of the Medical Staff Bylaws revisions approved/adopted 12/21/10). When informed RN #1 was not hired by the hospital in 2003, but continues to provide patient care as a member of the interventional cardiac catheter ablation team, the Manager acknowledged "...thus lies the problem". The process for credentialing involves several steps including a review of the application, in accordance with the Medical Staff Bylaws, before a professional is considered for employment and eventual recommendation to the Governing Body for credentialing and appointment. It was also confirmed by the Manager of the Medical Staff Operations that because RN #1 had not been appropriately credentialed, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process, every two years, as well as through a mid cycle evaluation to assure each appointee is meeting the minimal job requirements.

When a credential file was requested for RN #1, surveyors were provided with a Faculty Evaluation file from an affiliated University through which the hospital has an agreement for educational programs. RN #1's most recent reappointment (dated 3/1/2010) was as a Research Associate. RN #1 stated in the Faculty reappointment application that his/her responsibilities included teaching, research and services professionally related: "Involved in mapping and ablating complex atrial and ventricular arrhythmias.

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| A 049 | <p>Continued From page 4</p> <p>Assisting the faculty Electrophysiologists extends the capability of the service. If I were not present then 2 Electrophysiologists would be required for each procedure". In addition, when RN #1 was first being considered for the role s/he is presently functioning in, the Director of Cardiac Electrophysiologists stated in a letter to the Chief of Cardiology, dated May/2003 " [His/her] participation in clinical EP (electrophysiology) procedures will be under the direct supervision of an EP faculty with credentials to perform EP procedures". No credentialing was ever brought forth, at that time or in the 7 years since, to the Medical Staff, nor was a request for a review of the RN's eligibility brought to the Governing Body for review as referenced in the Medical Staff Bylaws Article IX 9.1</p> <p>Per interview on 1/13/11 at 2:54 PM, the Director of Cardiac Electrophysiology confirmed RN #1's title was Research Associate and is a "Primary assist in ablation procedures where (the RN) performs essentially every aspect of the procedure. (RN #1) performs ablations". The Director further stated RN#1 would be accountable to the Director who is then accountable to the Chief of Cardiology. However the Director added " I am not sure that is the way it is; it isn't in writing; it's just the way I understood it to be."</p> | A 049 | <p>SEE ATTACHED PLAN of Correction 2/9/2011</p> | |
| A 118 | <p>482.13(a)(2) PATIENT RIGHTS: GRIEVANCES</p> <p>The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, hospital</p> | A 118 | <p>See ATTACHED PLAN of Correction 2/18/2011</p> | |

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| A 118 | <p>Continued From page 5</p> <p>staff failed to implement the Grievance policy in response to an unresolved patient complaint for Patient #1. Findings include:</p> <p>Per record review, during an outpatient physician visit following a clinical procedure performed at the hospital's Cardiac Catheter Lab, Patient #1 had expressed concerns to the participating physician (Physician #1), regarding care and services provided during the procedure. The medical record revealed information that indicated that although Physician #1 had attempted to address the patient's concerns, s/he was aware that the patient was clearly not satisfied with the physician's response and attempt to resolve the issues identified. Despite the knowledge that s/he was unable to resolve the patient's complaint, there was no evidence that Physician #1 had referred the complaint on to Patient/Family Advocacy for further review, in accordance with the facility's policy. The policy, titled Customer Feedback Policy, stated under the Complaints section: 3. Staff persons receiving the complaint shall: "Refer complaints...if the staff person does not have the knowledge or authority to resolve the complaint or if the staff person is unable to resolve the complaint to the complainant's satisfaction."</p> <p>During interview, at 9:56 AM on 1/13/11, the Manager of Patient/Family Advocacy confirmed that the complaint voiced to Physician #1 had not been referred to their department.</p> <p>During a telephone interview at 2:54 PM on 1/13/11, Physician #1 confirmed that Patient #1 had not been satisfied with his/her response to the patient's complaints, and further confirmed that s/he had not referred the complaint to</p> | A 118 | <p>See ATTACHED PLAN of Correction 2/18/2011</p> |

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| A 118 | Continued From page 6 Patient/Family Advocacy, acknowledging that, "...it never crossed my mind" but "...that's a good idea." | A 118 | | |
| A 276 | 482.21(b)(2)(ii) QAPI IDENTIFY IMPROVEMENT | A 276 | | |

[The hospital must use the data collected to—]

(ii) Identify opportunities for improvement and changes that will lead to improvement.

This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to identify a significant quality deficient practice involving the ongoing clinical practice of an individual for whom there was no appropriately defined accountability and responsibility for the delineation of that clinical practice. Findings include:

Based on information obtained through staff interviews and record reviews, there was an ongoing failure over a 7 year period from 2003 through 1/13/11, to identify the lack of accountability and responsibility for the conduct and oversight of the clinical practice of an individual (RN #1) who held a current RN license and who performed specialized clinical services for patients in the Cardiac Cath Lab. Although RN #1 began to participate in clinical practice in 2003 with no defined job classification, no review of qualifications or determination of to whom s/he would be accountable to for their practice, the hospital failed to identify these issues. In addition, although RN #1 continues, to date, to participate in the same clinical role as a member of a cardiac interventional team, the facility has continuously failed to identify and recognize that for the past 7 years this individual has not received a written evaluation, was not required to complete yearly

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| A 276 | <p>Continued From page 7</p> <p>mandatory competencies and has functioned without a job description in a role which the Governing Body was not aware existed.</p> <p>The Nurse Manager for Cath and Invasive Cardiology during interview on the afternoon of 12/20/10, stated RN #1 was not a hospital employee and did not fall under nursing purview for oversight of their clinical practice, but was, instead, under the direct supervision of one of the cardiologists. Per interview on 1/11/11 at 2:25 PM the VP of Nursing Operations stated that the Nurse Manager for Cath and Invasive Cardiology had recently started to look at RN #1's role from an RN scope of practice and found it was indeed different than what the nurses in the cardiac lab were doing. The VP of Nursing Operations further stated that it was his/her understanding that RN #1 was only involved in the technical aspect of the procedure; not performing nursing duties; but only performing those aspects of ablation that the VP of Nursing Operations had, inaccurately, assumed RN #1 had been credentialed to perform by the Medical Staff.</p> <p>Per interview on 1/12/11 at 10:05 AM the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but "...a little unusual because [RN #1 is] not a provider; not a physician and not an advanced practice nurse". However, despite the lack of credentialing, this individual was provided the opportunity and responsibility to perform and assist the attending physician in highly technical interventional cardiac catheter ablations (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "...was not</p> | A 276 | <p>SEG ATTACHED</p> <p>PLAN OF Correction</p> <p>2/8/2011</p> |

