STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050441	A. BUILDING _____ B. WING _____	11/14/2024

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STANFORD HEALTH CARE	300 PASTEUR DRIVE STANFORD, CA 94305

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A 000	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during a complaint validation survey conducted on 11/14/2024. For Complaint Numbers CA00726440 and CA00741242, regarding Patient's Rights, Condition of Participation was met. For Facility Reported Incident (FRI) CA00897679, regarding QAPI, Nursing Services, and Radiologic Services, Conditions of Participation were not met (Refer to A-263, A-283, A-385, A-398, A-528, and A-535). For FRIs CA00921709, CA00921835, CA00923542, CA00925245 regarding Patient's Rights, Condition of Participation was met. For FRI CA00922124, regarding Governing Body, QAPI, and Nursing Services, Condition of Participation: Nursing Services was not met. (Refer to A-385 and A-398). For FRIs CA00923103, CA00924653, CA00925432, CA00925567, CA00927533, regarding Nursing Services, Condition of Participation was met. For Complaint Number CA00924450, regarding Patient's Rights and Nursing Services, Conditions of Participation were met. For Complaint Numbers CA00924540, CA00925878, and CA00927261 regarding Patient's Rights, Condition of Participation was met.	A 000	Preparation and submission of this Plan of Correction does not constitute an admission or agreement by Stanford Health Care (SHC) (the "Hospital") of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies. The Hospital is submitting this plan of correction as required by the state and federal regulations. This Plan of Correction documents the actions by the hospital to address the alleged deficiencies.	12/12/24

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

Marina Ayoub Bahoura | Ex. Director Quality & Safety | 12/12/24

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.

POC accepted 12/13/24 Yalima

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A 000	Continued From page 1 For FRI CA00925232, regarding Governing Body, Patient's Rights, and QAPI, Conditions of Participation were met. However, standard deficiencies were identified (Refer to A-131 and A-168). For Complaint Number CA00928274, regarding Governing Body, Nursing Services, QAPI, and Radiologic Services, Conditions of Participation for Nursing Services, QAPI and Radiologic Services were not met (Refer to A-263, A-283, A-385, A-398, A-528, and A-535). Inspection was limited to the specific Conditions of Participation authorized by CMS: 42 CFR §482.12 Governing Body, 42 CFR §482.13 Patient's Rights, 42 CFR §482.21 QAPI, 42 CFR §482.23 Nursing Services, and 42 CFR §482.26 Radiologic Services and does not reflect the findings of a full inspection of the hospital.	A 000		
A 131	PATIENT RIGHTS: INFORMED CONSENT CFR(s): 482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This STANDARD is not met as evidenced by: Based on interview and record review, the	A 131	A131 PATIENT RIGHTS: INFORMED CONSENT	12/12/24

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A 131	Continued From page 2 hospital failed to ensure two of 31 patients (Patients 12 and 24) were informed of their health status when: 1. Patient 12 did not receive the results of a colonoscopy (a procedure that uses a colonoscope [flexible tube with a light and camera on one end] to examine the inside of the colon [large intestine]) from 2018 that showed lymphoma (type of blood cancer); 2. Patient 24 did not receive information on her PET/CT (a combined picture from a positron emission tomography [PET] scan and a computed tomography [CT] scan) results with recommendations for further evaluation. These failures resulted in the patients not being informed of their abnormal procedure results timely and had the potential to result in delayed treatment. Findings: 1. Review of Patient 12's medical record indicated the patient was scheduled for a colonoscopy with biopsy (procedure that involves removing tissue or cells from the body for examination) on 12/12/18. Review of Patient 12's Pathology Specimen Review, dated 12/12/18 indicated eight specimens were collected during the colonoscopy and examined. The Review further indicated, " ... findings support a diagnosis of mantle cell lymphoma [cancer of white blood cells]" and was signed by the gastroenterologist (GI) physician (GIP).	A 131	A131 - 1- The documents listed below are referenced in the POC and are submitted as attachments: • Informatics Education (AskInformatics) • What's New in SHC Epic? The patient was admitted for a colonoscopy procedure on December 12, 2018, and was physically discharged three hours later. However, the patient was not marked as discharged in Epic until 43 days later, on January 24, 2019. Standard practice is that patients be discharged in Epic no later than three days after their physical discharge. During the procedure, a biopsy was collected and submitted to pathology for testing, with the results finalized on December 17, 2018. However, because the patient was not properly discharged in Epic and was still recorded as "admitted," the Anatomic Pathology (AP) Epic in-basket messages were suppressed by design. This design choice was made to prevent unnecessary alerts, as providers conduct regular rounds for their assigned admitted patients and do not require additional in-basket notifications that could flood their messaging system. To identify other patients who may be affected by the same deficient practice, SHC conducted an audit of patients with similar admission statuses from January 2007 to July 2024. This audit aimed to assess any clinical impacts and to identify instances of delayed or missed discharges in EHR (Epic), which could result in missed in-basket alerts to providers. For those cases identified with delayed or missed discharges in Epic, the patient's chart were reviewed to determine if there was documentation from a clinical provider of the pathology results. If there was no documentation of pathology results, the case and clinical chart were reviewed by the pathology team to determine if there was clinical impact. No other patients were found to be impacted by missed Epic in-basket alerts. As of May 15, 2024, SHC made a decision to permanently discontinue the suppression of AP (Anatomic Pathology) Epic in-basket messages to authorizing providers, regardless of the patient's admission status. What's New in Epic? (attached) education form went to all staff and providers at SHC. Similar information was added to provider's Knowledge Base as a form of dissemination of the new process (attached). This decision represents a permanent corrective action. Since AP Epic in-basket messages now route to ordering providers regardless of patient's admission status in Epic, the timeliness of patient discharge out of Epic should have no impact on notification of pathology results. We have conducted reviews of the Epic message generation processes and have found no exceptions or deficiencies.	12/12/24

