



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
DEBBY RANSOM, R.N., R.H.I.T. – Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, Idaho 83720-0009
PHONE: (208) 334-6626
FAX: (208) 364-1888
E-mail: fsb@dhw.idaho.gov

CERTIFIED MAIL: 7012 3050 0001 2125 5686

December 15, 2015

Marlon Michael, Administrator
Southern Idaho Surgery Center
3235 N Towerbridge Way, Suite 100
Meridian, ID 83646-5721

RE: Southern Idaho Surgery Center, Provider #13C0001069

Dear Dr. Michael:

This is to notify you that we are recommending to the Centers for Medicare/Medicaid Services (CMS) that it terminate its Medicare provider agreement with your ASC based on the immediate jeopardy findings identified on December 10, 2015.

We have notified CMS that the following Condition of Participation is not met:

Surgical Services (42 CFR 416.42)

We have also informed CMS that substantial noncompliance representing an immediate and serious threat to patient health and safety has been identified.

This deficiency was discussed with you and/or your staff during the exit conference. The Statement of Deficiencies is enclosed for your reference.

If this recommendation is accepted by CMS, they will send you a formal notice of termination. This notice will include information about appeal rights, the time schedule for termination and the steps you can take to halt the termination action.

We urge you to begin correction immediately. CMS's time frame for termination is very short

Marlon Michael, Administrator
December 15, 2015
Page 2 of 2

when deficiencies pose immediate jeopardy to patient health and safety.

I would like to extend a thank you to you and your staff for the courtesies and assistance provided to us during the investigation. If you have any questions, or if we can be of assistance to you, please contact me at (208) 334-6626, option 4.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicole Wisenor". The signature is fluid and cursive, written over a light blue horizontal line.

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

nw/pt

Enclosures

cc: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Lynnette Osias, CMS Region X Office

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
Seattle Regional Office, M/S-400
701 Fifth Avenue, Suite 1600
Seattle, WA 98104



CORRECTED NOTICE – PLEASE READ CAREFULLY

**THIS SERVES AS OFFICIAL NOTICE SENT VIA FACSIMILE PURSUANT TO 42 CFR §488.
NO HARD COPY TO FOLLOW.**

January 4, 2016

Marlon Michael, Administrator
Southern Idaho Surgery Center
3235 N Towerbridge Way, Suite 100
Medicare, ID 83646-5721

CMS Certification Number: 13C0001069

**Re: Notice of Enforcement Action
Recertification Survey completed on December 10, 2015
Conditions for Coverage Not Met
Immediate Jeopardy found – Abated
Placed on 90 day termination track**

Dear Dr. Michael:

After careful review of the facts, the Centers for Medicare and Medicaid Services (CMS) has determined that Southern Idaho Surgery Center no longer meets the requirements for participation as a supplier of services in the Medicare program established under Title XVIII of the Social Security Act. This is to notify you that effective **March 10, 2016**, the Secretary of the Department of Health and Human Services intends to terminate its provider agreement with Southern Idaho Surgery Center. We will publish a legal notice in the Idaho Statesman fifteen days prior to the termination date.

Background

To participate as a supplier of services in the Medicare and Medicaid Programs, an ambulatory surgery center (ASC) must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services. When an ASC is found to be out of substantial compliance, the facility no longer meets the requirements for participation as a supplier of services in the Medicare program. The Social Security Act Section 1866(b) authorizes the Secretary to terminate an ASC's Medicare provider agreement if the facility no longer meets the federal requirements. Regulations at 42 Code of Federal Regulations (CFR) § 489.53 authorize CMS to terminate Medicare provider agreements when a supplier, such as Southern Idaho Surgery Center no longer meets the Conditions for Coverage for ASCs.

On December 10, 2015, the Idaho Bureau of Facility Standards (State survey agency) conducted a recertification survey and found that Southern Idaho Surgery Center was not in substantial compliance with federal requirements for ASCs participating in the Medicare and/or Medicaid programs. Immediate Jeopardy was found on December 10, 2015 and abated on December 21, 2015. The following Conditions for Coverage were found not met during the December 10, 2015 survey:

42 CFR § 416.41	Governing Body and Management
42 CFR § 416.42	Surgical Services (Immediate Jeopardy Abated)
42 CFR § 416.43	Quality Assessment and Performance Improvement
42 CFR § 416.44	Environment
42 CFR § 416.45	Medical Staff
42 CFR § 416.46	Nursing Services
42 CFR § 416.47	Medical Records
42 CFR § 416.49	Laboratory and Radiologic Services
42 CFR § 416.50	Patient Rights
42 CFR § 416.51	Infection Control

This deficiency limits the capacity of Southern Idaho Surgery Center to furnish services of adequate level and quality. The details of the above deficiencies are listed on the enclosed Statement of Deficiencies and Plan of Correction (Form CMS 2567).

This termination action can be avoided by correcting the deficiency prior to the effective date of the termination. CMS must receive and approve a **credible allegation of compliance** in a timely manner, verified by an unannounced revisit by the State survey agency that the deficiency has been corrected. **Complete your plan of correction in the space provided on the CMS-2567.** An acceptable plan of correction, which includes acceptable completion dates, must contain the following elements:

- Plan of Correction for each specific deficiency cited;
- Procedure/process for implementing the acceptable plan of correction for each deficiency cited;
- Monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements;
- Address process improvement and demonstrate how the hospital has incorporated improvement actions into its Quality Assessment and Performance Improvement (QAPI) program. Address improvement in systems to prevent the likelihood of re-occurrence of the deficient practice.
- A completion date for correction of each deficiency cited;
- The plan must include the individual responsible for implementing the acceptable plan of correction with signature and title.

Please send your plan of correction to the State survey agency and to CMS by January 15, 2016.

**DHHS Center for Medicare and Medicaid Services
Division of Survey, Certification & Enforcement – Region 10
Attention: Lynnette Osias
701 Fifth Avenue, Suite 1600, M/S-400
Seattle, WA 98104**

PUBLIC NOTICE OF TERMINATION

In accordance with 42 CFR 489.53(d) CMS will publish legal notice of your pending termination action in a newspaper within Southern Idaho Surgery Center's locale prior to the termination date or by February 25, 2016.

APPEAL RIGHTS

Southern Idaho Surgery Center has the right to appeal this determination by requesting a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). The regulations governing this process are set out in 42 CFR § 498.40 et seq. You will find the DAB's e-filing procedures on the internet at the following URL:

<http://www.hhs.gov/dab/divisions/civil/procedures/filing-and-service.html>

A request for a hearing should identify the specific issues, and the findings of fact, and conclusions of law with which you disagree. The request should also specify the basis for contending that the findings and conclusions are incorrect. Evidence and arguments may be presented at the hearing and you may be represented by legal counsel at your own expense. **A hearing request must be filed not later than 60 days after the date you receive this letter.**

If you have any questions, please contact Lynnette Osias of my staff, Seattle Regional Office at (206) 615-2407 or by email at lynnette.osias@cms.hhs.gov.

Sincerely,



Patrick Thrift, Manager
Survey, Certification and Enforcement Branch

Enclosure: CMS-2567 Statement of Deficiencies

cc: Idaho Bureau of Facility Standards
Office of General Counsel
Noridian Healthcare Solutions
Idaho Medicaid

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

PRINTED: 01/06/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001069	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/10/2015
NAME OF PROVIDER OR SUPPLIER SOUTHERN IDAHO SURGERY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 3235 N TOWERBRIDGE WAY, SUITE 100 MERIDIAN, ID 83646	
(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
Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification survey of your Ambulatory Surgery Center conducted from 12/08/15 through 12/10/15. Surveyors conducting the recertification were:</p> <p>Gary Guiles, RN, HFS, Team Leader Rebecca Lara, RN, BA, HFS</p> <p>Acronyms used in this report include:</p> <p>AORN - Association of Perioperative Registered Nurses ASC - Ambulatory Surgery Center CDC - Centers for Disease Control CLIA - Clinical Laboratory Improvement Amendments CPR - Cardiopulmonary Resuscitation CRNA - Certified Registered Nurse Anesthetist DA - Dental Assistant EMS - Emergency Medical Services ETT - Endotracheal Tube GA - General Anesthesia GB - Governing Body H&P - History and Physical HCG - Human Chorionic Gonadotropin IV - Intravenous IP - Infection Preventionist LMA - Laryngeal Mask Airway LPN - Licensed Practical Nurse OR - Operating Room OSHA - Occupational Safety and Health Administration PACU - Post Anesthesia Care Unit PALS - Pediatric Advanced Life Support PIP - Performance Improvement Project PLLC - Professional Limited Liability Company</p>	Q 000	<p>SEE ATTACHED</p> <p>RECEIVED</p> <p>FEB 17 2016</p> <p>FACILITY STANDARDS</p>	

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

[Signature]
MDMBA

TITLE

MEDICAL DIRECTOR

(X6) DATE

02.16.2016

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Q 000	Continued From page 1 PPE - Personal Protective Equipment QA - Quality Assurance QAPI - Quality Assessment Performance Improvement RN - Registered Nurse SISC - Southern Idaho Surgery Center TB - Tuberculosis Immediate Jeopardy was identified at Q64 and the ASC was notified on 12/10/15 at 2:15 PM. The ASC did not submit an Immediate Plan of Correction. On 12/18/15 at 3:40 PM, the ASC submitted a plan which stated the ASC would suspend seeing patients, effective 12/21/15 at 6:00 PM, while they continued to resolve the circumstance which resulted in the Immediate Jeopardy. On 12/24/15 at 11:55 AM, the ASC submitted an acceptable Plan of Correction, which alleged the circumstance which resulted in the Immediate Jeopardy would be resolved as of 12/29/15 at 8:00 AM. On-site verification of the plan's implementation was completed by the survey team on 12/29/15 at 2:25 PM.	Q 000			
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.	Q 040			

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Q 040	Continued From page 2 This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of meeting minutes and policies, it was determined the ASC failed to ensure the Governing Body provided oversight and supervision necessary to ensure all patients of the ASC received safe and appropriate care. The Governing Body failed to assume responsibility for determining, implementing, and monitoring policies. This resulted in a lack of operational direction for ASC staff and the implementation of practices that placed the health and safety of patients at risk. This had the potential to impact all patients receiving services at the facility. The findings include: 1. Two Governing Body meeting minutes were documented between 12/01/14 and 12/08/15. They were dated 1/12/15 and 12/08/15. The 12/08/15 meeting was held after the survey was initiated. The 1/12/15 Governing Body meeting minutes stated in the "Old Business" section that the "cleaner" and the bookkeeper were terminated and new staff was hired. The minutes also listed other personnel changes and stated new dentists were granted privileges and staff received flu vaccinations. The "New Business" section of the minutes included staff information and changes and stated the Christmas party went well. Attached to the minutes was a "GB/Credentialing Committee" meeting note, dated 1/16/15, that listed 15 dentists who were approved for privileges. No mention of the ASC's provision of care and services, actions by the Governing Body, or future	Q 040			

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Q 040	<p>Continued From page 3 plans were documented.</p> <p>The 12/08/15 Governing Body meeting minutes were reviewed. The "Old Business" section contained several items word for word from the "New Business" section of the 1/12/15 meeting minutes. The "New Business" section included staff information and changes and a statement that a CMS survey was in process. The minutes did not mention the ASC's provision of care and services, actions by the Governing Body, or future plans.</p> <p>The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he lived out of state. He stated he came to the ASC every few months. He said he spoke to ASC personnel all of the time. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality. He stated he was also responsible for administrative functions.</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies. When asked 12/09/15 beginning at 10:40 AM, he stated there was no record of his visits to the ASC to perform administrative functions.</p> <p>The Medical Director was interviewed again on 12/10/15 beginning at 2:15 PM. He stated he provided direct oversight to clinical personnel. He stated he provided supervision by telephone and there was no documentation of oversight activities. He stated onsite supervision of staff was not required.</p> <p>The Governing Body failed to ensure sufficient</p>	Q 040			