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| A 276 | Continued From page 8 getting traditional oversight" for the clinical services h/she was specifically providing. In relation to the Governing Body's approval process and accountability of the medical staff to request a review for privileging for RN #1, the Chief of Cardiology stated "...it had fallen within the cracks...". Per interview on 1/12/11 at 8:55 AM, the Manager of Medical Staff Operations (who is designated by the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as a "Allied Health Care professional" (referencing Article IX of the Medical Staff Bylaws revisions approved/adopted 12/21/10). S/he also confirmed that because RN #1 had not been appropriately credentialed, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process, every two years, as well as through a mid cycle evaluation to assure each appointee is meeting the minimal job requirements. | A 276 | | | |
| A 338 | 482.22 MEDICAL STAFF The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. This CONDITION is not met as evidenced by: Based upon staff interviews and record reviews, the Condition of Participation: Medical Staff was not met as evidenced by the medical staff's failure to implement the Medical Bylaws for the delineation of privileges for an individual who provides specialized care for patients who undergo invasive cardiac procedures. Findings | A 338 | | | |

SEE ATTACHED

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| A 338 | <p>Continued From page 9 include:</p> <p>Based on staff interview, it was confirmed that a job classification, a review of qualifications, and a determination of responsibilities were not presented to the medical staff for credentialing, or to the Governing Body for approval for an individual (RN #1), who has practiced as a member of a cardiac interventional team since 2003. For the past 7 years, RN #1 has not received a written evaluation, was not required to complete yearly mandatory competencies and has functioned without a job description. In addition, the Governing Body was not aware that the role existed.</p> <p>Per interview on 1/12/11 at 11:00 AM, the Chief Medical Officer (CMO) who is responsible for the Institute of Quality, confirmed that the Medical Staff did not initiate the process for delineation of clinical privileges for RN #1 in accordance with the credentialing process identified in their Bylaws. The CMO stated the Governing Body is "...extremely engaged in the credentialing process", and that two members of the Governing Body attend every credentialing meeting bringing all information back to the Governing Body for review and consideration prior to approval of any appointments or reappointments. The CMO confirmed the medical staff are "...well aware" of the credentialing process and the Medical Bylaws. The Health Care Service Leader, also known as the Chair of a Department for each of the clinical services offered at the hospital, was identified by the CMO as the responsible person to ensure staff within their departments are privileged and/or have medical staff membership. At the time of this interview, the CMO stated the Governing Body was not aware of the issues</p> | A 338 | <p>SEE ATTACHED PLAN of Correction</p> <p>2/8/2011</p> |

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| NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HOSPITAL OF VERMONT | | STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT 05401 | |
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| A 338 | <p>Continued From page 10</p> <p>related to RN #1, stating "...we missed this" and "This is surprising to me".</p> <p>Per interview on 1/12/11 at 10:05 AM the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but was not a provider, not a physician and not an advanced practice nurse. However, despite the lack of credentialing, this individual was provided the opportunity and responsibility to perform and assist the attending physician in highly technical interventional cardiac catheter ablations (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "...was not getting traditional oversight" for the clinical services h/she was specifically providing. In relation to the Governing Body's approval process and accountability of the medical staff to request a review for privileging for RN #1, the Chief of Cardiology stated "...it had fallen within the cracks...".</p> <p>Per interview on 1/12/11 at 8:55 AM, the Manager of Medical Staff Operations (who is designated by the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as a "Allied Health Care Professional" (referencing Article IX of the Medical Staff Bylaws revisions approved/adopted 12/21/10). When informed RN #1 was not hired by the hospital in 2003, but continues to provide patient care as a member of the interventional cardiac catheter ablation team, the Manager acknowledged "...thus lies the problem". The process for credentialing involves several steps, including a</p> | A 338 | <p>SEE ATTACHED Plan of Correction</p> <p>2/8/2011</p> |

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| A 338 | Continued From page 11 review of the application in accordance with the Medical Staff Bylaws before a professional is considered for employment and eventual recommendation for credentialing and appointment. It was also confirmed by the Manager of Medical Staff Operations that because RN #1 had not been appropriately credentialed, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process every two years, as well as through a mid cycle evaluation ensuring the minimal job requirements were met. | A 338 | SEE ATTACHED PLAN OF CORRECTION | 2/18/2011 |
| A 386 | 482.23(a) ORGANIZATION OF NURSING SERVICES The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. This STANDARD is not met as evidenced by: Based on staff interviews and record review, the facility failed to delineate responsibility and accountability for the clinical nursing practice of an individual who held a current RN (Registered Nurse) license and who performed specialized clinical services for patients in the Cardiac Cath Lab. Findings include: Per interview at 1:33 PM on 12/20/10, RN #1 stated that s/he had worked in the Cardiac Cath Lab assisting in the performance of cardiac ablation procedures since 2003. The RN stated | A 386 | SEE ATTACHED PLAN OF CORRECTION | 2/17/2011 |

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| A 386 | <p>Continued From page 12</p> <p>that cardiac ablations are performed by a team of individuals including a physician, nurses and at times an anesthesiologist, who is present when the patient is undergoing an Atrial Fibrillation ablation.. S/he further stated that the role in which s/he worked was similar to that of "a first assist in surgery" and it takes a team to do the procedure. The nurse further stated one team member manipulates the catheter, another member is running the stimulator and another is creating the 3-D image on the computer. RN #1 confirmed he is the only nurse involved in this specific procedure.</p> <p>The Nurse Manager for Cath and Invasive Cardiology stated, during interview on the afternoon of 12/20/10, that RN #1's was not a hospital employee and did not fall under nursing purview for oversight of their clinical practice, but was, instead, under the direct supervision of one of the cardiologists.</p> <p>Per interview on 1/11/11 at 2:25 PM, the VP of Nursing Operations stated that the Nurse Manager for Cath and Invasive Cardiology had recently started to look at RN #1's role from an RN scope of practice and found it was different than what the nurses in the cardiac lab were doing. S/he further stated that it was his/her understanding that RN #1 was only involved in the technical aspect of the procedure; not performing nursing duties; but only performing those aspects of ablation that the VP of Nursing Operations had, inaccurately, assumed RN #1 had been credentialed to perform by the Medical Staff.</p> <p>Per interview at 2:19 PM on 1/11/11, the Director for Clinical Services and Training stated that s/he had been employed in the role of Supervisor of the Cardiology Practice in 2003 at the time that</p> | A 386 | <p>SEE ATTACHED PLAN OF CORRECTION</p> <p>2/17 2011</p> |