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A 131	Continued From page 3 There was no documentation in Patient 12's medical record that indicated the patient was informed of his colonoscopy/biopsy results and diagnosis of mantle cell lymphoma. Review of Patient 12's Surgical General results, dated 10/2/24 indicated he had a colonoscopy with biopsy and esophagogastroduodenoscopy, (EGD, procedure that uses an endoscope [flexible tube with a light and camera on one end] to examine the upper digestive tract [esophagus, stomach, or small intestine]) with biopsy on 10/2/24. The results further indicated a diagnosis of residual/recurrent mantle cell lymphoma. Review of Patient 12's Progress Notes, dated 10/10/24 indicated, "Called patient with Spanish interpreter to discuss recent EGD/Colonoscopy biopsy results showing mantle cell lymphoma of the colon as well as adenocarcinoma [a type of cancer that starts in the glands lining the inside of organs] (likely invasive) of the colon. I disclosed that pathology results from his colonoscopy in 2018 also showed mantle cell lymphoma. The patient reports he was never informed of the pathology results from 2018 and was surprised to hear about this result. I explained to the patient that [the hospital] is looking into what occurred in 2018 to understand why he was not informed about the biopsy results. The patient needs to be evaluated by a medical oncologist for his mantle cell lymphoma and a colorectal surgeon for his colon adenocarcinoma. I will place expedited referrals to these two specialties today." During an interview on 11/6/24 at 3 p.m., the Executive Director of Quality & Safety (EDQS) stated there was a technology issue that affected how the results were sent to the provider. The	A 131	SHC is actively monitoring the success of this corrective actions to prevent the recurrence of similar events by conducting audits over three consecutive months. These audits will ensure that provider in-basket messages are not missed and that providers are acknowledging pathology results. Additionally, SHC has implemented a measure that provides patient access to their electronic health information (EHI) through a personal health application (MyHealth), which enables patients to view their medical information. The Executive Director, DSL Quality and Operations, is responsible for the completion of this POC. A131 2- The documents listed below are referenced in the POC and are submitted as attachments: • CVH clinical operations and physician leadership meeting attendance. • Draft of procedure This was discovered after the patient was discharged from SHC. No other patients were identified as impacted at that time. During the week of 11/18/2024, the Cardiac Vascular Health (CVH) clinical operations and physician leadership workgroup assessed the standard workflow of in-basket coverage for providers who go on extended leave, outlined provider-to-provider coverage plan, and developed a clear patient escalation pathway. Enhancements to standardized procedure of in-basket coverage for providers on extended leave, refinement of provider-to-provider coverage plan, improvement of the communication process to the Care Team of the coverage plan, and development of a structured escalation pathway are the immediate measures that were implemented. On 12/09/2024, the CVH clinical operations and physician leadership workgroup finalized a draft of a standardized procedure for in-basket coverage for providers on extended leave. Weekly audits of in-basket coverage during providers extended leave will be performed by CVH operations management to prevent recurrence of similar events. By 12/16/2024, standardized procedure for in-basket coverage will be approved and implemented and all CVH clinic faculty and staff will be trained on the new process. The Executive Director, DSL Quality and Operations, is responsible for the completion of this POC.	

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A 131	Continued From page 4 EDQS stated the doctor was devastated that the results were missed. During an interview on 11/12/24 at 2:56 p.m., the Laboratory Quality Director (LQD) and Director of Surgical Pathology (DSP) stated the ordering provider was the GIP. The LQD and DSP stated once reports are finalized, they are available for providers and the GIP should have informed Patient 12 of his 2018 colonoscopy results. 2. Review of the hospital's grievance records indicated Patient 24 reported that she was not informed about her PET/CT) findings which was performed on 12/20/23. Review of Patient 24's medical record indicated she had an outpatient visit to the facility's heart failure clinic on 12/20/23 for routine follow-up. Review of Patient 24's Study Result for PET/CT Heart Sarcoidosis (a rare autoimmune disease that causes inflammation and scarring in the heart), dated 12/20/23, indicated two impressions. The result indicated, "Intense radiotracer uptake (displays when cells in a specific area of the body absorb more of a radiotracer than the surrounding tissues) in the uterus (a hollow muscular organ located in the female pelvis) unlikely to be physiologic (normal fuctioning) given age, recommend further evaluation with pelvic ultrasound (an imaging test) and gynecologic exam (a physical exam of the reproductive organs)." Review of Patient 24's Heart Failure Clinic Patient Follow Up, dated 12/20/23, indicated, "PET done earlier today for evaluation of cardiac sarcoid - results pending though initial images do not appear overly positive."	A 131		

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A 131	Continued From page 5 During an interview and record review on 11/13/24 at 10:16 a.m. with Quality Specialist (QS) D, she confirmed there was no documentation indicating Patient 24 was informed about the PET/CT finding of intense radiotracer uptake in the uterus or recommended for the further evaluation with pelvic ultrasound and gynecologic exam. During a review of the hospital's policy and procedure (P&P) titled, "Patient Rights and Responsibilities Policy," approved 11/2024, the P&P indicated, "Patients have the right to: ... 5. Receive information about the health status, the course of treatment, prospects for recovery, and outcomes of care (including unanticipated outcomes) in a manner that the patient can understand and in their preferred language."	A 131		
A 168	PATIENT RIGHTS: RESTRAINT OR SECLUSION CFR(s): 482.13(e)(5) §§482.13(e)(5) - The use of restraint or seclusion must be in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to obtain an order for the use of restraints (any manual method or device that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely) for one of three patients (Patient 21) when Patient 21 was placed in bilateral (both sides) wrist restraints without a physician order. This failure	A 168	**A168** PATIENT RIGHTS: RESTRAINT OR SECLUSION The documents listed below are referenced in the corrective action plan and are submitted as attachments: • Active Orders Compliance Data • Restraints Documentation Standards Attestation • Inpatient leader Townhall • Care Delivery Update Email Communication This was discovered while the patient was inpatient at SHC. Upon awareness, this was corrected. Random daily review of patients has shown no additional concerns for impact to other patients. On 12/6/24, education was provided to L4 staff on expectations around the use of restraints and the necessity of a provider order (please see attached). A new SHC Active Daily Management (ADM) process began 10/30/24. SHC Unit leadership review patients actively restrained. This process includes reviewing information about patients currently in restraints and appropriateness of their orders. Focused daily reviews of patients in restraints on L4 began 11/18/24 (attachement for email communication). SHC Town Hall was held with SHC Physician Leadership on 11/13/24 to set expectations for review of restraints during interdisciplinary rounds effective immediately (attached Townhall slides). Audits of patients in restraints on SHC Unit L4 will be conducted daily by SHC Nursing Quality to ensure compliance with all state and federal regulations. These audits will continue for 3 weeks. SHC will reduce to audits once daily for an additional month with spot checks to occur monthly for an additional 3 months. Monthly reports will be submitted to SHC leadership for review. Any gaps will be identified and corrected with ongoing training and education. As of 12/09/2024, compliance with active orders with restraints is 100% (attached compliance data). The SHC Director of Nursing Quality is responsible for ensuring and sustaining the correction.	12/12/24

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A 168	Continued From page 6 had the potential to result in an inappropriate and prolonged use of restraints. Findings: Review of Patient 21's medical record indicated she was admitted to the facility on 11/05/24 for stereo intracranial EEG lead placement (a procedure where electrodes are surgically inserted into the skull to monitor brain activity). Review of Patient 21's restraints flowsheet, dated 11/06/24 to 11/12/24, indicated the patient had soft restraints on the right wrist and left wrist, starting on 11/06/24 at 7:49 a.m. Review of Patient 21's physician's orders, dated 11/07/24 to 11/12/24, indicated the patient had an order for restraints for both wrists. There was no order for restraints for both wrists on 11/06/24. During an interview and record review on 11/12/24 at 10 a.m. with Nursing Quality Management Coordinator (NQMC) A, he confirmed there was no order for bilateral wrist restraints on 11/06/24. During a review of the hospital's policy and procedure (P&P) titled "Restraint and Seclusion," approved 2/2024, the P&P indicated, "All assessments, care provided, and orders will be documented in the patient's EHR. In an emergency, trained RN can initiate the application of restraints and obtain an order from a LIP/APP as soon as patient has been safely restrained. LIP/APP orders for non-violent restraints must specify the following: type of restraints used; description of condition requiring restraints; criteria for release; order duration."	A 168		