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Q 040	Continued From page 4 oversight and operational direction over the ASC was provided. 2. Refer to Q41 as it relates to the Governing Body's failure to ensure contracted staff provided services in a safe manner. 3. Refer to Q60 Condition for Coverage: Surgical Services and associated standard level deficiencies as they relate to the Governing Body's failure to ensure the facility's systems related to nursing care and infection control were sufficiently developed, implemented and monitored necessary to ensure the health and safety of all patients receiving care at the facility. 4. Refer to Q80 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive, ongoing, data-driven QAPI program was developed and implemented. 5. Refer to Q100 Condition for Coverage: Environment and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a safe and sanitary environment was provided and maintained. 6. Refer to Q120 Condition for Coverage: Medical Staff and associated standard level deficiencies as they relate to the Governing Body's failure to ensure all practitioners providing care in the facility were accountable to the Governing Body. 7. Refer to Q140 Condition for Coverage: Nursing Service and the associated standard level deficiency as it relates to the Governing	Q 040			

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Q 040	Continued From page 5 Body's failure to ensure nursing staff were provided with sufficient direction and supervision. 8. Refer to Q160 Condition for Coverage: Medical Records and the associated standard level deficiency as it relates to the Governing Body's failure to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented. 9. Refer to Q200 Condition for Coverage: Laboratory and Radiological Services and associated standard level deficiencies as they relate to the Governing Body's failure to ensure diagnostic testing and x-rays were performed in a safe manner. 10. Refer to Q219 Condition for Coverage: Patient Rights and associated standard level deficiencies as they relate to the Governing Body's failure to ensure all patients receiving services at the ASC were fully informed of their rights and that patient rights were upheld. 11. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented, and monitored.	Q 040			
Q 041	416.41(a) CONTRACT SERVICES When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on observations, review of personnel files,	Q 041			

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Q 041	<p>Continued From page 6</p> <p>policy review and interview, it was determined the ASC failed to ensure contracted staff provided services in a safe manner. This failure had the potential to impact all patients receiving care at the ASC and directly impacted 1 of 2 patients (Patient #7) whose care was observed. This resulted in a lack of training and monitoring of CRNA practices necessary to ensure patient health was not compromised. The findings include:</p> <p>1. Patient #7 was a 6 year old male who had 2 teeth extracted and other dental work performed under general anesthesia on 12/09/15. His procedure was observed from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM.</p> <p>a. Patient #7 had a history of Kawasaki Disease when he was 2. Kawasaki Disease is an autoimmune disease in which the medium-sized blood vessels throughout the body become inflamed. It is largely seen in children under 5 years of age. It affects many organ systems, mainly those including the blood vessels, skin, mucous membranes, and lymph nodes. It can seriously affect the heart although Patient #7 did not have a history of cardiac complications.</p> <p>During the pre-operative assessment at 9:55 AM on 12/09/15, Patient #7's mother stated he had experienced a fever of 103 the evening prior to surgery and he seemed ill. The RN took Patient #7's vital signs. His temperature was 99.3. The RN listened to his chest. CRNA then spoke with the parent. She did not listen to Patient #7's chest or physically examine him prior to administering anesthesia.</p>	Q 041			

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Q 041	<p>Continued From page 7</p> <p>CRNAA was interviewed on 12/10/15 at 9:50 AM. She confirmed she did not listen to Patient #7's chest to assess heart and lung sounds. She stated she did not normally listen to patients or physically assess them prior to surgery in order to keep them calm.</p> <p>CRNAA failed to physically assess Patient #7 prior to administering anesthesia.</p> <p>b. During the observation of Patient #7's care on 12/09/15, CRNAA was not observed to adhere to standard infection control practices, as follows:</p> <p>Patient #7 was anesthetized at 10:30 AM. The dentist was not in the room. Patient #7 was attended by CRNAA and DA B. While DA B was applying sealants to Patient #7's teeth, CRNAA took her gloves off, attached an IV to a pump, then donned new gloves. She did not perform hand hygiene during this time.</p> <p>CRNAA wrote on a paper chart, touched her face multiple times, then sat with her gloved hands folded. At 10:58 AM, CRNAA charted on paper and then dropped her pen on the floor. She picked up the pen, charted again, and touched her face. At 11:03 AM, CRNAA was observed to sit on her gloved hands.</p> <p>Dentist B and DA B entered the room at 11:05 AM. CRNAA charted and touched her face. She removed her gloves, adjusted the IV pump, drew up Propofol (an IV anesthetic) and placed the syringe on the blanket on top of Patient #7. She then sat with her hands between her legs. At 11:14 AM she got a bottle of an inhalation anesthetic and placed it on the anesthesia machine. She replaced the Propofol syringe on</p>	Q 041			

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Q 041	<p>Continued From page 8 the IV pump and sat on her hands.</p> <p>At 11:18 AM, CRNA A picked up her cell phone and touched the screen. She picked up a rag and wiped at something below waist level. At 11:22 AM, CRNA A picked up a small computer from a handbag and typed on it. At 11:27 AM, she adjusted the pump on the anesthesia machine. She then put on gloves and sat with her hands between her legs.</p> <p>The procedure ended at 11:29 AM. CRNA A got a wet wipe from a container on her cart and began wiping down monitor cables and tubes. CRNA A then suctioned Patient #7 and removed his breathing tube. She removed the positioning blocks from under Patient #7, wiped them down and turned Patient #7 on his side. She wrote on Patient #7's chart and made a phone call. After the call, CRNA A removed the Propofol from the IV pump and cleaned the cable and tubing. Then she removed her gloves and cleaned her hands with an alcohol based product.</p> <p>CRNA A was interviewed on 12/09/15 beginning at 11:40 AM. She stated she did not know if the ASC had a hand hygiene policy or not. She stated she had performed hand hygiene once following the intubation of Patient #7. She stated she typically performed hand hygiene 2 times, after intubating the patient and when the procedure was over. She stated she did not touch patients during a procedure, only their blankets and tubes.</p> <p>Section 6 "Patient Care Policies" of the ASC's Infection Prevention Manual included a policy, dated July 2011, which was titled "Hand Hygiene." The policy stated "Handwashing [sic]/hand</p>	Q 041			

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Q 041	<p>Continued From page 9</p> <p>hygiene is generally considered the most important single procedure for preventing healthcare-associated infections." The policy stated hand washing was to occur "When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, and in case of a patient with a spore-forming organism (e.g., C. difficile), after going to the restroom, and before eating, perform hand hygiene with either a non-antimicrobial soap and water or an antimicrobial soap and water."</p> <p>The policy also stated waterless hand washing products could be used. The policy stated "If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under 'Handwashing' [sic] above."</p> <p>The policy did not include information related to other time points or circumstances in which hand hygiene was to be performed.</p> <p>The CDC "Guidelines for Hand Hygiene in Health-Care Settings" and "Hand Hygiene Basics" information, accessed via the CDC website www.cdc.gov on 12/11/15, stated "Healthcare providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients including: before patient contact; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before invasive procedures; and after removing gloves (wearing gloves is not enough to prevent the transmission of pathogens in healthcare settings)." The guidelines stated hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, was</p>	Q 041			

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Q 041	<p>Continued From page 10</p> <p>recommended including when hands were not visibly soiled, after contact with patient's intact skin, when moving from a contaminated body site to a clean body site, and after contact with inanimate objects in the immediate vicinity of the patients.</p> <p>CRNA A's personnel file was reviewed. The file documented she had been contracted to work at the ASC on 10/23/12. Her file did not include documentation of orientation training, including the use of emergency equipment, infection control, or any other ongoing inservice training. There was no evidence of self-evaluation forms, or observational compliance checklists, or a competency or performance evaluation.</p> <p>Further, the ASC contracted with 1 other CRNA (CRNA B contracted on 7/15/13). CRNA B's file did not include documentation of orientation training, including the use of emergency equipment, infection control, or any other ongoing inservice training. There was no evidence of self-evaluation forms, or observational compliance checklists, or a competency or performance evaluation.</p> <p>On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide evidence of any infection control training.</p>	Q 041			

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Q 041	Continued From page 11 The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked about staff infection control training and monitoring, he stated there was no infection control training program for staff. When asked which nationally recognized infection control guidelines the ASC was following, he stated the facility did not follow any specific, nationally recognized infection control guidelines. The Medical Director was interviewed on 12/10/15 beginning at 2:15 PM. He stated he provided direct oversight to clinical personnel. He stated he provided supervision by telephone and there was no documentation of oversight activities. He stated onsite supervision of staff was not required. The ASC failed to ensure contracted staff were provided with initial and ongoing training, and monitoring and oversight necessary to ensure safe care was provided to patients.	Q 041			
Q 060	416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC This CONDITION is not met as evidenced by: Based on observations, staff interview, and record review, it was determined the ASC failed to ensure the facility's systems related to nursing care and infection control were sufficiently	Q 060			

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Q 060	Continued From page 12 developed, implemented and monitored necessary to ensure the health and safety of all patients receiving care at the facility. These systemic failures placed patients in serious and immediate jeopardy from the potential to experience serious harm, impairment, or death as a result of procedural complications and/or infection. The findings include: 1. Refer to Q61 as it relates to the ASC's failure to ensure a comprehensive assessment was performed prior to the administration of anesthesia. 2. Refer to Q64 as it relates to the ASC's failure to ensure facility staff were trained and equipment and supplies were kept in a sanitary manner necessary to ensure procedures were performed in a safe environment.	Q 060			
Q 061	416.42(a)(1) ANESTHETIC RISK AND EVALUATION A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. This STANDARD is not met as evidenced by: Based on observation, review of policies and records, and interview, it was determined the ASC failed to ensure a comprehensive assessment was performed prior to the administration of anesthesia for 1 of 2 patients (Patient #7) whose procedures were observed. The failure to perform a comprehensive assessment resulted in an increased risk of patient safety during the procedure. The findings include:	Q 061			

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Q 061	<p>Continued From page 13</p> <p>1. Patient #7 was a 6 year old male who had 2 teeth extracted and other dental work performed under general anesthesia on 12/09/15. His procedure was observed from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM.</p> <p>Patient #7 had a history of Kawasaki Disease when he was 2. Kawasaki Disease is an autoimmune disease in which the medium-sized blood vessels throughout the body become inflamed. It is largely seen in children under 5 years of age. It affects many organ systems, mainly those including the blood vessels, skin, mucous membranes, and lymph nodes. It can seriously affect the heart although Patient #7 did not have a history of cardiac complications.</p> <p>During the pre-operative assessment at 9:55 AM on 12/09/15, Patient #7's mother stated he had experienced a fever of 103 the evening prior to surgery and he seemed ill. The RN took Patient #7's vital signs. His temperature was 99.3. The RN listened to his chest. CRNA A then spoke with the parent. Neither the CRNA nor a physician listened to Patient #7's chest or physically examined him prior to administering anesthesia.</p> <p>CRNA A was interviewed on 12/10/15 at 9:50 AM. She confirmed she did not listen to Patient #7's chest to assess heart and lung sounds. She stated she did not normally listen to patients or physically assess them prior to surgery in order to keep them calm.</p> <p>The facility failed to ensure a comprehensive assessment was performed by a qualified practitioner prior to the administration of</p>	Q 061		

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Q 061	Continued From page 14 anesthesia.	Q 061			
Q 064	416.42 STANDARD LEVEL TAG FOR SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to develop, implement, and monitor systems to address the training of staff and monitoring of facility practices for nursing care and infection control. These failures directly impacted 1 of 2 patients (Patient #7) whose care was observed and had the potential to impact all patients receiving care at the facility. These systemic failures resulted in the inability of the facility to ensure patient safety and placed patients in serious and immediate jeopardy for the potential to experience serious harm, impairment, or death as a result of procedural complications and/or infection. The findings include: Policy 2.300 "Duties of Medical Director," not dated, stated the Medical Director would "Oversee all medical and nursing responsibilities at the ASC." Policy 3.300 "Organization of Nursing Personnel," not dated, stated "Nursing personnel will provide comprehensive nursing care to outpatients under the direction of the Medical Director." No policy specified how oversight of medical and	Q 064			

