VERMONT

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

Division of Licensing and Protection
HC 2 South, 280 State Drive
Waterbury VT 05671-2060
http://www.dail.vermont.gov
Survey and Certification Voice/TTY (802) 241-0480
Survey and Certification Fax (802) 241-0343
Survey and Certification Reporting Line: (888) 700-5330
To Report Adult Abuse: (800) 564-1612

January 5, 2024

Dan Bennett, CEO
Gifford Medical Center
44 South Main Street
Randolph, VT 05060

Dear Mr. Bennett:

The Division of Licensing and Protection completed a recertification survey at your facility on **December 14, 2023**. The purpose of the survey was to determine if your facility met the conditions of participation for Critical Access Hospitals found in 42 CFR Part 485.

Following the survey, your facility submitted a Plan of Corrections (POC) which was found to be acceptable on **January 5, 2024.**

Sincerely,

Suzanne Leavitt, RN, MS
State Survey Agency Director
Assistant Director, Division of Licensing & Protection

Enclosure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	471301	A. BUILDING _____ B. WING _____	12/14/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GIFFORD MEDICAL CENTER	44 SOUTH MAIN STREET RANDOLPH, VT 05060

(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
C 000	INITIAL COMMENTS An unannounced, onsite Centers for Medicare/Medicaid Services (CMS) authorized re-certification survey was conducted by the Division of Licensing and Protection from 12/12/23 through 12/14/23 to determine compliance with the Conditions of Participation for Critical Access Hospitals (CAH's) at 42 CFR. Part 485, Subpart F. The following regulatory violations were identified:	C 000		
C1140	SURGICAL SERVICES CFR(s): 485.639 If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section. This CONDITION is not met as evidenced by: Based on observation, interview, and policy review the Condition of Surgical services was not met as evidenced by the Critical Access Hospital's (CAH's) failure to assess how prolonged low humidity levels affect the safety of the perioperative suite's operation, supplies, instruments, and equipment; and the failure to ensure the methods for preventing and controlling the transmission of infections were followed as evidenced by blood observed on an Operating Room (OR) table in an OR that was cleaned, an opened package of intubation (putting a tube down one's throat to breathe) instruments left on an anesthesia cart in an OR that was cleaned, opened patient care supplies in the OR's and Endoscopy Suite (area in which instruments are introduced into the body to give a view of its	C1140	**See Attached**	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

President and CEO | 1/5/2024

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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C1140	Continued From page 1	C1140		

internal parts) for undetermined times and dates, and inconsistencies with staff performing hand hygiene while cleaning an operating room after a surgical case. The cumulative effect of these systemic problems resulted in the CAH's inability to ensure the quality of health care in a safe environment.

Findings include:

1.) During a tour of the perioperative suite on 12/12/23 at 1:00 PM the humidity level in the sterile instrument storage area read 15% and the temperature read 69 degrees. The humidity level in the sink area between OR #1 and OR #2 was 15% and the temperature read 68 degrees. The humidity level in the endoscopy suite read 19% and temperature read 69.7 degrees. When asked what the acceptable humidity level was, the Nurse Manager stated that it should be above 20% and confirmed that the facility has had some "humidity issues" lately; and further stated that the CAH was aware of the problem and was working with a contractor. S/He stated that the staff in the perioperative suite monitor the temperature and humidity daily; and that S/He had noticed a trend of low levels starting in November 2023.
On 12/13/23 at 11:00 AM, a second tour of the perioperative area was made. The humidity of the sterile instrument storage area read 15% and temperature read 68 degrees. In OR #1, The humidity level read 15% and the temperature read 68.2. In OR #2, the humidity level read 10% and the temperature read 68 degrees. Per interview with the Nurse Manager at that time, S/He was not aware of any policy/procedure that the facility had to monitor the supplies, instruments, equipment, and/or plans to cease