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A 263	QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on interview and document review, the hospital failed to develop an effective, ongoing, hospital wide, data driven quality assessment and performance improvement (QAPI) program as evidenced by: 1. Failure to identify the hospital's MRI hazard checklist was complete in accordance with American College of Radiology (ACR) in order to prevent patient safety events (Refer to A-283); 2. Failure to review and revise the hospital's MRI Safety policy as required (Refer to A-283). These cumulative failures resulted in the hospital's inability to provide quality health care as required by the QAPI Program Condition of Participation and provide care to their patients in	A 263	**A263 -** The documents listed below are referenced in the corrective action plan and are submitted as attachments: • MRI Policy • MRI Screening Form in EHR (Epic) • MRI Safety mtg Content 12.11.24 (Radiology) • MRI Safety Meeting 12-11-24 Attendance Radiology • MRI Radiology training FU 11.13.24 • MRI Safety SBAR Attestation Completion (Nursing) • Nursing Attestation Form for MRI Screening SHC leadership conducted a thorough review and in-depth analysis of the MRI event to identify contributing factors and develop an improvement plan that addresses each contributing factor. Following a comprehensive random review of SHC patients receiving an MRI across SHC, no other patients were identified as impacted. SHC leadership ensured the review and update of the MRI safety policy, and the update of the MRI screening form in Epic to include the systematic review of the existence of probes on patients. The SHC Magnetic Resonance (MR) Safety Committee will meet and review best practice on MR Safety annually. Education to the Nursing and all MRI staff on screening form was developed and rolled out. Consistent monitoring of daily work around screening was created and deployed as part of the ongoing effort to improve quality. The SHC MRI policy was reviewed and updated and approved on 12/06/24 which included updates to the screening of SHC MRI patients. The tracking of MRI safety will be on the PSC committee monthly meeting agenda, starting January 2025. Meanwhile, MRI screening compliance results will be reviewed by SHC leadership weekly during the weekly huddle. The Executive Director of Quality and Safety is responsible for ensuring and sustaining the correction.	12/12/24

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A 263	Continued From page 8 a safe environment. Patient 18 had an esophageal temperature probe (a device used to measure core body temperature) and underwent a magnetic resonance imaging (MRI, a medical imaging procedure that uses strong magnetic fields to create images of the inside of the body) scan, and it resulted in Patient 18 sustaining burn injuries to the lips, mouth, and tongue.	A 263	A283 The documents listed below are referenced in the corrective action plan and are submitted as attachments: • Updated QAPI Plan • MRI Safety mtg Content 12.11.24 (Radiology) • MRI Safety Meeting 12-11-24 Attendance Radiology • MRI Radiology training FU 11.13.24 • MRI Safety SBAR Attestation Completion (Nursing) • Nursing Attestation Form for MRI Screening	12/12/2024
A 283	QUALITY IMPROVEMENT ACTIVITIES CFR(s): 482.21(b)(2)(ii), (c)(1), (c)(3) (b) Program Data (2) [The hospital must use the data collected to -.....] (ii) Identify opportunities for improvement and changes that will lead to improvement. (c) Program Activities (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to fully implement its Quality	A 283	SHC leadership conducted a thorough review and in-depth analysis of the MRI event to identify contributing factors and develop an improvement plan that addresses each contributing factor. Following a comprehensive random review of SHC patients receiving an MRI across SHC, no other patients were identified as impacted. On 12/06/24, SHC revised the QAPI plan to include the tracking and analysis of imaging safety events, including MRI. On 12/06/24, SHC revised the QAPI plan to include tracking of quality improvement activities related to MRI safety, and the reporting of compliance with MRI safety screening to the hospital's Patient Safety Committee (PSC). PSC then reports to SHC Quality, Patient Safety, and Effectiveness Committee and to the SHC Governing Board. Education to the Nursing and all MRI staff on screening form was developed and rolled out. Consistent monitoring of daily work around screening was created and deployed as part of the ongoing effort to improve quality. The SHC MRI policy was reviewed and updated and approved on 12/06/24 which included updates to the screening of SHC MRI patients. SHC Quality Management Department will continue to monitor all QAPI related activities including the tracking of policy and they will ensure timely review and updates as needed. The tracking of MRI safety will be on the PSC committee monthly meeting agenda, starting January 2025. Meanwhile, MRI screening compliance results will be reviewed by SHC leadership weekly during the weekly leadership huddle. The Executive Director of Quality and Safety is responsible for ensuring and sustaining the correction.	

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A 283	Continued From page 9 Assessment and Performance Improvement (QAPI) program when the program did not identify the hospital's magnetic resonance imaging (MRI, a medical imaging procedure that uses strong magnetic fields to create images of the inside of the body) screening process was inadequate and did not meet standards of practice. The QAPI program also did not identify the hospital's MRI Safety policy required to be reviewed and revised. These deficient practices resulted in burns to Patient 18's lips, mouth, and tongue and had the potential to jeopardize the health and safety of patients. Findings: Review of Patient 18's Vascular Surgery Progress Note, dated 4/25/24 indicated the patient was admitted to the hospital on 4/6/24 with diagnoses including ruptured abdominal aortic aneurysm (AAA, enlargement of the aorta, the main blood vessel that delivers blood to the body). The note indicated Patient 18 underwent a procedure to repair the aneurysm, was intubated (a medical procedure that involves inserting an endotracheal tube [ETT] into a person's airway to help them breathe), sedated (in a state of calmness, relaxation, or sleepiness caused by certain drugs) and required continuous renal replacement therapy (CRRT, a type of dialysis that removes wastes, toxins, and excess fluid from the body). Review of Patient 18's Flowsheets, from 4/6/24 to 5/28/24 indicated on 4/22/24 at 10 a.m., Patient 18 had a temperature of 38.4 degrees Celsius (measurement of temperature) and the temperature source (how the temperature was	A 283		

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STANFORD HEALTH CARE	300 PASTEUR DRIVE STANFORD, CA 94305

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A 283	Continued From page 10 taken) was "esophageal." Patient 18's Flowsheets also indicated on 4/25/24 the patient temperature source was "esophageal" at 2 a.m., 3 a.m., 4 a.m., 5 a.m., and 6 a.m. Review of Patient 18's Comprehensive Critical Care Notes, dated 4/25/24 indicated on 4/24/24 the patient had an MRI of the brain and it was recommended that Patient 18 have an MRI of the spine. Review of Patient 18's Screening Form Questions, dated 4/25/24 indicated Patient 18 had an appointment scheduled on 4/25/24 at 3 p.m. for MR Thoracic and Lumbar Spine (middle and lower section of the backbone). The form also indicated the answer to the question, "Does your patient have a temperature sensitive Foley?" was "No." The form did not include a question regarding an esophageal temperature probe. Review of Patient 18's Study Result MR Thoracic and Lumbar Spine indicated the patient's exam ended on 4/25/24 at 5:25 p.m. Review of Patient 18's Flowsheets, dated 4/25/25 indicated the patient had wounds to the left lateral (to the side) lip and mouth, first assessed on 4/25/24 at 7:25 p.m. The Flowsheets also described the mouth wound as tongue white blistering and surrounding skin was edematous (swollen with fluid). Review of Patient 18's Comprehensive Critical Care Note, dated 4/26/24 indicated, "... esophageal temp probe found melted in mouth with wire exposed, some burns noted along lips ..."	A 283		