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Q 064	<p>Continued From page 15</p> <p>nursing services would occur. No policy specified a process for the day to day supervision of care activities at the ASC.</p> <p>The RN was interviewed on 12/10/15 at 2:00 PM. She stated the ASC did not have a Director of Nursing. She stated the Office Manager was her supervisor. She stated if she had a problem or needed to report to someone, she would tell the Office Manager.</p> <p>The Office Manager was interviewed on 12/10/15 at 2:00 PM. She stated she did not have a clinical background. She stated no person at the ASC was responsible for supervision of clinical services. She stated she could call the Medical Director if there was a problem.</p> <p>The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he lived out of state. He stated he came to the ASC every few months. He said he spoke to ASC personnel all of the time. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The Medical Director was interviewed again on 12/09/15 beginning at 10:40 AM. He stated there was no record of his visits to the ASC to perform administrative functions.</p> <p>The "Infection Prevention Manual SISC 2011" was reviewed. The manual contained 10 sections. Section 1 "Infection Prevention Program" included a policy titled "Infection Prevention Program Overview," dated July 2011. The policy stated "The Governing Body is ultimately responsible for the Infection Prevention Program...Responsibility is delegated to the</p>	Q 064		

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Q 064	<p>Continued From page 16</p> <p>Infection Preventionist (IP) to carry out the daily functions of the Infection Prevention Program. Those functions are described in the IP job description..." The policy documented the IP was also the ASC's Medical Director.</p> <p>The Infection Prevention Manual included the IP job description. The job description stated the IP had multiple responsibilities which included, but were not limited to, the following:</p> <ul style="list-style-type: none"> - "Does on-going monitoring of healthcare-associated infections." - "Identifies infection prevention problems and makes recommendations for corrective action." - "Serves as a resource for all departments and personnel." - "Initiates, reviews and revises infection prevention policies and procedures." - "Provides educational offerings for orientation and on-going in-services." - "Participates in quality improvement activities." - "Participates in short and long range planning for the infection prevention department." <p>The policy and job description did not include information regarding how the IP could "...carry out the daily functions of the Infection Prevention Program," as stated in the "Infection Prevention Program Overview" policy, or how the IP was to provide sufficient oversight of the infection control program through off-site monitoring.</p> <p>The Medical Director was interviewed on 12/10/15 beginning at 2:15 PM. He stated he provided direct oversight to clinical personnel. He stated he provided supervision by telephone and there was no documentation of oversight activities. He stated onsite supervision of staff</p>	Q 064			

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Q 064	<p>Continued From page 17 was not required.</p> <p>However, patient care and infection control practices were not performed in accordance with ASC policy, nationally recognized standards of practice and manufacturer's instructions during observations conducted on 12/08/15, 12/09/15 and 12/10/15. These systemic failures resulted in the inability of the facility to ensure patient safety and placed all patients at risk of serious and immediate harm, impairment and/or death due to potential procedural complications and/or infection, as follows:</p> <p>1. Patient #7 was a 6 year old male who had 2 teeth extracted and other dental work performed under general anesthesia on 12/09/15. His procedure was observed from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM.</p> <p>Patient #7 had a history of Kawasaki Disease when he was 2. Kawasaki Disease is an autoimmune disease in which the medium-sized blood vessels throughout the body become inflamed. It is largely seen in children under 5 years of age. It affects many organ systems, mainly those including the blood vessels, skin, mucous membranes, and lymph nodes. It can seriously affect the heart although Patient #7 did not have a history of cardiac complications.</p> <p>During the pre-operative assessment at 9:55 AM on 12/09/15, Patient #7's mother stated he had experienced a fever of 103 the evening prior to surgery and he seemed ill. The RN took Patient #7's vital signs. His temperature was 99.3. The RN listened to his chest. CRNA then spoke with the parent. She did not listen to Patient #7's</p>	Q 064		
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Q 064	<p>Continued From page 18</p> <p>chest or physically examine him prior to administering anesthesia.</p> <p>CRNA A was interviewed on 12/10/15 at 9:50 AM. She confirmed she did not listen to Patient #7's chest to assess heart and lung sounds. She stated she did not normally listen to patients or physically assess them prior to surgery in order to keep them calm.</p> <p>CRNA A failed to physically assess Patient #7 prior to administering anesthesia.</p> <p>CRNA A's personnel file was reviewed. The file documented she had been contracted to work at the ASC on 10/23/12. Her file did not include documentation of orientation training, including the use of emergency equipment or any other ongoing inservice training. There was no evidence of a competency or performance evaluation.</p> <p>Further, the ASC contracted with 1 other CRNA (CRNA B contracted on 7/15/13) and employed 1 RN (hired on 1/26/12), and 1 LPN (hired on 11/12/14). The nurses' personnel files were reviewed. None of the nurses' files included documentation of orientation training, including the use of emergency equipment or any other ongoing inservice training. There was no evidence that a competency or a clinically based performance evaluation had been completed for any of the nurses.</p> <p>The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated around 16 dentists performed procedures at the ASC. He stated each dentist had their own dental assistants who assisted them with procedures</p>	Q 064		

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Q 064	<p>Continued From page 19</p> <p>and performed other duties such as caring for that dentist's instruments. He stated the ASC did not have a formal relationship with the assistants. He stated they were not employees and they had not been granted privileges by the Governing Body. He stated the dentists who employed them were responsible for their actions. He stated the ASC was not responsible for their actions.</p> <p>The ASC failed to ensure nursing personnel was provided with training, oversight and monitoring necessary to ensure each patient was provided with safe care.</p> <p>2. During the observation of Patient #7's care on 12/09/15, CRNAA and DA B were not observed to adhere to standard infection control practices, as follows:</p> <p>Patient #7 was anesthetized at 10:30 AM. The dentist was not in the room. Patient #7 was attended by CRNAA and DA B. Dental x-rays were taken by DA B. After taking the x-rays, DA B changed her gloves but did not perform hand hygiene. She suctioned Patient #7, then cleaned and put sealants on his teeth. During this procedure, the suction catheter slipped off the table and came to rest on her scrub pants. It stayed there for approximately 1 minute. She used it again to suction the child without cleaning it. She then removed her gloves and left the room. She did not perform hand hygiene.</p> <p>While DA B was applying the sealants, CRNAA took her gloves off, attached an IV to a pump, then donned new gloves. She did not perform hand hygiene during this time. CRNAA wrote on a paper chart, touched her face multiple times, then sat with her gloved hands folded. At 10:58</p>	Q 064			

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Q 064	<p>Continued From page 20</p> <p>AM, CRNAA charted on paper and then dropped her pen on the floor. She picked up the pen, charted again, and touched her face. At 11:03 AM, CRNAA was observed to sit on her gloved hands. Dentist B and DA B entered the room at 11:05 AM. CRNAA charted and touched her face. She removed her gloves, adjusted the IV pump, drew up Propofol (an IV anesthetic) and placed the syringe on the blanket on top of Patient #7. She then sat with her hands between her legs. At 11:14 AM she got a bottle of an inhalation anesthetic and placed it on the anesthesia machine. She replaced the Propofol syringe on the IV pump and sat on her hands. At 11:18 AM, CRNAA picked up her cell phone and touched the screen. She picked up a rag and wiped at something below waist level. At 11:22 AM, CRNAA picked up a small computer from a handbag and typed on it. At 11:27 AM, she adjusted the pump on the anesthesia machine. She then put on gloves and sat with her hands between her legs.</p> <p>The procedure ended at 11:29 AM. CRNAA got a wet wipe from a container on her cart and began wiping down monitor cables and tubes. CRNAA then suctioned Patient #7 and removed his breathing tube. She removed the positioning blocks from under Patient #7, wiped them down and turned Patient #7 on his side. She wrote on Patient #7's chart and made a phone call. After the call, CRNAA removed the Propofol from the IV pump and cleaned the cable and tubing. Then she removed her gloves and cleaned her hands with an alcohol based product. She was not observed to change her gloves or perform hand hygiene during the observation until the procedure was over.</p>	Q 064			

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Q 064	<p>Continued From page 21</p> <p>CRNA A was interviewed on 12/09/15 beginning at 11:40 AM. She stated she did not know if the ASC had a hand hygiene policy or not. She stated she had performed hand hygiene once following the intubation of Patient #7. She stated she typically performed hand hygiene 2 times, after intubating the patient and when the procedure was over. She stated she did not touch patients during a procedure, only their blankets and tubes.</p> <p>Section 6 "Patient Care Policies" of the ASC's Infection Prevention Manual included a policy, dated July 2011 which was titled "Hand Hygiene." The policy stated "Handwashing [sic]/hand hygiene is generally considered the most important single procedure for preventing healthcare-associated infections." The policy stated hand washing was to occur "When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, and in case of a patient with a spore-forming organism (e.g., C. difficile), after going to the restroom, and before eating, perform hand hygiene with either a non-antimicrobial soap and water or an antimicrobial soap and water."</p> <p>The policy also stated waterless hand washing products could be used. The policy stated "If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under 'Handwashing' [sic] above."</p> <p>The policy did not include information related to other time points or circumstances in which hand hygiene was to be performed.</p>	Q 064		

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Q 064	<p>Continued From page 22</p> <p>The CDC "Guidelines for Hand Hygiene in Health-Care Settings" and "Hand Hygiene Basics" information accessed via the CDC website www.cdc.gov on 12/11/15 stated "Healthcare providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients including: before patient contact; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before invasive procedures; and after removing gloves (wearing gloves is not enough to prevent the transmission of pathogens in healthcare settings)." The guidelines stated hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, was recommended including when hands were not visibly soiled, after contact with patient's intact skin, when moving from a contaminated body site to a clean body site, and after contact with inanimate objects in the immediate vicinity of the patients.</p> <p>The ASC failed to ensure its hand hygiene policy was sufficiently developed and implemented.</p> <p>Additionally, the 2015 Edition AORN Guidelines for Perioperative Practice, state "All individuals who enter the semi-restricted and restricted areas should wear scrub attire that has been laundered at a health care-accredited laundry facility or disposable scrub attire provided by the facility and intended for use within the perioperative setting. Using health care accredited laundry facilities is recommended because they meet industry standards. Reusable scrub attire should be left at the health care facility for laundering."</p> <p>However, an undated ASC policy, titled "Washing of Scrubs and Patient Gowns, Blankets, etc., "</p>	Q 064		

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Q 064	<p>Continued From page 23</p> <p>stated "All linen will be washed in the ASC washing machine in warm water (>120 degrees F)... Either the dental assistant or the registered nurse will be responsible for laundry, depending on the workload."</p> <p>During a tour of the ASC on 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program as it related to laundering of ASC linens. The laundry room was observed during the tour, which contained a household style washer and dryer. The Office Manager stated patient gowns, blankets and staff scrubs were laundered at the ASC. She stated the contracted housekeeping staff performed laundry duties, but that other ASC staff helped with laundry duties as well. When asked if a log was maintained that included temperature monitoring of water and the washing machine and dryer temperature, she stated she was not aware of such a log. When asked what type of laundry detergent was used, she stated "regular laundry detergent." When asked if training for how to launder ASC linens was provided, the Office Manager stated she was not aware of any such training.</p> <p>Without appropriate equipment, detergent, temperature monitoring, and staff training, the ASC would not be able to ensure all linens, including the blanket used by Patient #7, were appropriately laundered.</p> <p>The personnel files of CRNA A, CRNA B, the RN and the LPN were reviewed. None of the nurses' files included documentation of hand hygiene or other initial and ongoing infection control training.</p> <p>However, Section 3 of the ASC's Infection</p>	Q 064		