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| A 386 | Continued From page 13 RN #1 was being considered for a position in the Cardiac Catheter Lab. S/he stated that there had been discussion, at that time, of where RN #1 would fit, as there was a very clear research component to his/her role and eventually s/he was placed in a research associate role with the affiliated university. | A 386 | | |
| 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, interview and record review, the infection control department failed to ensure the maintenance of a sanitary environment on McClure I in the Cardiac Catheterization/ Ablation special procedure room. Findings include: During a tour of the Cardiac Catheterization/ Ablation special procedure room on 1/12/11 at 2:10 PM, the floor was soiled with debris and a reddish brown stain of unknown origin was noted on the base of a monitor stand positioned beside the procedure table. The nurse manager for cardiac catheterization and invasive cardiology stated, at that time, that nursing staff is responsible for cleaning the room in between cases, and at the end of each day dedicated housekeeping staff would provide daily terminal care of the room in the evening. A follow up tour of the same room was conducted on 1/13/11 at 8:17 AM, prior to the first scheduled procedure of the day. Despite the fact that Nurse #2, present | A 749 | SEE ATTACHED PLAN OF CORRECTION | 2/18 2011 |

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| A 749 | <p>Continued From page 14</p> <p>during the morning tour, confirmed that housekeeping had been in the room because the trash had been emptied, the floor was still soiled and there was debris and a build up of grime around the columns supporting the procedure table. The rest of the floor still had debris including packing stickers and stains, and there was a layer of dust surrounding all 4 sides of a ridge on the gas column where the anesthesia equipment is stored and utilized. In addition, the stain on the base of the monitor equipment stand, initially noted during tour on the afternoon of 1/12/11, remained. When surveyors asked to have the base of the stand cleaned, the nurse educator for the Cardiac Cath Lab who was present during the observations, failed to don gloves and, using a disinfectant wipe towel, cleaned the stain from the stand with bare hands. It was agreed the stain was either Betadine solution or blood.</p> <p>Also observed during the morning tour, there were cables attached to cardiac mapping equipment, used during the ablation procedure, that were noted to be stained with dried blood. The nurse acknowledged it is the responsibility of the nursing staff to clean the cables after each procedure and commented that "...the cables do not touch the patients..." However, staff who handle the cables could then conceivably touch the patient and other environmental surfaces within the room, potentially contaminating everything touched.</p> <p>The Training and Development Supervisor for Environmental Services confirmed on 1/13/11 at 8:40 AM, that the room required deep cleaning and what was observed on the floors especially around the special procedure table had been</p> | A 749 | <p>SEE ATTACHED PLAN OF CORRECTION</p> | 2/18 2011 |

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| A 749 | Continued From page 15 there for "...definitely more than one day". Per interview, on 1/13/11 at 12:27 PM, the Infection Control Manager confirmed Environment of Care safety audits are conducted throughout the hospital, twice yearly, and that the most recent inspection/audit of the Cardiac Catheterization/Ablation special procedure room was completed on 12/2/10. When informed of the observations made earlier in the day, the comment by one of the nurses in the Cath lab regarding blood found on cables and the failure of another nurse to wear gloves when cleaning unknown substance on an environmental surface, the Infection Control Manager stated it was "...concerning". Reference: CDC/HICPAC Guidelines for the Disinfection and Sterilization in Healthcare Facilities 2008/Disinfection of Healthcare Equipment. | A 749 | SEE ATTACHED PLAN of CORRECTION 2/18 2011 |

PLAN OF CORRECTION

A 000 INITIAL COMMENTS

An unannounced on-site complaint investigation was conducted by the Division of Licensing and Protection on 12/20/10 – 12/12/2010 and 1/11/11 – 1/13/11 as authorized by the Centers for Medicare and Medicaid Services, to review the Conditions of Participation for: Patient Rights, Quality Assurance, Medical Staff, Nursing Services, Medical Records, Surgical Services, Infection Control and Governing Body. The Conditions of Participation for Governing Body and Medical Staff were not met.

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 information obtained through staff interviews and record reviews, the hospital failed to ensure that accountability and responsibility for the qualifications, conduct, and oversight of an individual's clinical practice was reviewed by an appropriate privileging body or clinical department.*

Plan of Action

We are responding to this condition-level deficiency through the Plans of Action below. Our Plans of Action are incorporated here by reference to the standard level deficiencies. We believe that our specific Plans of Action fully ensure accountability and responsibility for the qualifications, conduct and oversight of clinical practice.

*Account 2.18.11
F. M. Smith*

Refer to Tags: A-0049 and A- 0338

A 049 432.12(a)(5) MEDICAL STAFF ACCOUNTABILITY

(The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

A 049

This STANDARD is not met as evidenced by. Based upon staff interviews and record reviews, the hospital's Governing Body failed to ensure that the medical staff demonstrated accountability for the delineation of privileges for an individual who provides specialized care for patients who undergo cardiac procedures. Findings include:

Based on staff interview, it was confirmed that a job classification, a review of qualifications, and determination of responsibilities were not presented to the medical staff for credentialing, or to the Governing Body for approval, for an individual who has practiced as a member of a cardiac interventional team since 2003. For the past 7 years this individual, who is also an RN (RN #1), has not received a written evaluation, was not required to complete yearly mandatory competencies and has functioned without a job description in a role which the Governing Body was not aware existed.

Per interview on 1/12/2011 at 11:00 AM, the Chief Medical Officer (CMO), who is responsible for the Institute of Quality as well as the Medical Staff, confirmed the Governing Body is "extremely engaged in the credentialing process.". The CMO also stated two members of the governing body attend every credentialing meeting, bringing all information back to the Governing Body for review and consideration prior to approval of any appointments or reappointments. The CMO confirmed the hospital medical staff are "well aware" of the credentialing process and the Medical Bylaws. The Clinical Leader and/or Health Care Service Leader, also known as the Chair of a Department for each of the clinical services offered at the hospital, was identified by the CMO as the responsible person to ensure staff within their departments are privileged and/or have medical staff membership. At the time of this interview, the CMO stated the Governing Body was not aware of the issues related to RN #1, stating "we missed this."

Per interview on 1/12/11 at 10:05 AM. the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but "...a little unusual because s/he's not a provider; not a physician and not an advanced practice nurse". The Chief of Cardiology also stated "If we did not have [RN #1] we would need to have 2 Electrophysiologists due to the complex ablations which require 2 people to work very closely in tandem with each other". However, despite the lack of credentialing, this individual was provided the opportunity to perform and assist the attending physician in highly technical interventional cardiac catheter ablation for atrial fibrillation (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "was not getting traditional oversight' for the clinical services s/he was specifically providing. In relation to the

Governing Body's approval process and accountability of the medical staff to request a review for privileging RN #1, the Chief of Cardiology stated "...it had fallen within the cracks". Per review, the Medical Staff Rules and Regulations, adopted 12/21/10, state "Health Care Service Leaders are responsible for ensuring that all members of the Medical Staff assigned to their service are subject to ongoing professional practice evaluations".