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A 283	Continued From page 11 Review of Patient 18's Otolaryngology - Head and Neck Surgery Consult History and Physical, dated 4/26/24 indicated, "Yesterday, patient was taken to radiology to undergo an MRI T and L spine. Unfortunately, an esophageal temperature probe was kept in place for the duration of the scan (approximately 90 minutes). Once the patient was received, primary team noticed the probe fused to his upper left lip, ETT and tongue. ENT consulted for evaluation of oral and OP burns and management." The consult also indicated the pertinent findings of a flexible fiber laryngoscopy were the following: temp probe adhered to ETT; Burns involving the left upper lip; burn with fibrinous tissue involving 40% of central tongue, 30% of soft and hard palate, right base of tongue. Review of Patient 18's Plastic and Reconstructive Surgery History and Physical/Consult Note, dated 4/26/24 indicated, "Plastic surgery was consulted to evaluate the lip burn ... Will require surgical reconstruction pending clinical stability." During an interview on 11/7/24 at 11:30 a.m., the MRI Manager (MRIM) stated when a patient has an order for an MRI, a screening form is generated for a nurse to complete. She stated once the form is completed, the MR technologist (tech) would review the answers and ask questions as needed. She stated when the patient was taken to the department, the MR tech does a visual check on the patient before the MRI procedure. The MR tech also waves a mental detecting wand over the patient to identify any unknown metal before the procedure. The MRIM stated Patient 18 was on a ventilator and the nursing team took the patient to get an MRI. She stated after Patient 18's MRI, the MRIM was alerted that there was a concern with a burn. The	A 283		

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A 283	Continued From page 12 MRIM stated a nurse did an assessment and saw that Patient 18 still had an esophageal temperature probe in place. The MRIM stated they reviewed the screening form the hospital used and identified that the form only asked if the patient had a foley catheter (a tube inserted in the urinary tract into the bladder to drain urine) temperature probe. She stated the form did not ask about other temperature probes, like an esophageal probe. The MRIM stated in an ideal world, the esophageal temp probe should have been identified by the MR tech during the visual check. She stated the MR tech did not realize there was an esophageal temp probe in place because it was white and looked like it was part of Patient 18's ET tube/respiratory equipment. She stated the MRI generated heat because of the metal in the esophageal probe, which caused the plastic on the probe to melt, and resulted in Patient 18's burns in his mouth. During an interview on 11/8/24 at 8:55 a.m., the MR tech (MRT) involved in Patient 18's 4/25/24 MRI stated the responsibility of the MR tech to confirm verbally with the nurse that the patient did not have any devices that could not go in the MR scanner. The MRT stated he did a visual check on Patient 18 and did not identify the esophageal probe because of the respiratory bundle surrounding the patient's mouth. The MRT stated that the hospital's MRI screening form did not have a question asking whether the patient has an esophageal probe. During an interview on 11/13/24 at 1:02 p.m., the MRIM stated the hospital's MR policy was not changed. During a telephone interview on 11/14/24 at 3:25	A 283		

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A 283	Continued From page 13 p.m. the Executive Director Quality & Safety (EDQS) stated the hospital uses The American College of Radiology as their reference. She stated the hospital policy was adapted from ACR, but it might not be 100 percent what is published. Review of the hospital's policy, "Magnetic Resonance Imaging (MRI) Safety", last approved 7/2019 indicated, "Practices outline here are aligned with the 2017 American College of Radiology (ACR) Practice Parameters for Performing and Interpreting MRI and the 2013 ACR Guidance Document on MRI Safe Practices." The policy also indicated, "All patients entering Zone 4 [MRI scanner magnet room] will be thoroughly screened for non-MRI conditional apparatuses prior to entry ... it is the responsibility of the MRI technologist to review the screening form with the patient and visually check for any metal objects." The policy further indicated, "This policy will be reviewed and/or revised every three years or as required by change of law or practice." The hospital's policy should have been updated in 2022. Review of "Appendix A; MRI Screening Procedure for Incapacitated Inpatients," of the hospital's "MRI Safety" policy, indicated, "The MR safety screening form is the final safety checkpoint for patients undergoing a MRI exam ... The screening for will then be filled out with the nurse who will go through the questions ..." Review of the ACR Guidance Document on MR Safe Practices: 2013 contained Appendix 2, which included a "Hazard Checklist for MRI Personnel." The checklist indicated an area to check yes or no to the following: Endotracheal tube, Swan-Ganz catheter (a tube placed inside	A 283		

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A 283	Continued From page 14 the heart to monitor heart function and blood flow), Extra ventricular device (a system that drains fluid from the brain), Arterial line transducer (a device used to measure blood pressures), Foley catheter with temperature sensor and/or metal clamp, Rectal probe (device inserted in the rectum to take temperature or examine the rectum), Esophageal Probe (device inserted in the esophagus to take temperature), Tracheotomy tube (tube inserted in the trachea to help with breathing), and Guidewires (a thin wire used to help place catheters in the body). According to the American College of Radiology (ACR) website, "MR Safety continues to evolve and in response, the ACR's Committee on MR safety created the ACR Manual on MR Safety with updates and critical new information which replaces all earlier versions of the ACR Guidance Document on MR Safe Practices." The website contained links to access documents, including the ACR Manual on MR Safety 2024 and Safety Screening Form for MR Procedures. Review of the "ACR Manual on MR Safety 2024" indicated, "This 2024 edition of the ACR Manual on MR Safety replaces all earlier versions." Review of ACR's Safety Screening for Magnetic Resonance (MR) Procedures indicated the Hazard Checklist for Level 2 MR Personnel included yes/no check boxes for the following: pulse oximetry device, EKG pads/leads, Endotracheal tube, Swan-Ganz catheter, Extra ventricular device, Arterial line transducer, Foley catheter with temperature sensor and/or metal clamp, Rectal probe, Esophageal Probe, Tracheotomy tube, Guidewires, Halo vest, and other. The screening procedures also indicated,	A 283		

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A 283	Continued From page 15 "If any Level 2 MR Personnel checklist items are answered yes, this should be brought to the attention to the covering MR Physician." Review of the hospital's "Quality Assessment and Performace Improvement Plan 2024," approved 2/2024 indicated, "Along with Management Guidance Team, Quality Councils, and Improvement Programs, [the hospital] seeks input from executive leadership, departments, and services from all areas involved with quality performace measurement and improvement to determine if there are gaps or opportunities for improvement."	A 283	**A385 Nursing Services**-The documents listed below are referenced in the POC and are submitted as attachments: • Stage 3 Penis HAPI report Out • December NA meeting • MRI Safety SBAR Attestation Completion (Nursing) • Nursing Attestation Form for MRI Screening • Condom Catheter Attestation 12.03.24 These events were discovered during hospitalization admissions for both patient, The Stanford Health Care (SHC) Wound Care Team was consulted on Patient 2 and Patient 18 to advise on treatment, and the recommended treatments were carried out according to wound treatment orders. No other SHC patients with a condom catheter while were identified as being impacted at that time. A random review of SHC patients with condom catheters or undergoing an MRI exam while an inpatient has shown similar concerns or (adverse) impact.	12/12/2024
A 385	NURSING SERVICES CFR(s): 482.23 The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on interview and record review, the hospital failed to comply with the Condition of Participation for Nursing Services as evidenced by: 1. Failure to implement hospital policy and procedure when nursing staff did not change the patient's condom catheter (a urine collection device that fits over the penis and is held in place with adhesive) (Refer to A-398). 2. Failure to identify and communicate the presence of an esophageal temperature probe (a device used to measure core body temperature) prior to a magnetic resonance imaging (MRI, a	A 385	1-An educational handout was distributed via email to SHC Unit staff around patient care expectations regarding following SHC policy and procedure on the inpatient unit (L5). This was further reviewed in staff huddles on starting 12/11/24. Audits of SHC patients with condom catheters on SHC Unit L5 will be conducted daily to ensure compliance with policy of changing condom catheters. These audits will continue for 3 weeks. SHC will reduce the frequency of these audits to twice per week for an additional month, with periodic checks to occur monthly for an additional 3 months. Monthly reports will be submitted to leadership for review. Any gaps in compliance will be identified and corrected with ongoing training and education. SHC's Healthcare Associated Conditions (HAC) Management Guidance Team (MGT) will meet and review best practice around the use of condom catheters. Auditing for compliance with external urinary catheter timely removal was initiated on 10/16/24. 2-Leadership on the Stanford Health Care (SHC) inpatient unit (J4) distributed an educational handout to staff via email on 12/3/24 on care expectations regarding checking for (thermometer) probes as part of preparing patients for MRI exams. This educational handout was further reviewed in daily staff huddles. from 9/22/24-10/05/24 (see attachment)	