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Q 064	<p>Continued From page 24</p> <p>Prevention Manual was titled "Infection Prevention Education." The "Infection Prevention Education" section included a July 2011 policy titled "Infection Prevention Orientation and Inservices." The policy stated "All new personnel will attend an orientation program that addresses infection prevention including basic principles and the infection control policies and procedures of this facility. OSHA bloodborne pathogens regulations and tuberculosis will be included."</p> <p>The policy stated "All personnel will attend at least one mandatory infection prevention update per year. OSHA bloodborne pathogens regulations and TB will be included as well as other infection prevention issues of importance to the facility." The policy stated the IP "...will conduct one-on-one training with personnel as practices are observed and corrections or changes in practice are needed."</p> <p>The policy stated records were to be maintained which included the date and time of training, the instructor and their qualifications, a content outline and the participants and their department.</p> <p>The "Infection Prevention Education" section of the Infection Prevention Manual also included a July 2011 policy titled "Infection Prevention Orientation Outline." The outline included general infection prevention principles (hand hygiene), employee health (work restrictions for communicable diseases, reporting exposure to infectious diseases, vaccines and TB skin tests), patient infections (prevention of infections, recognition and reporting), standard precautions and other barrier precautions (Employee protection against bloodborne pathogens, OSHA regulations, CDC recommendations), standard</p>	Q 064		

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Q 064	<p>Continued From page 25</p> <p>precaution policy, components of standard precautions (barriers for protection, safe sharps devices, biomedical waste, linen handling), transmission-based precautions (airborne, droplet and contact), and additional infection concepts (standard precautions/transmissions based precautions, principles of asepsis including clean and sterile technique, and separation of clean and dirty procedures).</p> <p>The policy also included "Compliance Monitoring" which involved staff self-evaluations and observation of practices. The corresponding "Orientation Checklist," a policy titled "OSHA Bloodborne Pathogens Standard Employee Training Outline," and a policy titled "Tuberculosis Employee Training Outline" all dated July 2011, were included in Section 3 of the ASC's Infection Prevention Manual.</p> <p>Further, Section 4 of the Infection Prevention Manual, titled "Isolation," included a July 2011 policy titled "Compliance Monitoring." The policy stated "Each employee providing direct patient care may be given self-evaluation forms to be completed annually. These forms will be reviewed by the Infection Preventionist and any problems will be discussed with the individual employee." The policy stated "Each new employee providing direct patient care will be observed during orientation. Specific items related to compliance with infection prevention policies will be included on the evaluation form. Specific compliance issues will be discussed with the individual employee involved..."</p> <p>Immediately behind the policy was a July 2011 "Staff Self-Evaluation Of Infection Control Practices" form which stated it was "To be done</p>	Q 064		

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Q 064	<p>Continued From page 26</p> <p>yearly when job appraisal is done." Section 4 of the Infection Control Manual also included a July 2011 checklist titled "Monitoring Compliance with Infection Prevention Policies by Observation" which also stated it was "To be done yearly when job appraisal is done."</p> <p>Additionally, Section 10 of the Infection Prevention Manual titled "Performance Improvement" included a July 2011 policy titled "Supervisory Review." The policy stated "Supervisory review will be conducted to assess compliance with infection prevention standards. The frequency and type of review will be determined based on the scope of problems identified and the effectiveness of corrective measures..." Section 10 included corresponding checklists for infection prevention, cleanliness and sanitation, sharps disposal, and standard precautions, all dated July 2011.</p> <p>The personnel files of CRNA A, CRNA B, the RN and the LPN did not include any of the training documentation, self-evaluation forms, or observational compliance checklists specified in the ASC's Infection Prevention Manual.</p> <p>On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide evidence of any infection control training.</p>	Q 064		
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Q 064	Continued From page 27 When asked about the DAs, the Office Manager stated the ASC did not maintain complete personnel files for the DAs. The Office Manager said the dentists, who had agreements to perform procedures in the ASC, employed their own DAs. She stated the DAs were not considered employees of the ASC, nor were they considered contracted employees, they were employed by each individual dentist and each dentist was responsible for the performance of his or her own DA. The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked about staff infection control training and monitoring, he stated there was no infection control training program for staff. When asked which nationally recognized infection control guidelines the ASC was following, he stated the facility did not follow any specific, nationally recognized infection control guidelines. The ASC failed to ensure comprehensive infection control training based on nationally recognized infection control guidelines was provided to all staff and that infection control practices were monitored, necessary to ensure patient risk of serious infection was minimized. 3. During a tour of the ASC on 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed about dental instrument reprocessing/sterilization in the ASC and those responsible for the procedure. She stated the ASC's RN and LPN, and the DAs were responsible for reprocessing instruments. The Office Manager said the dentists, who had	Q 064			

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Q 064	<p>Continued From page 28</p> <p>agreements to perform procedures in the ASC, employed their own DAs and that DAs processed instruments only for the dentist, by whom they were employed. The Office Manager said the DAs used the ASC's equipment and supplies to reprocess instruments, then packaged and stored instruments in carts assigned to each, individual dentist.</p> <p>When asked about the credentialing process used to determine the DAs acceptable scope of practice in the facility, the Office Manager stated the ASC did not maintain credentialing files for the DAs. She stated each dentist was responsible for the performance of his or her own DA.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. The ASC's infection control program, as it related to the instrument sterilization process, was discussed. The Medical Director stated he was responsible for infection control in the ASC. He stated the ASC nurses were responsible for reprocessing only two small pieces (blades) of the laryngoscopes (a tubular scope equipped with a light and mirrors used for examination of the larynx) used by the CRNAs when intubating patients. The Medical Director also said each DA reprocessed/sterilized instruments only for the dentist by whom they were employed.</p> <p>Observations of reprocessing were conducted on 12/09/15 and 12/10/15. Reprocessing was not completed in accordance with manufacturer's instructions and ASC policies, as follows:</p> <p>The ASC used a SciCan STATIM 2000/5000 G4</p>	Q 064			

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Q 064	<p>Continued From page 29</p> <p>Cassette Autoclave for reprocessing instruments. The manufacturer instructions for the autoclave stated the autoclave was designed to provide complete sterilization for unwrapped and wrapped instruments using steam sterilization.</p> <p>a. The autoclave manufacturer's instructions stated it included a "Process Enforced Usage" mechanism which, when activated, required employees to enter a personal identification number at the beginning and at the end of each cycle. The instructions stated "Any user can stop a cycle and remove the cassette even with Process Enforced usage ON [sic]. However, the cycle data will record that an unauthorized user has stopped the cycle and/or removed the cassette."</p> <p>During observations of reprocessing conducted on 12/09/15, beginning at approximately 11:15 AM, and on 12/10/15, at approximately 1:00 PM, personal identification numbers were not observed to be used.</p> <p>Section 6 titled "Patient Care Policies," of the ASC's Infection Prevention Manual, included a July 2011 "Monitoring of Sterilizers" policy. The policy stated the facility shall "Monitor each load with mechanical (e.g. time, temperature, pressure) and chemical (internal and external) indicators."</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a sterilization log that included documentation of each item autoclaved, a lot number, duration, temperature, the date, the results of the autoclaving, and the name of the staff who had run the load, the RN stated she was not aware of</p>	Q 064		

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Q 064	<p>Continued From page 30</p> <p>such a log. She stated she was only aware of a log which was used to document the use of biologic indicators.</p> <p>b. The autoclave instructions included a section for "Preparing and Loading Instruments." The instructions stated "Before loading any instruments into the STATIM, consult the manufacturer's reprocessing instructions."</p> <p>The ASC's dentists used various instruments from various manufacturers. For example, when asked, on 12/11/15 at approximately 9:00 AM, the Office Manager stated Dentists A and B used Hu-Friedy instruments and Dentist C used Henry Schein Instruments.</p> <p>The instrument manufacturers' instructions were accessed and reviewed, on 12/11/15, via the Hu-Friedy manufacturer website, www.hu-friedy.com, and the Henry Schein manufacturer website, www.henryschein.com. Both sets of instructions included information related to reprocessing the instruments.</p> <p>i. The Hu-Friedy instrument instructions stated before processing the instruments they must be pre-treated to remove impurities and organic matter. The Hu-Friedy instrument instructions stated a detergent was to be selected that was compatible with the instruments and to "Use an enzymatic cleaner...or precleaning product ... For other cleaning agents and disinfectants the instructions of the manufacturer must be observed."</p> <p>The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a</p>	Q 064			

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Q 064	<p>Continued From page 31</p> <p>tepid or lukewarm water or detergent bath for at least 10 minutes...Note: The use of enzyme detergents is preferred as they help to break up organic soil more readily and rapidly than do conventional detergents."</p> <p>Section 6 titled "Patient Care Policies," of the ASC's Infection Prevention Manual, included a July 2011 "Approved Sterilizing, Disinfecting and Hand Hygiene Agents" form. The form stated "The following agents have been approved for use in this facility. Note: Follow manufacturer's instructions in use of all products." The form included sections for approved sterilizing agents, high level disinfectants for instruments/equipment, disinfectants for environmental cleaning, etc. The form was blank. No documentation of approved products was present on the form. However, the ASC's policy and procedure manual, dated July 2013, included a "Cleaning Agents Approved by the ASC" policy which stated "Instrument cleaners: A specific cleaner/decontaminate shall be used to wash dirty instruments, such as Enzy-Clean."</p> <p>The policy did not include information related to ensuring cleaning agents were compatible with and used per the dental instrument manufacturers' instructions.</p> <p>Reprocessing was observed on 12/09/15 beginning at approximately 11:15 AM. DA B, the DA for Dentist B, who used Hu-Friedy instruments, was interviewed and observed while preparing dental instruments for reprocessing.</p> <p>A large container of liquid detergent, McKesson Low Suds Liquid Instrument Detergent, was observed on the counter top, beside the sink.</p>	Q 064		

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Q 064	<p>Continued From page 32</p> <p>When asked when the detergent was used, DA B stated the detergent was used for pre-soaking. She said the nurses in the ASC prepared the soaking solution in the morning, before surgical cases began.</p> <p>During a second reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated she placed the dirty instruments in a tub of detergent solution that had been prepared by the ASC nurses. When asked, DA C stated she had never seen any manufacturer's guidelines for any of the cleaning solutions. She said she thought most of the cleaning solutions were "ok to use on any manufacturer's dental instruments, but the cleaning process might be different."</p> <p>During an interview with the ASC RN on 12/09/15 at approximately 2:00 PM, she stated she had not received any type of training specific to infection control or education about the manufacturer's guidelines for any of the chemicals used in the instrument sterilization process. She stated she prepared the detergent solution for pre-soaking dirty instruments. She stated "I use 2-3 pumps of the detergent, in the tub, and then I add some water." When asked, she confirmed she did not measure the amount of detergent or water that was added to the soaking tub.</p> <p>The McKesson Low Suds Liquid Instrument Detergent label stated "Pour product into basin or sink at a dilution of 1/8 ounce to 2 ounces of product per 1 gallon of water." Further, the Material Safety Data Sheet for the McKesson Low Suds Liquid Instrument Detergent stated the pH concentrate was 9.0 to 10.0.</p>	Q 064			

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Q 064	<p>Continued From page 33</p> <p>The Hu-Friedy instrument manufacturer's instructions stated "Detergents or disinfectants containing the following substances must not be used: strong alkalines (> pH 9), strong acids (< pH 4)..."</p> <p>Without appropriate mixing and testing, the ASC could not ensure the pH level of the cleaning solution was compatible with the Hu-Friedy instruments. The ASC failed to ensure the cleaning detergent was used in accordance with the manufacturer's instructions and that chemical concentration was monitored.</p> <p>ii. The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a tepid or lukewarm water or detergent bath for at least 10 minutes..."</p> <p>During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated the instruments would remain in the tub of solution prepared by the ASC nurse until she had time to scrub them with a brush under running water.</p> <p>The ASC failed to ensure the soak time was monitored to ensure soaking was completed in a manner consistent with the Henry Schein instrument instructions.</p> <p>iii. During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was observed to scrub all instruments in accordance with the Hu-Friedy</p>	Q 064		