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C1140	Continued From page 2 operation. S/He stated that there was a fire mitigation protocol that was followed if the humidity and temperature levels went above 60% and/or 75 degrees. Per review of the perioperative suite humidity log, the humidity range given was 20-60%. The following values represent the number of times the humidity was checked, the area checked, and how many times the humidity was in/out of range. These checks were done once a shift, randomly between the hours of 7:00 AM to 3:30 PM by the perioperative staff: October 2023: OR 1 checked 15 times, 1/15 out of range (<20% humidity) OR 2 checked 15 times, all in range. OR 3 checked 15 times, all in range. November 2023: OR 1 checked 12 times, 12/12 out of range (<20% humidity) OR 2 checked 13 times, 11/13 out of range (<20% humidity) OR 3 checked 13 times, 7/13 out of range (<20% humidity) Endoscopy checked 10 times, 9/10 times out of range (<20% humidity) December 2023: OR 1 checked 6 times, 6/6 out of range (<20% humidity) OR 2 checked 6 times, 6/6 out of range (<20% humidity) OR 3 checked 6 times, 5/6 out of range (<20% humidity) Endoscopy checked 6 times, 1/6 out of range (<20% humidity) There is no notation in these logs regarding the	C1140		

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C1140	Continued From page 3 action that was taken when the values were out of range. Per interview on 12/12/23 at 4:26 PM with the Director of facilities, S/He stated that S/He was aware of the low humidity levels in the perioperative and endoscopy areas. S/He stated that low humidity was not ideal because of the potential for fires. S/He stated that the hospital had fire policies in place; and that S/He was working with a group of contractors to fix the system. S/He further stated that the humidity was checked daily between 8:00 and 9:00 AM by a staff member from maintenance and that "a lot of times when it's low" we "cannot do anything about it". S/He also stated that S/He was not aware of any recommendations from the manufacturers related to supplies, instruments, and equipment when there are consistently low levels of humidity in the perioperative and endoscopy suites. Per interview on 12/12/23 at 4:43 PM with the Vice President of Nursing, S/He stated that humidity in the perioperative and endoscopy suites was monitored daily by facilities. The CAH's policy refers to the upper limits of humidity, not low limits. The reference used for clinical practice and policy development is Association of periOperative Registered Nurses (AORN). S/He stated that with low humidity the worry is fire and that there is a procedure that is followed for fire mitigation. On 12/13/23 at approximately 9:00 AM, S/He confirmed that there was no policy to monitor supplies, instruments, and equipment when the humidity is low and out of range. "Prolonged variations in temperature and humidity in perioperative areas can have serious effects on surgical services (eg, increased	C1140		

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C1140	Continued From page 4	C1140		

infection risk, decreased patient safety, disruptions in business continuity, significant fiscal loss). Rapid identification of temperature or humidity variations can prevent adverse consequences by promoting timely restoration of environmental controls and proactive relocation of at-risk supplies and other items. In the case of prolonged disruption to temperature and humidity, exiting guidelines advise performing a risk assessment to guide mitigation. Perioperative personnel should make patient safety the top consideration when assessing and responding to these events."

Reference: Curless, M., Bow, L., Lentz, T, Trexler, P, Maragakis, L. (2021) "Management and Mitigation Temperature and Humidity Events in the Perioperative Setting" AORN Vol 114, (6), 563-571.

2.) On 12/12/23 at approximately 1:15 PM, a tour of OR #1 was made, a blood stain approximately the size of the bottom of a coffee cup was noted on the base of the operating table, an opened package containing a laryngoscope blade and a stylet (tools used to put a tube down one's throat to breathe) were noted on the anesthesia cart; clear tubing was attached to the suction canister located on the anesthesia cart; and a package containing a Yank-our (type) suction tip (removes secretions from one's mouth) was opened and located on top of the suction canister. There was no indication when the clear tubing and Yank-our were opened and/or how long they had been in the room. Per interview with the Nurse Manager at that time, S/He confirmed that this OR had been cleaned and that there should be no opened packages containing instruments and no visible blood in the operating room after cleaning. S/He