Per interview on 1/12/11 at 8:55 AM, the Manager of Medical Staff Operations (who is designated by the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as an "Allied Health Care Professional" (referencing Article IX of the Medical Staff Bylaws revisions approved/adopted 12/21/10). When informed RN #1 was not hired by the hospital in 2003, but continues to provide patient care as a member of the interventional cardiac catheter ablation team, the Manager acknowledged "thus lies the problem". The process for credentialing involves several steps including a review of the application, in accordance with the Medical Staff Bylaws, before a professional is considered for employment and eventual recommendation to the Governing Body for credentialing and appointment. it was also confirmed by the Manager of the Medical Staff Operations that because RN #1 had not been appropriately credentialled, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process, every two years, as well as through a mid cycle evaluation to assure each appointee is meeting the minimal job requirements.

When a credential file was requested for RN #1, surveyors were provided with a Faculty Evaluation file from an affiliated University through which the hospital has an agreement for educational programs. RN #1's most recent reappointment (dated 3/1/2010) was as a Research Associate. RN #1 stated in the Faculty reappointment application that his/her responsibilities included teaching, research and services professionally related: "Involved in mapping and ablating complex atrial and ventricular arrhythmias

Assisting the faculty Electrophysiologists extends the capability of the service. "If I were not present then 2 Electrophysiologists would be required for each procedure". In addition, when RN #1 was first being considered for the role s/he is presently, functioning in, the Director of Cardiac Electrophysiologists stated in a letter to the Chief of cardiology, dated May 1, 2003 [His/her] participation in clinical EP (electrophysiology) procedures will be under the direct supervision of an EP faculty with credentials to perform EP procedures". No credentialing was ever brought forth, at that time or in the 7 years since, to the Medical Staff, nor was a request for a review of the RN's eligibility brought to the Governing Body for review as referenced in the Medical Staff Bylaws Article IX 9.1

Per interview on 1/13/11 at 2:54 PM, the Director of Cardiac Electrophysiology confirmed RN #1's title was Research Associate and is a "Primary assist in ablation procedures where (the RN) performs essentially every aspect of the procedure. (RN #1) performs ablations". The Director further stated RN#1 would be accountable to the Director who is then accountable to the Chief of Cardiology. However the Director added "I am not sure that is the way it is; it isn't in writing: it's just the way I understood it to be."

Plan of Action

- The RN identified through the survey process was noted as being an employee of the University of Vermont at the time of the survey and therefore did not go through the Fletcher Allen on boarding process. Fletcher Allen has two established processes for on boarding of staff that provide organizational oversight for clinical practice. These processes were reviewed by the Vice President for Nursing, Vice President for Human Resources, the Vice President for the James Jeffords Institute for Quality and the Chief Medical Officer to ensure compliance with the CMS COP. Specifically reviewed were the Human Resources on boarding and annual evaluation process and the Medical Staff credentialing process. In addition these two processes were reviewed at the 12/18/2011 Vice President meeting and later was reinforced at the 2/1/2011 Vice President meeting.

- The Vice Presidents communicated the expectation to their Directors that all clinical staff in their respective areas have gone through either the Human Resource process or the Medical Staff credentialing process. Each Director conducted an inventory in their areas to validate that clinical staff have gone through either the Human Resource or the Medical Staff credentialing process as appropriate to their role. This inventory was completed on 2/8/2011.
- The Vice President of Nursing and the Medical Director of Cardiology are currently working with the Vermont Board of Nursing to establish a "Scope of Practice" document for the referenced RN cardiology position with in Fletcher Allen Health Care. A "Request for Position Statement" document was filed on 1/24/2011 with the Vermont Board of Nursing. Once finalized and approved, the position will go through the appropriate Fletcher Allen process. The University of Vermont employee identified through the survey has been removed from the clinical setting and is performing research duties at the University until such time as the scope of practice has been approved and the appropriate Fletcher Allen on-boarding has been completed.
- The Chief Medical Officer reviewed Fletcher Allen leadership's responsibility and oversight function for ensuring qualifications, conduct, and oversight of an individual's clinical practice at the Strategic Management Committee meeting on 2/3/2011. This committee is comprised of Health Care Service Physician Leaders and Senior Leadership, to include the Chief Executive Officer. Specifically highlighted was the expectation that all clinical staff have completed the Human Resource or the Medical Staff credentialing on boarding and performance review process
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the medical staff at the Medical Executive Committee meeting on 2/3/2011.
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the with the Medical Directors at the Medical Director meeting on 2/8/2011.
- The Chief Medical Officer communicated electronically to all Medical Staff on 2/07/2011, the expectation that all clinical staff in their areas have gone through either the Human Resource process or the Medical Staff credentialing process.
- The Chief Medical Officer reviewed Fletcher Allen leadership's responsibility and oversight function for ensuring qualifications, conduct, and oversight of an individual's clinical practice with the Governing Body at the Board of Trustee meeting on 2/8/011.

Performance Improvement

- Each Manager, on an ongoing basis, will verify that clinical staff in their areas have gone through either the Human Resource or the Medical Staff credentialing process as appropriate to their role.
- Each Director, at the time of the annual performance evaluations will conduct an inventory in their areas to ensure that all clinical staff has gone through either the Human Resource process or the Medical Staff credentialing process as appropriate to their role. Results will be shared with the Vice Presidents for any required action.

POC aamt 2.18.11 f. mcgilton

A 118:482.13(a)(2) PATIENT RIGHTS: GRIEVANCES

The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

This STANDARD is not met as evidenced by:

Based on interview and record review, hospital staff failed to implement the Grievance policy in response to an unresolved patient complaint for Patient #1. Findings include:

Per record review, during an outpatient physician visit following a clinical procedure performed at the hospital's Cardiac Catheter Lab. Patient #1 had expressed concerns to the participating physician (Physician #1), regarding care and services provided during the procedure. The medical record revealed information that indicated that although Physician #1 had attempted to address the patient's concerns, s/he was aware that the patient was clearly not satisfied with the physician's response and attempt to resolve the issues identified. Despite the knowledge that s/he was unable to resolve the patient's complaint, there was no evidence that Physician #1 had referred the complaint on to Patient/Family Advocacy for further review, in accordance with the facility's policy. The policy, titled Customer Feedback Policy, stated under the, Complaints section: 3. Staff persons receiving the complaint shall: "Refer complaints.. if the staff person does not have the knowledge or authority to resolve the complaint or if the staff person is unable to resolve the complaint to the complainant's satisfaction."