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Q 064	<p>Continued From page 34</p> <p>instrument manufacturer instructions. She then sprayed the instruments with a disinfectant (CaviCide), and placed the instruments in soft, pliable packages. DA B then placed the packages containing the instruments on a tray and placed the tray in the autoclave.</p> <p>When asked how long the instruments would process in the autoclave, DA B stated the sterilizer could be set to run with instruments that had been covered, as she had done by placing the instruments in packages, or set to run for a shorter period of time when instruments were processed uncovered. DA B said when instruments were processed uncovered, the processing time was shorter. She said the covered method was preferred, and that she only processed uncovered instruments when the dentist did not have sufficient instruments to conduct the next case.</p> <p>However, the Hu-Friedy instructions stated the instruments were to be "...packaged for sterilization in material suitable for steam sterilization. The material must be sufficient to protect the instruments and the packaging against mechanical damage."</p> <p>The Hu-Friedy instrument manufacturer's instructions did not include information related to the placement of unwrapped instruments into an autoclave.</p> <p>Further, the McKesson Low Suds Liquid Instrument Detergent label stated "Wrap instruments and proceed with further processing." Additionally, the ASC's Infection Prevention Manual included Section 7, titled "Department Policies." Section 7 included a July 2011 policy</p>	Q 064		

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Q 064	<p>Continued From page 35 titled "Central Sterile Processing." The policy stated items were to be "...cleaned, rinsed and wrapped for sterilization."</p> <p>The ASC failed to ensure instruments were packaged for sterilization in accordance with the instrument manufacturers' instructions, the cleaning detergent instructions and the ASC's policy.</p> <p>iv. The Hu-Friedy instructions stated once sterilization and drying was completed, sterilization could only be maintained if the instruments remained packaged or wrapped to prevent exposure to micro-organisms, and if stored in a dry and dust free clean area.</p> <p>On the morning of 12/10/15 at approximately 8:00 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, asked the surveyor to review her method of storing instruments. In one of the procedure rooms, sterilized instruments had been prepared for an early morning procedure on 12/10/15. The sterilized instruments were unpackaged, arranged on trays and covered with a paper drape. DA B stated if there were early morning procedures scheduled it was her practice to prepare the instruments the prior evening, leaving them as viewed, overnight. DA B confirmed that housekeeping staff cleaned the building, including procedure rooms, after hours each evening. DA B agreed she had no way to verify that the instruments remained sterile until the following morning. She indicated she would no longer use the practice and planned to store the sterilized, packaged instruments in Dentist B's cart and set them up the following morning.</p>	Q 064		

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Q 064	<p>Continued From page 36</p> <p>The ASC failed to ensure sterilized instruments were not compromised prior to use.</p> <p>c. The autoclave manufacturer's instructions included a section for "Routine Monitoring." The instructions stated "Chemical process indicators [a means to assess physical conditions, such as temperature, during the sterilization process] suitable for steam sterilizers should be included in or on each package or load being sterilized. In addition, the weekly use of biological indicators, [a means of monitoring the sterilization process for the presence of resistant microorganisms] which allows you to ascertain whether instruments have been exposed to sterilization condition, is recommended..."</p> <p>During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was asked how often she ran biologic indicators and chemical indicators. She stated she did not do so because the ASC nurses were responsible for running indicators.</p> <p>During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, was asked if she used biological or chemical indicators. She stated she did not and indicated the ASC nurses were responsible for running indicators.</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a chemical and biological indicator log, the RN stated she ran biological indicators one time per month. She then presented a notebook that contained pages titled "STERILIZER." The pages</p>	Q 064			

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Q 064	<p>Continued From page 37</p> <p>contained a column for the date and a column for the person's initials. The last 10 dates, accompanied by a nurse's initials, were as follows: 1/23, 3/23, 4/23, 5/23, 6/22, 7/22, 8/31, 9/28, 10/22 and 11/23. The month of February was missing, and the year was not included on the dates.</p> <p>Biological and chemical indicators were not used in accordance with the autoclave manufacturer's instructions.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. He stated the nurses were responsible for running biologic indicators once monthly. When asked whether chemical indicators were included with each tray of instruments, the Medical Director stated chemical indicators were not necessary.</p> <p>However, the ASC's Patient Care Policies, dated July 2011, included a policy titled "Monitoring of Sterilizers." The policy stated the facility shall "Monitor each load with...chemical (internal and external) indicators." The policy also stated "Use biological indicators to monitor the effectiveness of sterilizers at least weekly..."</p> <p>The ASC failed to ensure biological and chemical indicators were used in accordance with the ASC's policy.</p> <p>d. The ASC's July 2011 policy titled "Central Sterile Processing" stated "For safety reasons, only an adequately instructed person may operate sterilizer [sic]."</p> <p>On 12/09/15 at approximately 11:15 AM DA B</p>	Q 064		

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Q 064	<p>Continued From page 38</p> <p>was asked if the ASC provided training related to instrument reprocessing/sterilization and/or other infection control training. She stated she was not aware of any training. She said she used similar equipment and cleaning solutions in the dentist office where she was employed and was therefore comfortable with the process at the ASC.</p> <p>On 12/10/15 at approximately 1:00 PM, DA C was asked whether the ASC had provided any training related to instrument reprocessing, or other infection control related training. She stated she had not received any training from the ASC.</p> <p>On 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed. When asked about the ASC's employee training program related to the use of the instrument reprocessing/sterilization equipment (autoclave) and necessary supplies, the Office Manager stated she was unaware of any training and was unable to provide evidence that training had occurred.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. When asked about training, the Medical Director confirmed the ASC had not provided training specific to instrument reprocessing/sterilization to the ASC nurses or the DAs.</p> <p>The ASC failed to ensure staff were trained and reprocessing was completed in accordance with the autoclave, instrument, and detergent's manufacturer's instructions and in accordance with ASC policies. These systemic failures resulted in the inability of the facility to ensure</p>	Q 064		

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Q 064	Continued From page 39 patient risk of serious infection was minimized. The cumulative effect of the deficient patient care and infection control practices compromised patient safety and placed patients in serious and immediate jeopardy, which the ASC was notified of on 12/10/15 at 2:15 PM. The ASC did not submit an Immediate Plan of Correction. On 12/18/15 at 3:40 PM, the ASC submitted a plan which stated the ASC would suspend seeing patients, effective 12/21/15 at 6:00 PM, while they continued to resolve the circumstance which resulted in the Immediate Jeopardy. On 12/24/15 at 11:55 AM, the ASC submitted an acceptable Plan of Correction, which alleged the circumstance which resulted in the Immediate Jeopardy would be resolved as of 12/29/15 at 8:00 AM. On-site verification of the plan's implementation was completed by the survey team on 12/29/15 at 2:25 PM.	Q 064			
Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of facility policies, it was determined the ASC failed to develop and implement a QAPI program for all patients receiving services at the facility. This resulted in the inability of the ASC to evaluate performance and improve the quality of patient care. The findings include: 1. Refer to Q81 as it relates to the ASC's failure to ensure a comprehensive, data-driven QAPI program that measured, analyzed, and tracked	Q 080			

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Q 080	Continued From page 40 quality indicators was maintained. 2. Refer to Q82 as it relates to the ASC's failure to ensure quality indicator data, including adverse event data, was collected and analyzed. 3. Refer to Q83 as it relates to the ASC's failure to ensure PIPs were conducted. 4. Refer to Q84 as it relates to the failure of the Governing Body to oversee the QAPI program. The cumulative effect of these systematic failures resulted in the inability of the ASC to effectively monitor its programs and services and identify opportunities for improvement.	Q 080		
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and	Q 081		

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Q 081	<p>Continued From page 41 severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies, meeting minutes, and quality documents, it was determined the ASC failed to ensure a comprehensive QAPI program was developed and implemented that measured, analyzed, and tracked quality indicators and focused on high risk, high volume, and problem-prone areas. This failure directly impacted 1 of 1 patient (Patient #3) whose record documented an adverse event and had the potential to impact all patients receiving services at the ASC. This prevented the ASC from monitoring its systems of care and identifying opportunities for improvement. The findings include:</p> <p>1. The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The ASC's Policy and Procedures Manual included an undated policy "Section 8.000 Quality Assurance," which stated "The Governing Body has formed a QA Committee with the sole intention of conducting an ongoing, comprehensive self-assessment of the quality of care provided." The policy stated QAPI was "constant and evolving as to the needs of the ASC and the patients..." The policy stated the QAPI program may include, but was not limited to informed consent, treatment planning, infection</p>	Q 081		

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Q 081	<p>Continued From page 42</p> <p>control, pre and post operative procedures and outcomes, follow up appointments and patient outcomes, parental/patient education, appropriateness and/or necessity of treatment performed, facilities/equipment assessment of functionality and effectiveness, patient satisfaction, nursing services, medical records, hospital admissions, and "any other area of focus that the QA Committee deems necessary or appropriate."</p> <p>The ASC's "Quality Assurance Program Updates" were reviewed. The 1/16/15 update stated the Medical Director would no longer be asking to look over 5 charts per month to ascertain medical necessity for the general anesthesia, as it was not necessary. The note stated there were no post operative hospitalizations, infections or episodes of severe intractable nausea/vomiting. However, Patient #3's record documented she had experienced an adverse event which resulted in her being taken to the hospital on 7/02/14. The incident was not included in the 1/16/15 "Quality Assurance Program Updates."</p> <p>The Medical Director was interviewed on 12/08/15 at 1:50 PM. When asked about Patient #3's record, he stated the CRNA had told him about the incident, but he had not reviewed the case and a peer review had not been completed.</p> <p>Further, the ASC's QAPI documentation did not include other information (e.g. other quality indicators being tracked and monitored, data, data analysis, information related to the chart reviews which had been done prior to the 1/16/15 update, information related to high risk, high volume, and problem-prone areas identified by the ASC, information related to identification of</p>	Q 081		

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Q 081	Continued From page 43 opportunities for improvement, etc.). All information related to the QAPI program was requested from the Medical Director, via email on 12/18/15 at 1:29 PM. No additional information related to quality indicator data which was being kept and analyzed was submitted for review.	Q 081		
Q 082	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.	Q 082		

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Q 082	<p>Continued From page 44</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of records, policies, meeting minutes, and quality documents, it was determined the ASC failed to ensure quality indicator data, including adverse event data, was collected and analyzed. This failure directly impacted 1 of 1 patient (Patient #3) whose record documented an adverse event and had the potential to impact all patients receiving services at the ASC. This prevented the ASC from monitoring its systems of care and identifying opportunities for improvement. The findings include:</p> <p>1. The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The ASC's policies and procedures included an undated Section 8.220 "Incident/Event Reporting" policy. The policy stated "All pertinent information concerning a patient or employee accident or injury should be fully documented in the patient's chart/employee file. The same type of information should be placed in the Incident/Event Report to alert the Administrator/Office Manager to possible problems and solutions."</p> <p>The ASC's QAPI documentation was reviewed. The documentation did not include any Incident/Event reports. Further, "Quality Assurance Program Updates" were reviewed. The 1/16/15 update stated the Medical Director would no longer be asking to look over 5 charts per month to ascertain medical necessity for the general anesthesia, as it was not necessary. The note stated there were no post operative</p>	Q 082			

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Q 082	<p>Continued From page 45</p> <p>hospitalizations, infections or episodes of severe intractable nausea/vomiting.</p> <p>However, Patient #3's record documented she had experienced an adverse event which resulted in her being taken to the hospital. Patient #3's record documented she was a 15 year old female admitted to the facility for a dental procedure using general anesthesia. The anesthesia record documented Patient #3 had a history of asthma and her last use of an inhaler was just prior to her procedure.</p> <p>The anesthesia record documented anesthesia began at 7:13 AM on 7/02/14. At 7:30 AM, the CRNA documented Patient #3's oxygen level dropped and she experienced apnea, which is a suspension of external breathing. The CRNA documented Patient #3 was "making resp [respiratory] effort as ev [evidenced] by chestwall/abd [abdominal] movement." However, the CRNA documented Patient #3's breath sounds were distant and inaudible on the right.</p> <p>The CRNA documented she was unable to pass a breath with the LMA and removed it. The CRNA administered 60 mg of succinylcholine (a drug used to induce muscle relaxation and short-term paralysis, usually to facilitate tracheal intubation) and orally intubated Patient #3 with a size 6.5 ETT. The CRNA documented there was good chest movement with breaths given, although Patient #3's breath sounds did not improve.</p> <p>Patient #3's oxygen levels continued to decrease down into the 30s and her heart rate went down into the 40s. The Mayo Clinic website, www.mayoclinic.org accessed on 12/21/15, stated</p>	Q 082			