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C1140	Continued From page 5 stated that anesthesia oversaw the suction set up and supplies and it was his/her understanding that the suction tubing was changed once it was used. S/He did not know how long it had been there and/or how long the opened package containing the Yank-our had been there. At approximately 2:15 PM, a tour of the endoscopy suite was made, a breathing mask was noted to be attached to tubing on an anesthesia cart, clear tubing was opened and attached to the suction canister, and a package containing a Yank-our suction tip was opened and located approximately one foot from the floor. All these patient care supplies had no date and/or time noted when opened. Per interview with the Nurse Manager at that time S/He confirmed that the mask was most likely used and should not have been left attached and that S/He did not know how long the suction tubing and/or Yank-our had been there. Per interview on 12/13/23 at 12:03 PM with an Anesthesia Provider, S/He stated that S/He checked his/her suction and supplies prior to every surgery and needed the suction supplies "at the ready" in case of an emergency. S/He confirmed that S/He did not know when the supplies were opened and/or how long they were usable when open in the OR and Endoscopy suites. S/He stated that best practice was not to have anything opened; however, every provider had their own practice. Per interview on 12/13/23 at 3:23 PM with the Infection Preventionist and Vice President of Quality and Compliance, they confirmed that the above observations were not acceptable infection control practices. On 12/14/23, during an interview at approximately	C1140		

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C1140	Continued From page 6 12:30 PM with the Vice President of Quality and Compliance, S/He revealed that the CAH had no policy related to suction tubing and supplies being left open in the OR's and/or Endoscopy Suite. Per review of the policy, "Infection Preventions in Surgical Services"-last reviewed 8/23/22, it states "Infection preventions involves the use of specific actions and activities to prevent contamination and maintain sterility of individual areas during operative and other invasive procedures. All individuals who are involved in operative or other invasive procedures have a responsibility to provide a safe environment for patients ....1. Healthcare workers should use standard precautions when caring for all patients in the perioperative setting (AORN) ...a. All personnel should follow established hand hygiene practices ...b. perioperative personnel should wear PPE whenever the possibility exists for exposure to blood or other potentially infectious materials." Per review of the policy, "Cleaning of Surgical Suite"-last reviewed 5/27/22, it states, "Effective cleaning of the OR suite insures a diminished risk of infection ...I. Cleaning and removal of soil should be done on a regular scheduled basis ...B. After each surgical procedure, the surgical staff will clean and disinfect the OR suite as outlined in AORN's Guidelines for Perioperative Practice." 3.) On 12/13/23 at 11:30 AM, during observation of the cleaning of OR #1 after a surgical case, Staff Member #2 entered OR #1 without gloves, used the computer that was in the room, without sanitizing his/her hands, proceeded to don gloves, and started to clean one of the anesthesia carts and then moved to the next cart. Once Staff Member #2 was finished with the carts,	C1140		

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C1140	Continued From page 7 S/He removed his/her gloves and without sanitizing his/her hands donned new gloves and proceeded to clean other areas of OR #1. Per interview at 11:42 AM with Staff Member #2, S/He stated that after removing gloves you were supposed to use "Purell (brand of hand sanitizer)" prior to donning clean gloves. Per review of the policy, "Hand Hygiene"-last reviewed 8/30/22, it states, "Hand Hygiene, a term that applies to hand washing, antiseptic hand wash, antiseptic hand rub or surgical antisepsis, is a core element of patient safety for the prevention of healthcare-associated infections and the spread of antimicrobial resistance. To prevent person to person transmission of infections decontaminate hands with either a hygienic alcohol based hand rub for 20-30 seconds or by washing hands with antimicrobial soap and water for at least 40-60 seconds ...1. Hand Hygiene should be performed ...A. Before patient contact/care ...B. Before putting on gloves ...G. After removing gloves ..."	C1140		
C1144	ANESTHETIC RISK AND EVALUATION CFR(s): 485.639(b)(1), 485.639(b)(2), 485.639(b)(3) (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed. (2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.	C1144	**See Attached**	