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A 385	Continued From page 16 medical imaging procedure that uses strong magnetic fields to create images of the inside of the body) (Refer to A-398). The cumulative effect of these deficient practices resulted in the facility's inability to provide quality health care in a safe environment. Patient 2 developed a condom catheter-related pressure injury (pressure-related damage to the skin and/or underlying tissue). Patient 18 suffered burn injuries to the lips, mouth, and tongue during the MRI.	A 385	By 12/12/2024, SHC had updated the SHC MRI Safety Checklist to include language regarding checking for probes and identify the type of probe used. Additionally, as of 5/24/24, the temperature probes were required to have associated SHC Provider order. Audits of the SHC MRI checklists for patients undergoing MRI exams on this inpatient unit (J4) will be conducted for each patient to ensure compliance with device review prior to MRI for 2 months : audit forms will be available to staff. Monthly reports will be submitted to leadership for review and follow up as needed. Any gaps (or non-compliance identified) will corrected with ongoing training and education. SHC's Patient Safety Committee will meet and review MRI safety practice and MRI screening audits' results. Auditing for compliance with accurate completion of screening form was initiated on 11/26/24. The SHC Director of Nursing Quality is responsible for ensuring and sustaining the correction.	12/12/2024
A 398	SUPERVISION OF CONTRACT STAFF CFR(s): 482.23(b)(6) All licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer). This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to implement its policies and procedures for two of 10 patients when: 1. Nursing staff did not change Patient 2's condom catheter (a urine collection device that fits over the penis and is held in place with adhesive); and 2. Nursing staff failed to identify and communicate the presence of Patient 18's esophageal temperature probe (a device used to	A 398	**A398** The documents listed below are referenced in the POC and are submitted as attachments: • Stage 3 Penis HAPI report Out • December NA meeting • MRI Safety SBAR Attestation Completion (Nursing) • Nursing Attestation Form for MRI Screening • Condom Catheter Attestation 12.03.24 These events were discovered during hospitalization admissions for both patient, The Stanford Health Care (SHC) Wound Care Team was consulted on Patient 2 and Patient 18 to advise on treatment, and the recommended treatments were carried out according to wound treatment orders. No other SHC patients with a condom catheter while were identified as being impacted at that time. A random review of SHC patients with condom catheters or undergoing an MRI exam while an inpatient has shown similar concerns or (adverse) impact. 1- A new active daily management (ADM) process began on 12/3/2024 on SHC Unit L5. SHC Unit leadership or designee reviews patients with condom catheters.. This daily review process includes confirming when the condom catheter was applied, when the condom catheter was last changed, and when skin was last assessed In alignment with the SHC policy. Audits of SHC patients with condom catheters on SHC Unit L5 will be conducted daily to ensure compliance with policy of changing condom catheters. These audits will continue for 3 weeks. SHC will reduce the frequency of these audits to twice per week for an additional month, with periodic checks to occur monthly for an additional 3 months.	12/12/2024

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A 398	Continued From page 17 measure core body temperature) prior to a magnetic resonance imaging (MRI, a medical imaging procedure that uses strong magnetic fields to create images of the inside of the body). These failures resulted in injuries for both patients. Patient 2 developed a condom catheter-related pressure injury (pressure-related damage to the skin and/or underlying tissue). Patient 18 suffered burn injuries to the lips, mouth, and tongue during the MRI. Findings: 1. Review of Patient 2's History & Physical, dated 9/14/24, indicated Patient 2 was admitted with diagnoses including Huntington's disease (a disease that causes nerve cells in the brain to decay over time) and perirectal abscess (a collection pus in the rectal area). Review of Patient 2's skin assessment, dated 9/15/24, indicated Patient 2 did not have any wounds or other skin issues at the time of this assessment. Review of Patient 2's External Urinary Catheter assessment indicated the hospital placed a condom catheter on Patient 2 on 9/15/24 at 7:30 p.m. The assessment further indicated the condom catheter was removed on 9/20/24 at 9:00 a.m. There was no documentation in the medical record that indicated the hospital changed Patient 2's condom catheter from the time it was placed to the time it was removed. Review of Patient 2's Progress Notes, dated 9/20/24, indicated Patient 2's condom catheter was accidentally pulled off when he turned in bed.	A 398	Monthly reports will be submitted to leadership for review. Any gaps in compliance will be identified and corrected with ongoing training and education. SHC's Healthcare Associated Conditions (HAC) Management Guidance Team (MGT) will meet and review best practice around the use of condom catheters. Auditing for compliance with external urinary catheter timely removal was initiated on 10/16/24. 2- A new active daily management (ADM) process began 12/3/2024 on SHC Unit J4 for patients who are scheduled for a MRI. This process includes a daily review of the patient condition and status with the patient's nurse prior to the MRI. Audits of ADM process will occur weekly to ensure leadership oversight for one month with spot checks for an additional 3 months. SHC's Patient Safety Committee will meet and review MRI safety practice and MRI screening audits' results. Auditing for compliance with accurate completion of screening form was initiated on 11/26/24. SHC's Patient Safety Committee will meet and review MRI safety practice and MRI screening audits' results. Auditing for compliance with accurate completion of screening form was initiated on 11/26/24. The SHC Director of Nursing Quality is responsible for ensuring and sustaining the correction.	12/12/24

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A 398	Continued From page 18 The Progress Notes further indicated a wound was found on Patient 2's penis. Review of Patient 2's Wound Ostomy Continence Nurse (WOCN) Note, dated 9/20/24 indicated, "Wound care consult for wound to penile area. Per primary RN [registered nurse] noted wound on removal of condom catheter. Patient denies having wound to area prior. Patient reports having catheter in place for 4 days." The WOCN Note further indicated the wound on Patient 2's penis was a stage 3 pressure injury (full-thickness loss of skin). Review of Patient 2's Neurology Discharge Note, dated 9/20/24, indicated he had a pressure-related wound on the penis. The note further indicated this was a condom catheter-related wound that needed wound care twice a day. During an interview and concurrent record review with quality specialist B (QS B) on 11/6/24 at 10:04 a.m., QS B acknowledged that the hospital's policy indicated condom catheters must be changed every two days. QS B reviewed Patient 2's medical record and confirmed it appeared as though Patient 2 had the same condom catheter from the time it was placed to the time it was removed. QS B stated he would conduct further review of Patient 2's medical record and try to find documentation that the condom catheter was changed. During an interview with interim assistant patient care manager C (IAPCM C) on 11/6/24 at 12:53 p.m., IAPCM C confirmed she was a wound specialist. IAPCM C explained it was important to change condom catheters every two days so the	A 398		