During interview, at 9:56 AM on 1/13/11, the Manager of Patient/Family Advocacy confirmed that the complaint voiced to Physician #1 had not been referred to their department.

During a telephone interview at 2:54 PM on 1/13/11, Physician #1 confirmed that Patient #1 had not been satisfied with his/her response to the patient's complaints, and further confirmed that s/he had not referred the complaint to Patient & Family Advocacy, acknowledging that it never crossed my mind" but" that's a good idea

Plan of Action

- The Vice President for the James Jeffords Institute for Quality reviewed the Fletcher Allen "Customer Feedback" policy at the 2/1/2011 Vice President meeting. Specifically highlighted was the expectation that if a staff person is unable to resolve a complaint to the complainant's satisfaction referrals can be made to the following: Supervisor or Department Head, Office of Patient and Family Advocacy or the Risk Management Department.
- The Vice Presidents have communicated the expectations noted in the Fletcher Allen "Customer Feedback" policy with their leadership teams. The policy will be shared again with staff via electronic communications and or staff meetings. This process will be completed by 2/18/2011.
- On 2/3/2011 the Chief Medical Officer presented the expectations outlined in the Fletcher Allen "Customer Feedback" policy to the Medical Executive Committee membership. Specifically discussed was the expectation that if a staff person is unable to resolve the complaint to the complainant's satisfaction referrals can be made to the following: Supervisor or Department Head, Office of Patient and Family Advocacy or Risk Management Department.
- On 2/3/2011 the Chief Medical Officer presented the expectations outlined in the Fletcher Allen "Customer Feedback" policy to the Strategic Management Committee membership. Specifically discussed was the expectation that if a staff person is unable to resolve the complaint to the complainant's satisfaction referrals can be made to the following: Supervisor or Department Head, Office of Patient and Family Advocacy or Risk Management Department.
- On 2/8/2011 the Chief Medical Officer presented the expectations outlined in the Fletcher Allen "Customer Feedback" policy to the Medical Directors meeting. Specifically discussed will be the expectation that if a staff person is unable to resolve the complaint to the complainant's satisfaction referrals can be made to the following: Supervisor or Department Head, Office of Patient and Family Advocacy or Risk Management Department.
- The Chief Medical Officer communicated electronically to all Medical Staff on 2/07/2011, the expectations outlined in the Fletcher Allen "Customer Feedback" policy to the Medical Directors meeting. Specially discussed will be the

expectation that if a staff person is unable to resolve the complaint to the complainant's satisfaction referrals can be made to the following: Supervisor or Department Head, Office of Patient and Family Advocacy or Risk Management Department

Performance Improvement

- Individual cases will be reviewed as part of the weekly Safety Adjudication Committee meeting to identify educational opportunities regarding Fletcher Allen "Customer Feedback" policy. The Safety Adjudication Committee is comprised of the Chief Medical Officer, the Vice President of the Institute for Quality, the Vice President of Nursing, the Director of Risk Management, the Manager of the Office of Patient and Family Advocacy, the Director of Patient Safety and the Director of Regulatory Readiness.

POC accepted 2-18-11

F. McIntyre

A 276. 482.21 (b)(2)(ii) QAPI IDENTIFY IMPROVEMENT

The hospital must use the data collected to-1

(ii) Identify opportunities for improvement and changes that will lead to improvement.

This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to identify a significant quality deficient practice involving the ongoing clinical practice of an individual for whom there was no appropriately defined accountability and responsibility for the delineation of that clinical practice. Findings include:

Based on information obtained through staff interviews and record reviews, there was an ongoing failure over a 7 year period from 2003 through 1/13/11, to identify the lack of accountability and responsibility for the conduct and oversight of the clinical practice of an individual (RN #1) who held a current RN license and who performed specialized clinical services for patients in the Cardiac Cath Lab. Although RN #1 began to participate in clinical practice in 2003 with no defined job classification, no review of qualifications or determination of to whom s/he would be accountable to for their practice, the hospital failed to identify these issues. In addition, although RN #1 continues, to date, to participate in the same clinical role as a member of a cardiac interventional team, the facility has continuously failed to identify and recognize that for the past 7 years this individual has not received a written evaluation, was not required to complete yearly mandatory competencies and has functioned without a job description in a role which the Governing Body was not aware existed.

The Nurse Manager for Cath and Invasive- Cardiology during interview on the afternoon of 12/20/10, stated RN #1 was not a hospital employee and did not fall under nursing purview for oversight of their clinical practice, but was, instead, under the direct supervision of one of the cardiologists. Per interview on 1/11/11 at 2:25 PM the VP of Nursing Operations stated that the Nurse Manager for Cath and Invasive Cardiology had recently started to look at RN #1's role from an RN scope of practice and found it was indeed different than what the nurses in the cardiac lab were doing. The VP of Nursing Operations further stated that it was his/her understanding that RN #1 was only involved in the technical aspect of the procedure; not performing nursing duties; but only performing those aspects of ablation that the VP of Nursing Operations had, inaccurately, assumed RN #1 had been credentialed to perform by the Medical Staff. Per interview on 1/12/11 at 10:05 AM the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but "...a little unusual because [RN #1 is] not a provider; not a physician and not an advanced practice nurse". However, despite the lack of credentialing, this individual was provided the opportunity and responsibility to perform and assist the attending physician in highly technical interventional cardiac catheter ablations (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "...was not getting traditional oversight' for the clinical services h/she was specifically providing. In relation to the Governing Body's approval process, and accountability of the medical staff to request a review for privileging for RN #1, the Chief of Cardiology stated"... it had fallen within the cracks".

Per interview on 11/12/2011 at 8:55 AM, the Manager; of Medical Staff Operations (who is designated by: 'the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as a "Allied Health Care professional" (referencing Article LX of the Medical Staff Bylaws revisions approved/adopted 12/2011). S/he also confirmed that because RN #1 had not been appropriately credentialed, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process, every two years, as well as through a mid cycle evaluation to assure each appointee is meeting the minimal job requirements.

Plan of Action

- The RN identified through the survey process was noted as being an employee of the University of Vermont at the time of the survey and therefore did not go through the Fletcher Allen on boarding process. Fletcher Allen has two established processes for on boarding of staff that that provide organizational oversight for clinical practice. These processes were reviewed by the Vice President for Nursing, Vice President for Human Resources, the Vice President for the James Jeffords Institute for Quality and the Chief Medical Officer to ensure compliance with the CMS COP. Specifically reviewed were the Human Resources on boarding and annual evaluation process and the Medical Staff credentialing process. In addition, these two processes were reviewed at the 12/18/2011 Vice President meeting and later was reinforced at the 2/1/2011 Vice President meeting.