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C1144	Continued From page 8 (3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section. This STANDARD is not met as evidenced by: Based on interview and record review the CAH failed to ensure that surgical patients prior to discharge were evaluated for proper anesthesia recovery regarding cardiopulmonary status, level of consciousness, follow-up care/observations, and complications for two of three records reviewed (Patient #4 and Patient #19). Findings include: 1.) Per record review Patient #4 has a history of right upper quadrant pain with nausea and biliary hyperkinesia (rapid contractions and emptying of the gallbladder). On 11/8/23, a laparoscopic cholecystectomy (gallbladder removal) was performed. Per review of the "Anesthesia Record" from 11/8/23, it states, "Recovery ...Location: ACC, Arrival Time: 1229, Vitals at 1231 ...Fully Awake ...Active Airways: None ...Supplemental Oxygen: Room Air." There is no evidence of follow up care/observations and complications noted in this evaluation. 2.) Per record review Patient #19 has a history of a fall with a left-sided distal fibular fracture (broken bone in ankle). On 11/21/23, Patient #19 underwent surgical repair of this fracture. Per review of the "Anesthesia Record", it states, "Recovery ...Location: PACU, Arrival Time: 1005 ...Vitals ... Responsiveness: [Left blank] ...Active Airways: None ...Supplemental Oxygen: Simple Mask". There is no evidence that the patient's level of consciousness, follow up care/observations, and complications were noted in this evaluation.	C1144		

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C1144	Continued From page 9 Per interview on 12/13/23 at 12:03 with an Anesthesia Provider, S/He stated that S/He does not write a post anesthesia evaluation unless the patient is admitted. Per review of the policy, "Documentation of Anesthesia Patient Care"-last reviewed 5/2022, it states, "Documentation is a factor in the provision of quality anesthesia care, and it is the responsibility of the Anesthesiologist/Anesthetist to accurately document the care provided ...III. Post-anesthesia ...A. Patient evaluation on admission and discharge from the post-anesthesia care unit. B. A time-based record of vital signs and level of consciousness. C. All drugs administered and their dosages. D. Type and amounts of intravenous fluids administered including blood and blood products. E. Any unusual events including post-anesthesia or post-procedural complications. F. Post-anesthesia visits."	C1144		
E 000	Initial Comments During an unannounced on-site re-certification survey, on 12/12/23 through 12/14/23, the Division of Licensing and Protection conducted a review of the Critical Access Hospital's (CAH's) Emergency Preparedness Program. The facility was found to be in substantial compliance with the Condition of Participation for CAH's at 485.625, Emergency Preparedness.	E 000		

Gifford Medical Center

Provider ID: 471301
Plan of correction for deficiencies noted December 12-14
Date: January 5, 2024

Tag ID	Program Criteria	Deficiency	Resolution & Monitoring	Status
C-1140	Surgical Services	Failure to assess how prolonged low humidity levels affect the safety of the perioperative suite operation, supplies, instruments, and equipment	TSP review of impact of low humidity on equipment in OR	Completed 12/22/2023
			Multidisciplinary team including TSP to evaluate impact of low humidity on supplies in OR area	Anticipated completion 1/19/2024
			Policy created based on AORN outlining a process for addressing out of range temp/humidity	Completed 1/4/2024
			Factory restart of humidification system	Completed 1/3/2024
			Final repairs to humidification system and verification of normal system function	Completed 1/4/2024 – system is in range with normal monitoring in place.
		Failure to ensure methods of preventing and controlling the transmission of infections as evidenced by 1) presence of blood on an OR table and in a room that was clean.	Education to OR staff on Environmental cleaning practices	Complete 1/4/2024 Monitoring underway
			Implemented a room turnover tracker with staff signing off on area cleaned	Complete 12/18/2023
			Review and revise policies to include AORN checklists	In progress
		2) opened supplies in an OR room	OR and Anesthesia education	Anesthesia education complete 1/2/2024

		and endoscopy room that were clean. 3) Inconsistency with OR staff performing hand hygiene	Monitoring: Observations 3 times weekly x 4 weeks Staff education Monitoring: Observations x 5 weeks	Monitoring underway Complete 12/28/2023 Monitoring underway
C-1144	Anesthesia Risk and Evaluation	Failure to ensure that surgical patients prior to discharge were evaluated for proper anesthesia recovery regarding cardiopulmonary status, level of consciousness, follow-up care/observations, and complications.	ANS-107 revised Documentation form in place (temp pending system update and downtime) Monitoring: 10 charts a week x 4 weeks	Policy revision complete 1/2/2024 Education complete 1/2/2024 Monitoring underway

The VP Quality and Compliance Officer will provide oversight and monitor completion of this corrective action plan through regular check-in with each responsible party.

Tags C1140 - C1144 POC accepted on 1/5/24 by T. Dougherty/S. Leavitt