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A 398	Continued From page 19 underlying skin can be assessed. IAPCM C confirmed that not changing a condom catheter could contribute to the development of a pressure injury. During a follow-up interview with QS B on 11/7/24 at 2:24 p.m., QS B confirmed there was no documentation that indicated Patient 2's condom catheter was changed from the time it was placed to the time it was removed. The hospital's policy and procedure titled "External Urinary Collection Devices," dated 5/2019, was reviewed. The section related to condom catheters indicated, "Change catheter when site is soiled, and condom catheter needs to be removed for adequate cleansing, if leaking is present or every two days." Review of Patient 18's Vascular Surgery Progress Note, dated 4/25/24 indicated the patient was admitted to the hospital on 4/6/24 with diagnoses including ruptured abdominal aortic aneurysm (AAA, enlargement of the aorta, the main blood vessel that delivers blood to the body). The note indicated Patient 18 underwent a procedure to repair the aneurysm, was intubated (a medical procedure that involves inserting an endotracheal tube [ETT] into a person's airway to help them breathe), sedated (in a state of calmness, relaxation, or sleepiness caused by certain drugs) and required continuous renal replacement therapy (CRRT, a type of dialysis that removes wastes, toxins, and excess fluid from the body). Review of Patient 18's Flowsheets, from 4/6/24 to 5/28/24 indicated on 4/22/24 at 10 a.m., Patient 18 had a temperature of 38.4 degrees Celsius (measurement of temperature) and the temperature source (how the temperature was	A 398		

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A 398	Continued From page 20 taken) was "esophageal." Patient 18's Flowsheets also indicated on 4/25/24 the patient temperature source was "esophageal" at 2 a.m., 3 a.m., 4 a.m., 5 a.m., and 6 a.m. It also indicated on 4/25/24 at 7 a.m. there was no temperature source documented. Review of Patient 18's Comprehensive Critical Care Notes, dated 4/25/24 indicated on 4/24/24 the patient had an MRI of the brain and it was recommended that Patient 18 have an MRI of the spine. Review of Patient 18's Screening Form Questions, dated 4/25/24 indicated Patient 18 had an appointment scheduled on 4/25/24 at 3 p.m. for MR Thoracic and Lumbar Spine (middle and lower section of the backbone). The Form also indicated the answer to the question, "Does your patient have a temperature sensitive Foley?" was "No." Review of Patient 18's Study Result MR Thoracic and Lumbar Spine indicated the patient's exam ended on 4/25/24 at 5:25 p.m. Review of Patient 18's Flowsheets, dated 4/25/25 indicated the patient had wounds to the left lateral (to the side) lip and mouth, first assessed on 4/25/24 at 7:25 p.m. The Flowsheets also described the mouth wound as tongue white blistering and surrounding skin was edematous (swollen with fluid). Review of Patient 18's Comprehensive Critical Care Note, dated 4/26/24 indicated, "... esophageal temp probe found melted in mouth with wire exposed, some burns noted along lips ..."	A 398		

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A 398	Continued From page 21 Review of Patient 18's Otolaryngology - Head and Neck Surgery Consult History and Physical, dated 4/26/24 indicated, "Yesterday, patient was taken to radiology to undergo an MRI T and L spine. Unfortunately, an esophageal temperature probe was kept in place for the duration of the scan (approximately 90 minutes). Once the patient was received, primary team noticed the probe fused to his upper left lip, ETT and tongue. ENT consulted for evaluation of oral and OP burns and management." The consult also indicated the pertinent findings of a flexible fiber laryngoscopy were the following: temp probe adhered to ETT; Burns involving the left upper lip; burn with fibrinous tissue involving 40% of central tongue, 30% of soft and hard palate [roof of the mouth], right base of tongue." Review of Patient 18's Plastic and Reconstructive Surgery History and Physical/Consult Note, dated 4/26/24 indicated, "Plastic surgery was consulted to evaluate the lip burn ... Will require surgical reconstruction pending clinical stability." During an interview on 11/7/24 at 11:30 a.m., the MRI Manager (MRIM) stated when a patient has an order for an MRI, a screening form is generated for a nurse to complete. She stated once the form is completed, the MR technologist (tech) would review the answers and ask questions as needed. She stated when the patient is taken to the department, the MR tech does a visual check on the patient before the MRI procedure. The MR tech also waves a mental detecting wand over the patient to identify any unknown metal before the procedure. The MRIM stated Patient 18 was on a ventilator and the nursing team took the patient to get an MRI. She	A 398		

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A 398	Continued From page 22 stated after Patient 18's MRI, the MRIM was alerted that there was a concern with a burn. The MRIM stated a nurse did an assessment and saw that Patient 18 still had an esophageal temperature probe in place. The MRIM stated they reviewed the screening form the hospital used and identified that the form only asked if the patient had a foley catheter (a tube inserted in the urinary tract into the bladder to drain urine) temperature probe. She stated the form did not ask about other temperature probes, like an esophageal probe. The MRIM stated in an ideal world, the esophageal temp probe should have been identified by the MR tech during the visual check. She stated the MR tech did not realize there was an esophageal temp probe in place because it was white and looked like it was part of Patient 18's ET tube/respiratory equipment. She stated the MRI generated heat because of the metal in the esophageal probe, which caused the plastic on the probe to melt, and resulted in Patient 18's burns in his mouth. During an interview on 11/8/24 at 8:55 a.m., the MR tech (MRT) involved in Patient 18's 4/25/24 MRI stated the responsibility of the MR tech to confirm verbally with the nurse that the patient did not have any devices that could not go in the MR scanner. The MRT stated he confirmed with Patient 18's nurse that the patient did not have any devices that could not go in the MR scanner. During an interview on 11/8/24 at 10 a.m., Registered Nurse E (RN E) stated he was Patient 18's primary nurse on 4/25/24. RN E stated he was not aware Patient 18 had an esophageal temperature probe. He stated he only found out about Patient 18's esophageal probe after the MRI on 4/25/24.	A 398		

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A 398	Continued From page 23 During an interview on 11/12/24 at 9:53 a.m., Quality Specialist B (QS B) stated RN E could not remember whether Patient 18's esophageal temp probe was communicated to him by the previous nurse. During an interview on 11/13/24 at 10:45 a.m., the Executive Director Quality & Safety (EDQS) stated Patient 18's flowsheet contained documentation of of an esophgeal probe and it is the nurse's responsibility to know and check for what items the patient has. Review of an email sent on 11/14/24 at 10:41 a.m., QS B indicated that there were no care plans prior to 4/25/24 specifically addressing esophageal probes. Review of the hospital's policy, "Magnetic Resonance Imaging (MRI) Safety," last approved 7/2019 indicated, "Practices outline here are aligned with the 2017 American College of Radiology (ACR) Practice Parameters for Performing and Interpreting MRI and the 2013 ACR Guidance Document on MRI Safe Practices." The policy also indicated, "All patients entering Zone 4 [MRI scanner magnet room] will be thoroughly screened for non-MRI conditional apparatuses prior to entry ... " Review of "Appendix A; MRI Screening Procedure for Incapacitated Inpatients," of the hospital's "MRI Safety" policy, indicated, "The MR safety screening form is the final safety checkpoint for patients undergoing a MRI exam ... The screening for will then be filled out with the nurse who will go through the questions ..."	A 398		