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Q 082	<p>Continued From page 46</p> <p>a pulse oximeter is a device used to measure blood oxygen levels. The website stated "Normal pulse oximeter readings range from 95 to 100 percent, under most circumstances. Values under 90 percent are considered low."</p> <p>The CRNA documented due to Patient #3's continued low oxygen level, poor breath sounds, and wheezing, she instructed the staff to contact EMS for transport to a hospital. At 7:45 AM, Patient #3 was transferred to an emergency department by EMS. Patient #3 was still using a breathing tube at the time of transfer.</p> <p>The Medical Director was interviewed on 12/08/15 at 1:50 PM. When asked about Patient #3's record, he stated the CRNA had told him about the incident, but he had not reviewed the case and a peer review had not been completed.</p> <p>The 1/16/15 "Quality Assurance Program Updates" documentation was not reflective of Patient #3's hospitalization and an analysis of the incident was not present. Further no other information (other quality indicators being tracked and monitored, data, data analysis, information related to the chart reviews which had been done prior to the 1/16/15 update, information related to high risk, high volume, and problem-prone areas identified by the ASC, etc.) was present in the notes.</p> <p>All information related to the QAPI program was requested from the Medical Director, via email on 12/18/15 at 1:29 PM. No additional information related to quality indicator data which was being kept and analyzed was submitted for review.</p> <p>The ASC failed to ensure comprehensive quality</p>	Q 082		

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Q 082	Continued From page 47	Q 082			
Q 083	<p>indicator data was collected and analyzed in order to identify opportunities for improvement.</p> <p>416.43(d) PERFORMANCE IMPROVEMENT PROJECTS</p> <p>(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.</p> <p>(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, review of policies and quality program documents, it was determined the ASC failed to ensure distinct ongoing quality improvement projects were defined and conducted. This limited the ASC's opportunities to improve patient care and patient safety. The findings include:</p> <p>1. The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The ASC's QAPI documentation included a "Turnover Time Study" dated January 2015. The study documented data had been collected from 1/20/15 through 2/28/15. The reason for the study was not documented and current PIP data collection was not present.</p>	Q 083			

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Q 083	<p>Continued From page 48</p> <p>The study stated the following:</p> <p>a. "Criteria #1: Entry time of the patient into the O.R. to turnover of patient to X-ray..." The study stated turn over time included induction, IV start, intubation, positioning and vitals.</p> <p>The study documented a sample size of 53 patients (excluding adult patients) and the average time between room entry and x-ray as 8.8 minutes.</p> <p>Additional analysis (e.g. analysis based on staff time differences, etc.), conclusions (e.g. if the turn over times were acceptable or needed to be improved) or goals related to the study were not documented. An identified opportunity for improvement or action taken as a result of the study was not included.</p> <p>b. "Criteria #2: Dentist's wait time between cases" stated wait time was the amount of time between when the dentist left the room after one patient until the dentist returned to see the next patient.</p> <p>The study documented a sample size of 29 patients and the average dentist wait time was 20.5 minutes.</p> <p>Additional analysis (e.g. analysis based on staff time differences, etc.), conclusions (e.g. if the wait times were acceptable or needed to be improved) or goals related to the study were not documented. An identified opportunity for improvement or action taken as a result of the study was not included.</p> <p>All information related to the QAPI program was</p>	Q 083		
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Q 083	Continued From page 49 requested from the Medical Director, via email on 12/18/15 at 1:29 PM. No additional information related to the study was submitted for review.	Q 083			
Q 084	The ASC failed to ensure distinct ongoing quality improvement projects were defined and conducted. 416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on staff interview and review of policies, meeting minutes, and quality documents, it was determined the Governing Body failed to provide sufficient monitoring and oversight of the QAPI program. This failure directly impacted 1 of 1 patient (Patient #3) whose record documented an adverse event and had the potential to impact all patients receiving services at the ASC. The Governing Body's lack of oversight resulted in a lack of a quality program which measured, analyzed, and tracked quality indicators and focused on high risk, high volume, and	Q 084			

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Q 084	<p>Continued From page 50 problem-prone areas. Findings include:</p> <p>1. The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The Medical Director was interviewed again on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>However, the quality assessment section of the ASC's policies and procedures included multiple changes, as follows:</p> <p>The ASC's Policy and Procedures Manual included an undated policy "Section 8.000 Quality Assurance," which stated "The Governing Body has formed a QA Committee with the sole intention of conducting an ongoing, comprehensive self-assessment of the quality of care provided." The policy stated QAPI was "constant and evolving as to the needs of the ASC and the patients..." The policy stated the QAPI program may include, but was not limited to, informed consent, treatment planning, infection control, pre and post operative procedures and outcomes, follow up appointments and patient outcomes, parental/patient education, appropriateness and/or necessity of treatment performed, facilities/equipment assessment of functionality and effectiveness, patient satisfaction, nursing services, medical records, hospital admissions, and "any other area of focus that the QA Committee deems necessary or appropriate."</p> <p>However, the ASC's undated Section 8.120</p>	Q 084		

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Q 084	<p>Continued From page 51</p> <p>"Quality Assurance & Performance Improvement (QAPI) Program" only included 6 quality indicators. The policy stated "Measure, analyze, and track quality indicators:...Data collection." The data collection section listed adverse patient events, patient complaints and staff suggestions and complaints. Patient satisfaction surveys was also listed, but had been lined through. Patient feedback at post-op visit was listed, but post-op visit had been lined through and "pacu" had been written in.</p> <p>The policy did not indicate when the handwritten changes had been made or who had made the changes. The policy did not include information related to the form (e.g. what information was to be garnered from patients in the PACU) and the frequency of the data collection (information elicited from all patients, 50% of patients, 25% of patients, etc.).</p> <p>The "Implementation" section of the "Quality Assurance & Performance Improvement (QAPI) Program" policy stated "Quarterly incident reviews, annual staff training, and documentation." The section also included peer medical chart review with "as needed" written in next to the statement. The implementation section also stated "Monthly staff meetings," which had been lined through. "GB meeting" had been written in next to the statement.</p> <p>The policy did not indicate when the handwritten changes had been made or who had made the changes. The policy did not include information related to how frequently data was to be analyzed.</p> <p>Further, the undated Section 8.200 "Quality</p>	Q 084			

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Q 084	<p>Continued From page 52</p> <p>Assurance Program" policy stated "A performance improvement program will be implemented to provide a mechanism to periodically review the current practice activities and the quality of care provided to patients at the ASC." The policy stated the program would be reviewed quarterly by the Governing Body and the Medical Director. The word quarterly had been lined through and "yearly" had been written in.</p> <p>The policy did not include information related to how annual reviews were sufficient to ensure quality problems were identified and addressed in a timely manner.</p> <p>The 8.200 "Quality Assurance Program" policy also included a "Programs that will be included" section. The section listed post-operative admissions to the hospital, severe post-operative nausea/vomiting, post-operative infections and anesthetic complications. The list also included "Necessity of the procedure performed," which had been lined through.</p> <p>The policy did not indicate when the handwritten changes had been made or who had made the changes. Further, the 4 quality indicators listed in the 8.200 "Quality Assurance Program" policy (post-operative admissions to the hospital, severe post-operative nausea/vomiting, post-operative infections and anesthetic complications) were not consistent with the quality indicators listed in the Section 8.120 "Quality Assurance & Performance Improvement (QAPI) Program" (adverse patient events, patient complaints and staff suggestions and complaints and patient feedback in the PACU).</p>	Q 084			

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Q 084	<p>Continued From page 53</p> <p>Section 8.220 "Incident/Event Reporting" stated "All pertinent information concerning a patient or employee accident or injury should be fully documented in the patient's chart/employee file. The same type of information should be placed in the Incident/Event Report to alert the Administrator/Office Manager to possible problems and solutions."</p> <p>The ASC's QAPI documentation was reviewed. The documentation did not include any Incident/Event reports. Further, "Quality Assurance Program Updates" were reviewed. The 1/16/15 update stated the Medical Director would no longer be asking to look over 5 charts per month to ascertain medical necessity for the general anesthesia, as it was not necessary. The note stated there were no post operative hospitalizations, infections or episodes of severe intractable nausea/vomiting.</p> <p>However, Patient #3's record documented she had experienced an adverse event which resulted in her being taken to the hospital on 7/02/14. The incident was not included in the 1/16/15 "Quality Assurance Program Updates." The updated was not reflective of Patient #3's hospitalization. The Medical Director was interviewed on 12/08/15 at 1:50 PM. When asked about Patient #3's record, he stated the CRNA had told him about the incident, but he had not reviewed the case and a peer review had not been completed.</p> <p>Further, no other information (other quality indicators being tracked and monitored, data, data analysis, information related to the chart reviews which had been done prior to the 1/16/15 update, information related to high risk, high volume, and problem-prone areas identified by</p>	Q 084			

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Q 084	Continued From page 54 the ASC, etc.) was present in the notes. Additionally, two Governing Body meeting minutes were documented between 12/01/14 and 12/08/15. They were dated 1/12/15 and 12/08/15. The minutes did not include information related to the QAPI program, provision of care and services, actions by the Governing Body, or future plans. The Governing Body failed to ensure a comprehensive QAPI program was developed, implemented and maintained.	Q 084		
Q 100	416.44 ENVIRONMENT The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. This CONDITION is not met as evidenced by: Based on observation, policy review, review of equipment manufacturer instructions, record review, and interview, it was determined the facility failed to ensure a safe and sanitary environment was provided and maintained for all patients receiving care at the facility. This resulted in a lack of appropriate environmental conditions, equipment, and personnel necessary to ensure patient health and safety. The findings include: 1. Refer to Q101 as it relates to the ASC's failure to ensure equipment reprocessing was conducted in a manner consistent with manufacturers' instructions. 2. Refer to Q106 as it relates to the ASC's failure to ensure staff were trained in the use of	Q 100		

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Q 100	Continued From page 55	Q 100			
Q 101	<p>emergency medical equipment.</p> <p>416.44(a)(1) PHYSICIAL ENVIRONMENT</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review, a review of equipment manufacturer instructions, and staff interview, it was determined the ASC failed to ensure equipment reprocessing was conducted in a manner consistent with manufacturers' instructions for 2 of 2 DAs (DA B and DA C) who were observed reprocessing instruments. This failure resulted in the ASC's inability to ensure the risk of infection was minimized for all patients receiving care at the ASC. The findings include:</p> <p>1. During a tour of the ASC on 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed about dental instrument reprocessing/sterilization in the ASC and those responsible for the procedure. She stated the ASC's RN and LPN, and the DAs were responsible for reprocessing instruments. The Office Manager said the dentists, who had agreements to perform procedures in the ASC, employed their own DAs and that DAs processed instruments only for the dentist by whom they were employed. The Office Manager said the DAs used the ASC's equipment and supplies to reprocess instruments, then packaged and stored instruments in carts assigned to each individual</p>	Q 101			