1/18/2011
Per VC
C. [unclear] 2/16/11
S.E. [unclear]

- The Vice Presidents communicated the expectation to their Directors that all clinical staff in their respective areas have gone through either the Human Resource process or the Medical Staff credentialing process. Each Director conducted an inventory in their areas to validate that clinical staff have gone through either the Human Resource or the Medical Staff credentialing process as appropriate to their role. This inventory was completed on 2/8/2011.
- The Vice President of Nursing and the Medical Director of Cardiology are currently working with the Vermont Board of Nursing to establish a "Scope of Practice" document for the referenced RN cardiology position with in Fletcher Allen Health Care. A "Request for Position Statement" document was filed on 1/24/2011 with the Vermont Board of Nursing. Once finalized and approved, the position will go through the appropriate Fletcher Allen process. The University of Vermont employee identified through the survey has been removed from the clinical setting and is performing research duties at the University until such time as the scope of practice has been approved and the appropriate Fletcher Allen on-boarding has been completed.
- The Chief Medical Officer reviewed Fletcher Allen leadership's responsibility and oversight function for ensuring qualifications, conduct, and oversight of an individual's clinical practice at the Strategic Management Committee meeting on 2/3/2011. This committee is comprised of Health Care Service Physician Leaders and Senior Leadership, to include the Chief Executive Officer. Specifically highlighted was the expectation that all clinical staff have completed the Human Resource or the Medical Staff credentialing on boarding and performance review process
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the medical staff at the Medical Executive Committee meeting on 2/3/2011.
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the with the Medical Directors at the Medical Director meeting on 2/8/2011.
- The Chief Medical Officer communicated electronically to all Medical Staff on 2/7/2011, the expectation that all clinical staff in their areas have gone through either the Human Resource process or the Medical Staff credentialing process.

Performance Improvement

- Each Manager, on an ongoing basis, will verify that clinical staff in their areas gone through either Human Resource Process or the Medical Staff Process as appropriate to their role.
- Each Director, at time of annual performance evaluations will conduct an inventory in their areas to be ensured all clinical staff has gone through either Human Resource Process or the Medical Staff Process as appropriate to their role. Results as appropriate will be shared with the Vice Presidents for any required action.

POC annt 2.18.11
F. Mitchell

A 338 482.22 MEDICAL STAFF

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

This CONDITION is not met as evidenced by.

Based upon staff interviews and record reviews, the Condition of Participation: Medical Staff was not met as evidenced by the medical staffs failure to implement the Medical Bylaws for the delineation of privileges for an individual who provides specialized care for patients who undergo invasive cardiac procedures. Findings

PLAN OF ACTION

We are responding to this condition-level deficiency through the Plans of Action below. Our "Plans of Action" are incorporated here by reference to the standard level deficiencies. We believe that our specified "Plans of Action" fully ensure accountability and responsibility for the qualifications, conduct and oversight of clinical practice

Based on staff interview, it was confirmed that a job classification, a review of qualifications, and a determination of responsibilities were not presented to the medical staff for credentialing, or to the Governing Body for approval for an individual (RN #1), who has practiced as a member of a cardiac interventional team since 2003. For the past 7 years, RN #1 has not received a written evaluation, was not required to complete yearly mandatory competencies and has functioned without a job description. In addition, the Governing Body was not aware that the role existed.

Per interview on 1/12/2011 at 11:00 AM, the Chief Medical Officer (CMO) who is responsible for the Institute of Quality confirmed that the Medical Staff did not initiate the process for delineation of clinical privileges for RN #1 in accordance with the credentialing process identified in their Bylaws. The CMO stated the Governing Body is "extremely engaged in the credentialing process", and that two members of the Governing Body attend every credentialing meeting bringing all information back to the Governing Body for review and consideration prior to approval of any appointments or reappointments- The CMO confirmed the medical staff are "...well aware" of the credentialing process and the Medical Bylaws. The Health Care Service Leader, also known as the Chair of a Department for each of the clinical services offered at the hospital, was identified by the CMO as the responsible person to ensure staff within their departments are privileged and/or have medical staff membership. At the time of this interview, the CMO stated the Governing Body was not aware of the issues related to RN #1, stating "...we missed this" and "This is surprising to me".

Per interview on 1/12/11 at 10:05 AM the Health Care Service Leader/Chief of Cardiology confirmed RN #1's role on the cardiac arrhythmia service is "unique". The physician stated RN #1 was a highly skilled team member but was not a provider, not a physician and not an advanced practice nurse- However, despite the lack of credentialing, this individual was provided the opportunity and responsibility to perform and assist the attending physician in highly technical interventional cardiac catheter ablations (a technique used to destroy parts of the abnormal electrical pathway that is causing a heart rhythm problem). The Chief of Cardiology also confirmed RN #1 "...was not getting traditional oversight" for the clinical services h/she was specifically providing. In relation to the Governing Body's approval process and accountability of the medical staff to request a review for privileging for RN #1, the Chief of Cardiology stated "...it had fallen within the cracks".

Per interview on 1/12/11 at 8:55 AM, the Manager of Medical Staff Operations (who is designated by the hospital to carry out the duties specified in the Medical Staff Bylaws) stated RN #1 should have been brought through the credentialing process as a "Allied Health Care Professional" (referencing Article IX of the Medical Staff Bylaws revisions approved/adopted 12/21/10). When Informed RN #1 was not hired by the hospital in 2003, but continues to provide patient care as a member of the interventional cardiac catheter ablation team, the Manager acknowledged"...thus lies the problem The process for credentialing involves several steps, including a Medical Staff Bylaws before a professional is considered for employment and eventual recommendation for credentialing and appointment. It was also confirmed by the Manager of Medical Staff Operations that because RN #1 had not been appropriately credentialed, there was no ongoing process to assure his/her clinical competencies, normally reviewed during the reappointment process every two years, as well as through a mid cycle I evaluation ensuring the minimal job requirements were met,