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A 398	Continued From page 24 Review of the hospital's policy, "Standards of Practice for Acute and Critical Care Nursing," approved 11/2021 indicated, "Through Assessment, the nurse collects data pertinent to the patient's condition or health status ... Documents relevant data in EHR [electronic health record] in a clear, timely manner ... The nurse caring for the patient develops a plan of care that prescribes strategies and alternatives to attain desired outcomes ... establishes priorities and continuity of care within the plan, including transfer of information and handoffs at shift change ... documents plan in the Care Plan system within the EHR and provides handoff of the plan in a clear, timely manner." Review of the "Appendix A: Critical Care Standard Work" from the policy, "Standards of Practice for Acute and Critical Care Nursing" indicated record temperature (and more frequently as needed) and document lines and tubes every four hours.	A 398	A528 The following documents are provided to support the completion of the POC: • MRI Policy • MRI Screening Form • MRI Safety mtg Content 12.11.24 (Radiology) • MRI Safety Meeting 12-11-24 Attendance Radiology • MRI Radiology training FU 11.13.24 The patient affected by this incident received medical attention following the MRI procedure to address the injuries sustained. A thorough investigation was conducted to identify contributing factors of the event. No other patients have been identified with similar occurrences following a comprehensive review of MRI safety incidents. SHC MRI screening form in the EHR (EPIC) was updated to include questions about temperature monitoring devices. If a device is present, the type must be documented and reviewed by SHC MRI staff in zone 3 prior to the patient entering the MRI suite in zone 4. SHC MRI policy has been updated and indicates a standardized review process for all patients prior to entering the SHC MRI Zone 4. During daily huddles, SHC MRI staff education sessions included physical demonstration of the esophageal temperature probe, education around the updated SHC MRI Screening Form, and staff screening expectations were reviewed. By 12/12/2024 the MRI staff was educated on their role on screening patients and completing their section of the screening form in Epic. On 4/29/24, education on the SHC MRI Screening Form updates was posted to SHC's MRI Visibility Wall (Viswall) under "MRI Safety". On 11/13/24, an EPIC MRI screening form audit tool was developed and implemented. Any "Yes" responses in the new end-of-exam questions triggers of an audit for review by SHC staff. Auditing for accurate completion of the SHC MRI screening form was initiated on 12/04/24. Audits showed 100% compliance. The results are shared with SHC leadership along with MRI and Nursing staff for awareness and to ensure continuous compliance. The SHC Magnetic Resonance (MR) Safety Committee will meet and review best practice on MR Safety annually.	12/12/2024
A 528	RADIOLOGIC SERVICES CFR(s): 482.26 The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to comply with the Condition of Participation for Radiologic Services as evidenced by: Failure to maintain compliance with facility policy	A 528		

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A 528	Continued From page 25 and in accordance with American College of Radiology (ACR)'s safe Magnetic Resonance Imaging (MRI, a medical imaging procedure that uses strong magnetic fields to create images of the inside of the body) practices (refer to A535). The cumulative effect of this systemic problem resulted in the hospital's inability to ensure the provision of quality health care in a safe environment. Patient 18 had an esophageal temperature probe (a device used to measure core body temperature) and underwent an MRI and it resulted in Patient 18 sustaining burn injuries to the lips, mouth, and tongue.	A 528		
A 535	SAFETY POLICY AND PROCEDURES CFR(s): 482.26(b) [§482.26 Condition of Participation: Radiologic Services §. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.] §482.26(b) Standard: Safety for Patients and Personnel The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to follow their Magnetic Resonance Imaging (MRI, a medical imaging procedure that uses strong magnetic fields to create images of the inside of the body) policy when the MR tech did not identify one of four patients (Patient 18)	A 535		

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A 535	Continued From page 26 had a device that was unsafe to be used in an MR scanner. The hospital also failed to ensure the MRI Safety policy was in accordance with American College of Radiology (ACR)'s safe MRI practices, and review and revise their policy as required. These failures resulted in Patient 18 sustaining burn injuries to the lips, mouth, and tongue when he had an esophageal temperature probe (a device used to measure core body temperature) when undergoing an MRI. Findings: Review of Patient 18's Vascular Surgery Progress Note, dated 4/25/24 indicated the patient was admitted to the hospital on 4/6/24 with diagnoses including ruptured abdominal aortic aneurysm (AAA, enlargement of the aorta, the main blood vessel that delivers blood to the body). The note indicated Patient 18 underwent a procedure to repair the aneurysm, was intubated (a medical procedure that involves inserting an endotracheal tube [ETT] into a person's airway to help them breathe), sedated (in a state of calmness, relaxation, or sleepiness caused by certain drugs) and required continuous renal replacement therapy (CRRT, a type of dialysis that removes wastes, toxins, and excess fluid from the body). Review of Patient 18's Flowsheets, from 4/6/24 to 5/28/24 indicated on 4/22/24 at 10 a.m., Patient 18 had a temperature of 38.4 degrees Celsius (measurement of temperature) and the temperature source (how the temperature was taken) was "esophageal." Patient 18's Flowsheets also indicated on 4/25/24 the patient temperature source was "esophageal" at 2 a.m., 3 a.m., 4 a.m., 5 a.m., and 6 a.m.	A 535	A535 The following documents are provided to support the completion of the POC: • MRI Policy • MRI Screening Form • MRI Safety mtg Content 12.11.24 (Radiology) • MRI Safety Meeting 12-11-24 Attendance Radiology • MRI Radiology training FU 11.13.24 The patient affected by this incident received medical attention following the MRI procedure to address the injuries sustained. A thorough investigation was conducted to identify contributing factors of the event. No other patients have been identified with similar occurrences following a comprehensive review of MRI safety incidents. Screening Enhancements: On May 2, 2024, the MRI screening form in the EHR (EPIC) was updated to include explicit questions about temperature monitoring devices. If a device is present, the type must be documented, and a discussion must occur between the RN and MRI technologist before the patient enters the MRI suite. the form was updated on 12/12/24 to delineate the completion section of the MRI staff. MRI staff was trained on the new process. SHC MRI safety policies now mandate a standardized review process for all patients prior to entering Zone 4 in the MRI suite. Staff education sessions were immediately conducted, including physical demonstration of the esophageal temperature probe and education of the MRI screening form updates during daily huddles. The incident was added to the MRI Visibility Wall (Viswall) under "MRI Safety" (posted April 29, 2024). A comprehensive in-service training session was conducted, and materials were distributed via email to all MRI staff and posted on MRI visibility board under "In Services" on 05/23/24. Revised MRI protocols require technologists to confirm, at the end of the exam, whether undisclosed items were identified during the procedure on November 13,2024. A robust audit process was established by adding an MRI screening form to Epic, on 11/13/24, triggering an audit for review if a confirmation of safety risk is identified. Quality audits on every exam were initiated on December 4, 2024 after two weeks of training had been completed. Results are shared with leadership and staff to ensure continuous process improvement. SHC MRI safety policies were reviewed, revised, and updated to align with guidelines for best practice on 12/6/2024. SHC MR Safety Committee reviews best practice on MR Safety annually. The Director of Imaging Services at SHC is responsible for ensuring and sustaining the correction.	12/12/2024