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Q 101	<p>Continued From page 56 dentist.</p> <p>When asked about the credentialing process used to determine the DAs acceptable scope of practice in the facility, the Office Manager stated the ASC did not maintain credentialing files for the DAs. She stated each dentist was responsible for the performance of his or her own DA.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. The ASC's infection control program, as it related to the instrument sterilization process, was discussed. The Medical Director stated he was responsible for infection control in the ASC. He stated the ASC nurses were responsible for reprocessing only two small pieces (blades) of the laryngoscopes (a tubular scope equipped with a light and mirrors used for examination of the larynx) used by the CRNAs when intubating patients. The Medical Director also said each DA reprocessed/sterilized instruments only for the dentist by whom they were employed.</p> <p>Observations of reprocessing were conducted on 12/09/15 and 12/10/15. Reprocessing was not completed in accordance with manufacturers' instructions and ASC policies, as follows:</p> <p>The ASC used a SciCan STATIM 2000/5000 G4 Cassette Autoclave for reprocessing instruments. The manufacturer instructions for the autoclave stated the autoclave was designed to provide complete sterilization for unwrapped and wrapped instruments using steam sterilization.</p> <p>a. The autoclave manufacturer's instructions</p>	Q 101			

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Q 101	<p>Continued From page 57</p> <p>stated it included a "Process Enforced Usage" mechanism which, when activated, required employees to enter a personal identification number at the beginning and at the end of each cycle. The instructions stated "Any user can stop a cycle and remove the cassette even with Process Enforced usage ON [sic]. However, the cycle data will record that an unauthorized user has stopped the cycle and/or removed the cassette."</p> <p>During observations of reprocessing conducted on 12/09/15, beginning at approximately 11:15 AM, and on 12/10/15, at approximately 1:00 PM, personal identification numbers were not observed to be used.</p> <p>Section 6 titled "Patient Care Policies," of the ASC's Infection Prevention Manual, included a July 2011 "Monitoring of Sterilizers" policy. The policy stated the facility shall "Monitor each load with mechanical (e.g. time, temperature, pressure) and chemical (internal and external) indicators."</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a sterilization log that included documentation of each item autoclaved, a lot number, duration, temperature, the date, the results of the autoclaving, and the name of the staff who had run the load, the RN stated she was not aware of such a log. She stated she was only aware of a log which was used to document the use of biologic indicators.</p> <p>b. The autoclave instructions included a section for "Preparing and Loading Instruments." The instructions stated "Before loading any</p>	Q 101			

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Q 101	<p>Continued From page 58 instruments into the STATIM, consult the manufacturer's reprocessing instructions."</p> <p>The ASC's dentists used various instruments from various manufacturers. For example, when asked on 12/11/15 at approximately 9:00 AM, the Office Manager stated Dentists A and B used Hu-Friedy instruments and Dentist C used Henry Schein Instruments.</p> <p>The instrument manufacturers' instructions were accessed and reviewed, on 12/11/15, via the Hu-Friedy manufacturer website, www.hu-friedy.com, and the Henry Schein manufacturer website, www.henryschein.com. Both sets of instructions included information related to reprocessing the instruments.</p> <p>i. The Hu-Friedy instrument instructions stated before processing the instruments they must be pre-treated to remove impurities and organic matter. The Hu-Friedy instrument instructions stated a detergent was to be selected that was compatible with the instruments and to "Use an enzymatic cleaner...or precleaning product ... For other cleaning agents and disinfectants the instructions of the manufacturer must be observed."</p> <p>The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a tepid or lukewarm water or detergent bath for at least 10 minutes...Note: The use of enzyme detergents is preferred as they help to break up organic soil more readily and rapidly than do conventional detergents."</p> <p>Section 6 titled "Patient Care Policies," of the</p>	Q 101			

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Q 101	<p>Continued From page 59</p> <p>ASC's Infection Prevention Manual, included a July 2011 "Approved Sterilizing, Disinfecting and Hand Hygiene Agents" form. The form stated "The following agents have been approved for use in this facility. Note: Follow manufacturer's instructions in use of all products." The form included sections for approved sterilizing agents, high level disinfectants for instruments/equipment, disinfectants for environmental cleaning, etc. The form was blank. No documentation of approved products was present on the form. However, the ASC's policy and procedure manual, dated July 2013, included a "Cleaning Agents Approved by the ASC" policy which stated "Instrument cleaners: A specific cleaner/decontaminate shall be used to wash dirty instruments, such as Enzy-Clean."</p> <p>The policy did not include information related to ensuring cleaning agents were compatible with and used per the dental instrument manufacturers' instructions.</p> <p>Reprocessing was observed on 12/09/15 beginning at approximately 11:15 AM. DA B, the DA for Dentist B, who used Hu-Friedy instruments, was interviewed and observed while preparing dental instruments for reprocessing.</p> <p>A large container of liquid detergent, McKesson Low Suds Liquid Instrument Detergent, was observed on the counter top beside the sink. When asked when the detergent was used, DA B stated the detergent was used for pre-soaking. She said the nurses in the ASC prepared the soaking solution in the morning, before surgical cases began.</p> <p>During a second reprocessing observation on</p>	Q 101		

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Q 101	<p>Continued From page 60</p> <p>12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated she placed the dirty instruments in a tub of detergent solution that had been prepared by the ASC nurses. When asked, DA C stated she had never seen any manufacturer's guidelines for any of the cleaning solutions. She said she thought most of the cleaning solutions were "ok to use on any manufacturer's dental instruments, but the cleaning process might be different."</p> <p>During an interview with the ASC RN on 12/09/15 at approximately 2:00 PM, she stated she had not received any type of training specific to infection control or education about the manufacturer's guidelines for any of the chemicals used in the instrument sterilization process. She stated she prepared the detergent solution for pre-soaking dirty instruments. She stated "I use 2-3 pumps of the detergent, in the tub, and then I add some water." When asked, she confirmed she did not measure the amount of detergent or water that was added to the soaking tub.</p> <p>The McKesson Low Suds Liquid Instrument Detergent label stated "Pour product into basin or sink at a dilution of 1/8 ounce to 2 ounces of product per 1 gallon of water." Further, the Material Safety Data Sheet for the McKesson Low Suds Liquid Instrument Detergent stated the pH concentrate was 9.0 to 10.0.</p> <p>The Hu-Friedy instrument manufacturer's instructions stated "Detergents or disinfectants containing the following substances must not be used: strong alkalines (> pH 9), strong acids (< pH 4)..."</p>	Q 101		

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Q 101	<p>Continued From page 61</p> <p>Without appropriate mixing and testing, the ASC could not ensure the pH level of the cleaning solution was compatible with the Hu-Friedy instruments. The ASC failed to ensure the cleaning detergent was used in accordance with the manufacturer's instructions and that chemical concentration was monitored.</p> <p>ii. The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a tepid or lukewarm water or detergent bath for at least 10 minutes..."</p> <p>During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated the instruments would remain in the tub of solution prepared by the ASC nurse until she had time to scrub them with a brush under running water.</p> <p>The ASC failed to ensure the soak time was monitored to ensure soaking was completed in a manner consistent with the Henry Schein instrument instructions.</p> <p>iii. During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was observed to scrub all instruments in accordance with the Hu-Friedy instrument manufacturer instructions. She then sprayed the instruments with a disinfectant (CaviCide), and placed the instruments in soft, pliable packages. DA B then placed the packages containing the instruments on a tray and placed the tray in the autoclave.</p>	Q 101			

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Q 101	<p>Continued From page 62</p> <p>When asked how long the instruments would process in the autoclave, DA B stated the sterilizer could be set to run with instruments that had been covered, as she had done by placing the instruments in packages, or set to run for a shorter period of time when instruments were processed uncovered. DA B said when instruments were processed uncovered, the processing time was shorter. She said the covered method was preferred, and that she only processed uncovered instruments when the dentist did not have sufficient instruments to conduct the next case.</p> <p>However, the Hu-Friedy instructions stated the instruments were to be "...packaged for sterilization in material suitable for steam sterilization. The material must be sufficient to protect the instruments and the packaging against mechanical damage."</p> <p>The Hu-Friedy instrument manufacturer's instructions did not include information related to the placement of unwrapped instruments into an autoclave.</p> <p>Further, the McKesson Low Suds Liquid Instrument Detergent label stated "Wrap instruments and proceed with further processing." Additionally, the ASC's Infection Prevention Manual included Section 7, titled "Department Policies." Section 7 included a July 2011 policy titled "Central Sterile Processing." The policy stated items were to be "...cleaned, rinsed and wrapped for sterilization."</p> <p>The ASC failed to ensure instruments were packaged for sterilization in accordance with the instrument manufacturers' instructions, the</p>	Q 101			

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Q 101	<p>Continued From page 63</p> <p>cleaning detergent instructions and the ASC's policy.</p> <p>iv. The Hu-Friedy instructions stated once sterilization and drying was completed, sterilization could only be maintained if the instruments remained packaged or wrapped to prevent exposure to micro-organisms, and if stored in a dry and dust free clean area.</p> <p>On the morning of 12/10/15 at approximately 8:00 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, asked the surveyor to review her method of storing instruments. In one of the procedure rooms, sterilized instruments had been prepared for an early morning procedure on 12/10/15. The sterilized instruments were unpackaged, arranged on trays and covered with a paper drape. DA B stated if there were early morning procedures scheduled it was her practice to prepare the instruments the prior evening, leaving them as viewed, overnight. DA B confirmed that housekeeping staff cleaned the building, including procedure rooms, after hours each evening. DA B agreed she had no way to verify that the instruments remained sterile until the following morning. She indicated she would no longer use the practice and planned to store the sterilized, packaged instruments in Dentist B's cart and set them up the following morning.</p> <p>The ASC failed to ensure sterilized instruments were not compromised prior to use.</p> <p>c. The autoclave manufacturer's instructions included a section for "Routine Monitoring." The instructions stated "Chemical process indicators [a means to assess physical conditions, such as</p>	Q 101			

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Q 101	<p>Continued From page 64</p> <p>temperature, during the sterilization process] suitable for steam sterilizers should be included in or on each package or load being sterilized. In addition, the weekly use of biological indicators, [a means of monitoring the sterilization process for the presence of resistant microorganisms] which allows you to ascertain whether instruments have been exposed to sterilization condition, is recommended..."</p> <p>During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was asked how often she ran biologic indicators and chemical indicators. She stated she did not do so because the ASC nurses were responsible for running indicators.</p> <p>During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, was asked if she used biological or chemical indicators. She stated she did not and indicated the ASC nurses were responsible for running indicators.</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a chemical and biological indicator log, the RN stated she ran biological indicators one time per month. She then presented a notebook that contained pages titled "STERILIZER." The pages contained a column for the date and a column for the person's initials. The last 10 dates, accompanied by a nurse's initials, were as follows: 1/23, 3/23, 4/23, 5/23, 6/22, 7/22, 8/31, 9/28, 10/22 and 11/23. The month of February was missing, and the year was not included on the dates.</p>	Q 101		

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Q 101	<p>Continued From page 65</p> <p>Biological and chemical indicators were not used in accordance with the autoclave manufacturer's instructions.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. He stated the nurses were responsible for running biologic indicators once monthly. When asked whether chemical indicators were included with each tray of instruments, the Medical Director stated chemical indicators were not necessary.</p> <p>However, the ASC's Patient Care Policies, dated July 2011, included a policy titled "Monitoring of Sterilizers." The policy stated the facility shall "Monitor each load with...chemical (internal and external) indicators." The policy also stated "Use biological indicators to monitor the effectiveness of sterilizers at least weekly..."</p> <p>The ASC failed to ensure biological and chemical indicators were used in accordance with the ASC's policy.</p> <p>d. The ASC's July 2011 policy titled "Central Sterile Processing" stated "For safety reasons, only an adequately instructed person may operate sterilizer [sic]."</p> <p>On 12/09/15 at approximately 11:15 AM, DA B was asked if the ASC provided training related to instrument reprocessing/sterilization and/or other infection control training. She stated she was not aware of any training. She said she used similar equipment and cleaning solutions in the dentist office where she was employed and was therefore comfortable with the process at the</p>	Q 101			