PLAN OF ACTION

- The RN identified through the survey process was noted as being an employee of the University of Vermont at the time of the survey and therefore did not go through the Fletcher Allen on boarding process. Fletcher Allen has two established processes for on boarding of staff that provide organizational oversight for clinical practice. These processes were reviewed by the Vice President for Nursing, Vice President for Human Resources, Vice President for the James Jeffords Institute for Quality and the Chief Medical Officer to ensure compliance with the CMS COP. Specifically reviewed were the Human Resources on boarding and annual evaluation process and the Medical Staff credentialing process. This two processes were reviewed at the ~~12/18/2011~~ ^{2/18/2011} Vice President meeting and later was reinforced at the 2/1/2011 Vice President meeting. *2/18/2011
S. J. C. M.*
- The Vice Presidents communicated the expectation to their Directors that all clinical staff in their respective areas have gone through either the Human Resource process or the Medical Staff credentialing process. Each Director conducted an inventory in their areas to validate that clinical staff have gone through either the Human Resource or the Medical Staff credentialing process as appropriate to their role. This inventory was completed on 2/8/2011.
- The Vice President of Nursing and the Medical Director of Cardiology are currently working with the Vermont Board of Nursing to establish a "Scope of Practice" document for the referenced RN cardiology position with in Fletcher Allen Health Care. A "Request for Position Statement" document was filed on 1/24/2011 with the Vermont Board of Nursing. Once finalized and approved, the position will go through the appropriate Fletcher Allen process. The University of Vermont employee identified through the survey has been removed from the clinical setting and is performing research duties at the University until such time as the scope of practice has been approved and the appropriate Fletcher Allen on-boarding has been completed.
- The Chief Medical Officer reviewed Fletcher Allen leadership's responsibility and oversight function for ensuring qualifications, conduct, and oversight of an individual's clinical practice at the Strategic Management Committee meeting on 2/3/2011. This committee is comprised of Health Care Service Physician Leaders and Senior Leadership, to include the Chief Executive Officer. Specifically highlighted was the expectation that all clinical staff have completed the Human Resource or the Medical Staff credentialing on boarding and performance review process
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the medical staff at the Medical Executive Committee meeting on 2/3/2011.
- The Chief Medical Officer reviewed the requirement that all clinical staff must go through either the Human Resource or the Medical Staff credentialing process with the with the Medical Directors at the Medical Director meeting on 2/8/2011.
- The Chief Medical Officer communicated electronically to all Medical Staff on 2/07/2011, the expectation that all clinical staff in their areas have gone through either the Human Resource process or the Medical Staff credentialing process.

Performance Improvement

- Each Manager, on an ongoing basis, will verify that clinical staff in their areas gone through either Human Resource Process or the Medical Staff Process as appropriate to their role.
- Each Director, at time of annual performance evaluations will conduct an inventory in their areas to be ensured all clinical staff has gone through either Human Resource Process or the Medical Staff Process as appropriate to their role. Results as appropriate will be shared with the Vice Presidents for any required action.

*Pol. comm. 2-18-11
S. J. C. M.*

A 386'482.23(a) ORGANIZATION OF NURSING SERVICES

The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

This STANDARD is not met as evidenced by:

Based on staff interviews and record review, the facility failed to delineate responsibility and accountability for the clinical nursing practice of an individual who held a current RN (Registered Nurse) license and who performed specialized clinical services for patients in the Cardiac Cath Lab. Findings include: Per interview at 1:33 PM on 12/20/2010, RN #1 stated that s/he had worked in the Cardiac Cath Lab assisting in the performance of cardiac ablation procedures since 2003. The RN stated that cardiac ablations are performed by a team of individuals including a physician, nurses and at times an anesthesiologist, who is present when the patient is undergoing an Atrial Fibrillation ablation. S/he further stated that the role in which s/he worked was similar to that of "a first assist in surgery" and it takes a team to do the procedure-The nurse further stated one team member manipulates the catheter, another member is running the stimulator and another is creating the 3-D image on the computer. RN #1 confirmed he is the only nurse involved in this specific procedure.

The Nurse Manager for Cath and Invasive Cardiology stated, during interview on the afternoon of 12/20/2010, that RN #1's was not a hospital employee and did not fall under nursing purview for oversight of their clinical practice, but was, instead, under the direct supervision of one of the cardiologists. Per interview on 1/11/11 at 2:25 PM, the VP of Nursing Operations stated that the Nurse Manager for Cath and Invasive Cardiology had recently started to look at RN #1's role from an RN scope of practice and found it was different than what the nurses in the cardiac lab were doing. S/he further stated that it was his/her understanding that RN #1 was only involved in the technical aspect of the procedure; not performing nursing duties; but only performing those aspects of ablation that the VP of Nursing Operations had, inaccurately, assumed RN #1 had been credentialed to perform by the Medical Staff.

Per interview at 2:19 PM on 1/11/11, the Director for Clinical Services and Training stated that s/he had been employed in the role of Supervisor of the Cardiology Practice in 2003 at the time that RN #1 was being considered for a position in the Cardiac Catheter Lab. S/he stated that there had been discussion, at that time, of where RN #1 would fit, as there was a very clear research component to his/her role and eventually s/he was placed in a research associate role with the affiliated university

PLAN OF ACTION

- The RN identified through the survey process was noted as being an employee of the University of Vermont at the time of the survey and therefore did not go through the Fletcher Allen on boarding process. Fletcher Allen has two established processes for on boarding of staff that provide organizational oversight for clinical practice. These processes were reviewed by the Vice President of Nursing, Vice President of Human Resources, Vice President of the James Jeffords Institute for Quality and the Chief Medical Officer to ensure compliance with the CMS COP. Specifically reviewed were the Human Resource on boarding and annual evaluation process and the Medical Staff credentialing process. This two processes were reviewed at the 12/18/2011 Vice President meeting and later was reinforced at the 2/1/2011 Vice President meeting.
2/16/11
S. [Signature]
- The Vice Presidents communicated the expectation to their Directors that all clinical staff in their respective areas have gone through either the Human Resource process or the Medical Staff credentialing process. Each Director conducted an inventory in their areas to validate that clinical staff have gone through either the Human Resource or the Medical Staff credentialing process as appropriate to their role. This inventory was completed on 2/8/2011.
- The Vice President of Nursing and the Medical Director of Cardiology are currently working with the Vermont Board of Nursing to establish a "Scope of Practice" document for the referenced RN cardiology position with in Fletcher Allen Health Care. A "Request for Position Statement" document was filed on 1/24/2011 with the Vermont Board of Nursing. Once finalized and approved, the position will go through the appropriate Fletcher Allen process. The University of Vermont employee identified through the survey has been removed from the clinical setting and is performing research duties at the University until such time as the scope of practice has been approved and the appropriate Fletcher Allen on-boarding has been completed.

- The Vice President of Nursing reinforced Fletcher Allen Nursing leadership's responsibility *and accountability for the clinical nursing practice with the Nursing Leadership Team at the Nursing Director Meeting on 2/17/2011*. Specifically reinforced was the expectation that all Nursing staff have completed the Human Resource or the Medical Staff credentialing on boarding and performance review process

Performance Improvement

- Each Nursing Manager, on an ongoing basis, will verify that clinical staff in their areas gone through either Human Resource Process or the Medical Staff Process as appropriate to their role.
- Each Nursing Director, at time of annual performance evaluations will conduct an inventory in their areas to be ensured all clinical staff has gone through either Human Resource Process or the Medical Staff Process as appropriate to their role. Results as appropriate will be shared with the Vice Presidents for any required action.