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A 535	Continued From page 27 Review of Patient 18's Comprehensive Critical Care Notes, dated 4/25/24 indicated on 4/24/24 the patient had an MRI of the brain and it was recommended that Patient 18 have an MRI of the spine. Review of Patient 18's Screening Form Questions, dated 4/25/24 indicated Patient 18 had an appointment scheduled on 4/25/24 at 3 p.m. for MR Thoracic and Lumbar Spine (middle and lower section of the backbone). The Form also indicated the answer to the question, "Does your patient have a temperature sensitive Foley?" was "No." The form did not include a question regarding an esophageal temperature probe. Review of Patient 18's Study Result MR Thoracic and Lumbar Spine indicated the patient's exam ended on 4/25/24 at 5:25 p.m. Review of Patient 18's Flowsheets, dated 4/25/25 indicated the patient had wounds to the left lateral (to the side) lip and mouth, first assessed on 4/25/24 at 7:25 p.m. The Flowsheets also described the mouth wound as tongue white blistering and surrounding skin was edematous (swollen with fluid). Review of Patient 18's Comprehensive Critical Care Note, dated 4/26/24 indicated, "... esophageal temp probe found melted in mouth with wire exposed, some burns noted along lips ..." Review of Patient 18's Otolaryngology - Head and Neck Surgery Consult History and Physical, dated 4/26/24 indicated, "Yesterday, patient was taken to radiology to undergo an MRI T and L spine. Unfortunately, an esophageal temperature probe	A 535		

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A 535	Continued From page 28 was kept in place for the duration of the scan (approximately 90 minutes). Once the patient was received, primary team noticed the probe fused to his upper left lip, ETT and tongue. ENT consulted for evaluation of oral and OP burns and management." The consult also indicated the pertinent findings of a flexible fiber laryngoscopy were the following: temp probe adhered to ETT; Burns involving the left upper lip; burn with fibrinous tissue involving 40% of central tongue, 30% of soft and hard palate [roof of the mouth], right base of tongue. Review of Patient 18's Plastic and Reconstructive Surgery History and Physical/Consult Note, dated 4/26/24 indicated, "Plastic surgery was consulted to evaluate the lip burn ... Will require surgical reconstruction pending clinical stability." During an interview on 11/7/24 at 11:30 a.m., the MRI Manager (MRIM) stated when a patient has an order for an MRI, a screening form is generated for a nurse to complete. She stated once the form is completed, the MR technologist (tech) would review the answers and ask questions as needed. She stated when the patient is taken to the department, the MR tech does a visual check on the patient before the MRI procedure. The MR tech also waves a mental detecting wand over the patient to identify any unknown metal before the procedure. The MRIM stated Patient 18 was on a ventilator and the nursing team took the patient to get an MRI. She stated after Patient 18's MRI, the MRIM was alerted that there was a concern with a burn. The MRIM stated a nurse did an assessment and saw that Patient 18 still had an esophageal temperature probe in place. The MRIM stated they reviewed the screening form the hospital	A 535		

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A 535	Continued From page 29 used and identified that the form only asked if the patient had a foley catheter (a tube inserted in the urinary tract into the bladder to drain urine) temperature probe. She stated the form did not ask about other temperature probes, like an esophageal probe. The MRIM stated in an ideal world, the esophageal temp probe should have been identified by the MR tech during the visual check. She stated the MR tech did not realize there was an esophageal temp probe in place because it was white and looked like it was part of Patient 18's ET tube/respiratory equipment. She stated the MRI generated heat because of the metal in the esophageal probe, which caused the plastic on the probe to melt, and resulted in Patient 18's burns in his mouth. During an interview on 11/8/24 at 8:55 a.m., the MR tech (MRT) involved in Patient 18's 4/25/24 MRI stated the responsibility of the MR tech to confirm verbally with the nurse that the patient did not have any devices that could not go in the MR scanner. The MRT stated he did a visual check on Patient 18 and did not identify the esophageal probe because of the respiratory bundle surrounding the patient's mouth. The MRT stated that the hospital's MRI screening form did not have a question asking whether the patient has an esophageal probe. During an interview on 11/13/24 at 1:02 p.m., the MRIM stated the hospital's MR policy was not changed. Review of the hospital's policy, "Magnetic Resonance Imaging (MRI) Safety", last approved 7/2019 indicated, "Practices outline here are aligned with the 2017 American College of Radiology (ACR) Practice Parameters for	A 535		

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A 535	Continued From page 30 Performing and Interpreting MRI and the 2013 ACR Guidance Document on MRI Safe Practices." The policy also indicated, "All patients entering Zone 4 [MRI scanner magnet room] will be thoroughly screened for non-MRI conditional apparatuses prior to entry ... it is the responsibility of the MRI technologist to review the screening form with the patient and visually check for any metal objects." The policy further indicated, "This policy will be reviewed and/or revised every three years or as required by change of law or practice." The hospital's policy should have been updated in 2022. Review of "Appendix A; MRI Screening Procedure for Incapacitated Inpatients," of the hospital's "MRI Safety" policy, indicated, "The MR safety screening form is the final safety checkpoint for patients undergoing a MRI exam ... The screening for will then be filled out with the nurse who will go through the questions ..." Review of the ACR Guidance Document on MR Safe Practices: 2013 contained Appendix 2, which included a "Hazard Checklist for MRI Personnel." The checklist indicated an area to check yes or no to the following: Endotracheal tube, Swan-Ganz catheter (a tube placed inside the heart to monitor heart function and blood flow), Extra ventricular device (a system that drains fluid from the brain), Arterial line transducer (a device used to measure blood pressures), Foley catheter with temperature sensor and/or metal clamp, Rectal probe (device inserted in the rectum to take temperature or examine the rectum), Esophageal Probe (device inserted in the esophagus to take temperature), Tracheotomy tube (tube inserted in the trachea to help with breathing), and Guidewires (a thin wire	A 535		

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A 535	Continued From page 31 used to help place catheters in the body). According to the American College of Radiology (ACR) website, "MR Safety continues to evolve and in response, the ACR's Committee on MR safety created the ACR Manual on MR Safety with updates and critical new information which replaces all earlier versions of the ACR Guidance Document on MR Safe Practices." The website contained links to access documents, including the ACR Manual on MR Safety 2024 and Safety Screening Form for MR Procedures. Review of the "ACR Manual on MR Safety 2024" indicated, "This 2024 edition of the ACR Manual on MR Safety replaces all earlier versions." Review of ACR's Safety Screening for Magnetic Resonance (MR) Procedures indicated the Hazard Checklist for Level 2 MR Personnel included yes/no check boxes for the following: pulse oximetry device, EKG pads/leads, Endotracheal tube, Swan-Ganz catheter, Extra ventricular device, Arterial line transducer, Foley catheter with temperature sensor and/or metal clamp, Rectal probe, Esophageal Probe, Tracheotomy tube, Guidewires, Halo vest, and other. The screening procedures also indicated, "If any Level 2 MR Personnel checklist items are answered yes, this should be brought to the attention to the covering MR Physician."	A 535		