PDC comm 2-18-11
F. McEntee 18

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, interview and record review, the infection control department failed to ensure the maintenance of a sanitary environment on McClure I in the Cardiac Catheterization/ Ablation special procedure room. Findings include:

During a tour of the Cardiac Catheterization/Ablation special procedure room on 1/12/11 at 2:10 PM, the floor was soiled with debris and a reddish brown stain of unknown origin was noted on the base of a monitor stand positioned beside the procedure table. The nurse manager for cardiac catheterization and invasive cardiology stated, at that time, that nursing staff is responsible for cleaning the room in between cases, and at the end of each day dedicated housekeeping staff would provide daily terminal care of the room in the evening. A follow up tour of the same room was conducted on 1/13/11 at 6:17 AM, prior to the first scheduled procedure of the day. Despite the fact that Nurse #2, present during the morning tour, confirmed that housekeeping had been in the room because the trash had been emptied, the floor was still soiled and there was debris and a build up of grime around the columns supporting the procedure table. The rest of the floor still had debris including parking stickers and stains, and there was a layer of dust surrounding all 4 sides of a ridge on the gas column where the anesthesia equipment is stored and utilized. In addition, the stain on the base of the monitor equipment stand, initially noted during tour on the afternoon of 1/11/2011, remained. When surveyors asked to have the base of the stand cleaned, the nurse educator for the Cardiac Cath Lab who was present during the observations, failed to don gloves and, using a disinfectant wipe towel, cleaned the stain from the stand with bare hands. It was agreed the stain was either Betadine solution or blood.

Also observed during the morning tour, there were cables attached to cardiac mapping equipment, used during the ablation procedure, that were noted to be stained with dried blood. The nurse acknowledged it is the responsibility of the nursing staff to clean the cables after each procedure and commented that "...the cables do not touch the patients..." However, staff who handle the cables could then conceivably touch the patient and other environmental surfaces within the room, potentially contaminating everything touched. The Training and Development Supervisor for Environmental Services confirmed on 1/13/11 at 8:40 AM, that the room required deep cleaning and what was observed on the floors especially around the special procedure table had been there for "...definitely more than one day".

Per interview, on 1/13/11 at 12:27 PM, the Infection Control Manager confirmed Environment of Care safety audits are conducted throughout the hospital, twice yearly, and that the most recent inspection/audit of the Cardiac Catheterization/Ablation special procedure room was completed on 12/2/10. When informed of the observations made earlier in the day, the comment by one of the nurses in the Cath lab regarding blood found on cables and the failure of another nurse to wear gloves when cleaning unknown substance on an environmental surface, the Infection Control Manager stated it was "...concerning". Reference: CDC/HICPAC Guidelines for the Disinfection and Sterilization in Healthcare Facilities 2008/Disinfection of Healthcare Equipment.

Plan of Action

- A multidisciplinary team comprised of the Safety Specialist, Environmental Service Educator, Environmental Service Supervisor, Invasive Cardiology Nurse Manager, Invasive Procedure Room Managers, Infection Prevention Practitioner, Director of Facilities and the Director of Regulatory have developed an "Invasive Procedure Room Cleaning Procedure" utilizing Association for Professionals in Infection Control, Association of Peri Operative Registered Nurses and American Hospital Association Guidelines. The procedure was approved by the Director of Facilities on 2/8/2011.
- Due to the complex nature of the electronic equipment contained in the EP laboratory an inventory of surfaces in the EP was completed by the Safety Specialist in collaboration with the EP Nurse Manager, Director of Facilities, Infection Prevention Manager, Environmental Service Educator and Supervisor. The inventory itemizes each surface and delineates the responsible cleaning staff, frequency of cleaning and appropriate cleaning product. This process was completed on 2/3/2011. This inventory will be replicated for other invasive procedure rooms and will be completed by 2/18/2011.
- The Environmental Service Educator will educate Environmental Service staff to the revised "Invasive Procedure Room Cleaning Procedure". Training will be complete by 2/18/2011.

- The Invasive procedure Nurse Managers will review standard infection prevention practices utilizing recent survey results as a teaching opportunity. In addition, staff from the invasive procedure rooms will be educated during staff meetings on the "Invasive Procedure Room Cleaning Procedure". This will be completed on 2/18/2011.
- The Environmental Service Educator developed an "EP/Cath Lab Cleaning Services" checklist which support compliance with the "Invasive Procedure Room Cleaning Procedure" by itemizing the practice necessary for between case cleaning, daily cleaning, weekly and monthly cleaning. This was completed on 2/3/2011.
- The Vice President for the James Jeffords Institute for Quality reviewed the need to reinforce standard infection prevention practices utilizing the recent survey results as a teaching opportunity at the Vice Presidents meeting on 2/1/2011.
- The Vice Presidents will reinforce standard infection prevention practices, utilizing the recent survey results as a teaching opportunity, with their leadership teams and request that their leaders disseminate the information via electronic communications and or staff meetings by 2/18/2011.
- The Chief Medical /Quality Officer reviewed standard infection prevention practices utilizing the recent survey as a teaching opportunity at the following forums:
 - Medical Executive Committee meeting on 2/3/2011
 - Strategic Management Committee on 2/3/2011
 - All Medical Staff Communication on 2/7/2011
 - Medical Director Meeting on 2/8/2011

Performance Improvement

- The Environment Service Supervisors will conduct a weekly quality assurance check of the invasive procedure rooms to ensure that the standards set forth in the "Invasive Procedure Cleaning Room Procedure" is being met. The supervisors will give feedback as required to the appropriate staff.
- The Environmental Service Educator will conduct monthly quality rounds with the Invasive Procedure Room Nurse Managers to ensure the standards set forth in the "Invasive Procedure Cleaning Room Procedure" are being met.
- The Environmental Service Supervisors will conduct monthly testing for verification of cleaning of high touch frequency surfaces. The supervisors will give feedback as required to the appropriate staff.
- The Regulatory team lead by the Regulatory Director will conduct mock surveys for compliance with the "Invasive Procedure Room Cleaning Procedure" with feedback for appropriate action at the Supervisor, Manager, Director and Vice President level.
- The Environment of Care team led by the Safety Specialist conducts safety rounds of the environment every 6 months with feedback to Manager and Director Level.

POC complete 2.18.11
F. Richter / JR