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Q 101	Continued From page 66 ASC. On 12/10/15 at approximately 1:00 PM, DA C was asked whether the ASC had provided any training related to instrument reprocessing, or other infection control related training. She stated she had not received any training from the ASC. On 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed. When asked about the ASC's employee training program related to the use of the instrument reprocessing/sterilization equipment (autoclave) and necessary supplies, the Office Manager stated she was unaware of any training and was unable to provide evidence that training had occurred. On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. When asked about training, the Medical Director confirmed the ASC had not provided training specific to instrument reprocessing/sterilization to the ASC nurses or the DAs.	Q 101			
Q 106	The ASC failed to ensure instruments were reprocessed in a safe manner. 416.44(d) EMERGENCY PERSONNEL Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC. This STANDARD is not met as evidenced by: Based on review of facility records and staff	Q 106			

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Q 106	Continued From page 67 interview, it was determined the ASC failed to ensure training in the use of emergency medical equipment was provided for 4 of 4 nursing staff (2 of 2 CRNAs, 1 of 1 RN and 1 of 1 LPN) whose personal files were reviewed. This resulted in the potential for patient health and safety to be compromised in the event of a medical emergency. The findings include: The ASC's undated Section 6.120 "Cardiac Arrest" policy stated "The following equipment shall be available to the ASC..." The policy listed available equipment as an emergency call system, a cardiac monitor, a ventilation support system, a defibrillator, suction equipment, equipment for CPR, equipment of airway management, and oxygen. The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. The nurses' personnel files did not include documentation of orientation training, including the use of emergency equipment, or any other ongoing inservice training. On 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed. When asked, the Office Manager was unable to provide evidence that training had occurred.	Q 106			
Q 120	The ASC failed to ensure staff were trained in the use of emergency medical equipment. 416.45 MEDICAL STAFF The medical staff of the ASC must be accountable to the governing body.	Q 120			

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Q 120	Continued From page 68 This CONDITION is not met as evidenced by: Based on observation, record review, review of the ASC's personnel/credentialing files, and staff interviews, it was determined the facility failed to ensure the Governing Body held the ASC's medical staff accountable for the training, competency and performance of all practitioners providing care in the facility. This failure resulted in non-physician practitioners (DAs) providing direct care to ASC patients, without credentialing, privileges, training, or competency verification. The findings include: 1. Refer to Q121 as it relates to the ASC's failure to ensure medical staff privileges were granted in accordance with recommendations from qualified personnel. 2. Refer to Q123 as it relates to the ASC's failure to ensure policies and procedures for the oversight and evaluation of non-physician practitioners were developed, implemented and monitored necessary to ensure appropriate patient care was provided. The cumulative effect of these deficient practices resulted in lack of practitioner accountability to the Governing Body.	Q 120			
Q 121	416.45(a) MEMBERSHIP AND CLINICAL PRIVILEGES Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified	Q 121			

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Q 121	<p>Continued From page 69 medical personnel.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of personnel/credentialing files and staff interviews, it was determined the facility failed to ensure the medical staff had been appointed and granted privileges for all DAs providing care at the facility, including 2 of 2 DAs (DA B and DA C) observed providing care. This prevented the ASC from ensuring personnel providing services were qualified and trained to provide those services in a safe and effective manner. The findings include:</p> <p>1. DA B and DA C were observed providing care, as follows:</p> <p>a. Patient #7 was a 6 year old male who had 2 teeth extracted and other dental work performed under general anesthesia on 12/09/15. His procedure was observed from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM.</p> <p>Patient #7 was anesthetized at 10:30 AM. The dentist was not in the room. Patient #7 was attended by CRNA A and DA B. DA B entered the room at 10:42 AM. She took dental x-rays. After taking the x-rays, DA B suctioned Patient #7, then cleaned and put sealants on his teeth. She irrigated Patient #7's mouth and suctioned the liquid. She cared for Patient #7's teeth alone until 11:05 AM when the dentist entered the room and assumed care.</p> <p>b. Patient #17 was a 5 year old male who was treated for tooth decay. Several silver crowns were applied on 12/10/15. His procedure was</p>	Q 121		

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Q 121	<p>Continued From page 70</p> <p>observed from the time he entered the procedure room, at approximately 10:40 AM, until approximately 11:15 AM.</p> <p>Patient #17 was anesthetized at 10:48 AM by CRNA B and the LPN. DA C was in the procedure room during this time. She was preparing trays that contained dental instruments and other supplies, and assisting with positioning Patient #17. Dentist C entered the procedure room after Patient #17 was anesthetized and positioned. Once the Dentist assumed care of Patient #17, DA C assisted by handing Dentist C instruments, equipment and supplies.</p> <p>The ASC's policy manual included an undated Section 2.000 policy that was titled "Medical Staff." The policy stated "Records of the medical staff membership and privileges will be kept in personnel files, including the staff member's record of education, training, and experience...Written documentation of re-appraisals of staff privileges and review of scope of procedures performed will be kept on file and will be amended as appropriate...Only those physicians and healthcare providers who are duly licensed in the State of Idaho, have current malpractice insurance policy, and are approved by the Governing Body (via the Medical Director) for specific procedure(s) may practice medicine/dentistry/anesthesia at the ASC."</p> <p>Included in the same manual was a policy titled "Section 2.100 Purpose of Medical Staff." The policy stated "The primary purpose of the ASC medical staff is to provide for the organization of physicians and other healthcare providers to:...Provide a means of effective organization for the observation and evaluation of professional</p>	Q 121			

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Q 121	<p>Continued From page 71</p> <p>practice in the ASC...Permit a high level of professional performance of physicians and other healthcare providers authorized to practice in the ASC through: Appropriate delineation of clinical privileges that each practitioner may exercise in the ASC...Continuing review and evaluation of each practitioner's performance...assure to each member privileges to practice at the level at which he/she is judged to be competent...Provide a means of further continuing education for medical staff to assist in maintaining scientific standards and leading to the advancement of professional knowledge and skill."</p> <p>The facility's personnel and credentialing files were reviewed. Personnel files were not provided for any of the DAs who were providing patient care in the ASC.</p> <p>During an interview on 12/08/15 beginning at approximately 8:00 AM, the Office Manager stated DAs were not employed by the ASC, nor were they considered contracted employees. She stated each dentist employed his or her own DA and was responsible for the performance of their DA. The Office Manager stated the ASC did not maintain personnel files for the DAs. She said the ASC did not require DAs to be credentialed and did not grant privileges to DAs. She stated DAs work under the direct supervision of the dentist who employed them.</p> <p>The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated each dentist that practiced at the ASC brought their own assistants to help them. He stated the DAs were not employees and were not overseen or supervised by the medical staff. He stated they did not have credential files which included their</p>	Q 121		

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Q 121	Continued From page 72 qualifications. He stated the Medical Staff had not requested information regarding the DAs' qualifications, and they had not been granted privileges. He stated the DAs did not have a formal relationship with the ASC.	Q 121		
Q 123	The ASC did not grant privileges to personnel who performed procedures. 416.45(c) OTHER PRACTITIONERS If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This STANDARD is not met as evidenced by: Based on observation, review of the ASC's policies and procedures and staff interview, it was determined the facility failed to ensure policies and procedures were developed, implemented and monitored to direct the oversight and evaluation of all DAs providing care at the facility, including 2 of 2 DAs (DA B and DA C) observed providing care. This failure resulted in an unknown number of DAs providing patient care at the ASC and resulted in the potential for patients to receive inadequate care. The findings include: 1. DA B and DA C were observed providing care, as follows: a. On 12/09/15 from 9:55 AM until approximately 11:35 AM, Patient #7's care was observed. DA B was observed providing care to Patient #7 during that time.	Q 123		

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Q 123	<p>Continued From page 73</p> <p>b. On 12/10/15, from approximately 10:35 AM until approximately 11:15 AM, Patient #17's care was observed. DA C was observed providing care to Patient #17 during that time.</p> <p>The ASC's Policy and Procedure Manual, titled "Ambulatory Surgery Center Policy & Procedure Manual" including the dates, "SEPTEMBER 2011, JUNE 2012 and JULY 2013," was reviewed during the survey. Policies that were approved by the Governing Body and that discussed the oversight and evaluation of the clinical activities of the DAs who provided care in the ASC, could not be found.</p> <p>On 12/08/15 beginning at approximately 8:00 AM, the Office Manager was interviewed. She stated DAs were not employed by the ASC, nor were they considered contracted employees. She stated each dentist employed his or her own DA and was responsible for the performance of their DA. The Office Manager stated the ASC did not maintain personnel files for the DAs. She said the ASC did not require DAs to be credentialed and did not grant privileges to DAs. She stated DAs work under the direct supervision of the dentist who employed them. The Office Manager confirmed there were no ASC policies specific to the oversight and evaluation of DAs providing patient care in the ASC.</p> <p>During an interview on 12/09/15, beginning at approximately 8:30 AM, the Medical Director was interviewed about the credentialing process. He confirmed the ASC did not require DAs to be credentialed or privileged. He said each dentist was responsible for the performance of his or her own DA. The Medical Director provided no ASC policies that discussed the oversight and</p>	Q 123			

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Q 123	Continued From page 74 evaluation of DAs providing patient care in the ASC.	Q 123			
Q 140	416.46 NURSING SERVICES The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.	Q 140			
Q 141	This CONDITION is not met as evidenced by: Based on record review and interview, it was determined the ASC failed to ensure nursing staff were provided with sufficient direction and supervision for all patients receiving care at the facility. This resulted in the inability of the facility to ensure qualified personnel were available to provide routine and emergency care in accordance with recognized standards of practice, thereby compromising patient health and safety. The findings include: 1. Refer to Q141 as it relates to the ASC's failure to ensure nursing service policies were developed and implemented necessary to ensure the organization and supervision of the nursing staff. 416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency	Q 141			

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Q 141	<p>Continued From page 75 treatment whenever there is a patient in the ASC.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies and personnel files and staff interview, it was determined the ASC failed to ensure nursing service policies were developed and implemented necessary to ensure the organization and supervision of the nursing staff for 2 of 2 RNs, and 1 of 1 LPN providing care at the facility. This impeded the ability of the ASC to provide safe and efficient nursing services. The findings include:</p> <p>The ASC employed 1 RN and 1 LPN. The ASC also employed a second RN to fill in on an as needed basis. The Office Manager stated, on 12/18/15 beginning at 8:30 AM, that the second RN had worked 2 days since April 2015, the last time in December of 2015.</p> <p>The LPN was interviewed on 12/08/15 beginning at 2:00 PM. She stated she had worked for the ASC for approximately 1 year. She stated this was her first nursing job. The RN was interviewed on 12/09/15 beginning at 1:45 PM. She stated since graduating she worked a nursing home and then came to work at the ASC. She stated she had no operating room experience.</p> <p>The policy "Staff Nurse Descriptions," not dated, stated "The ASC will employ a registered nurse who will act as the pre-, intra-, and post-op nurse." The policy then listed "...some, but not all, of the nursing responsibilities..." such as confirming the narcotic count and monitoring the patient in recovery. The policy "5.201 Evaluation</p>	Q 141			

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Q 141	<p>Continued From page 76</p> <p>Tool for Registered Nurses," not dated, was a tool to assess the performance of RNs.</p> <p>The policy "Organization of Nursing Personnel," not dated, stated "Nursing personnel will provide comprehensive nursing care to outpatients under the direction of the Medical Director...Nursing care is delivered according to policies and procedures authorized by the medical staff and the Governing Body...Nursing hours are determined based on the needs of the ASC...The ASC will be staffed by a PALS-certified nurse whenever a patient is present."</p> <p>No other policies specific to nursing services were included in the policy manual. No Policies or job descriptions specific to LPNs were included in the policy manual.</p> <p>The Office Manager and the RN were interviewed on 12/10/15 at 2:00 PM. The Office Manager stated there were no other policies for nursing services. The RN stated the ASC did not have a Director of Nursing. She stated the Office Manager was her supervisor. She stated if she had a problem or needed to report to someone, she would tell the Office Manager. The Officer Manager stated she did not have a clinical background. She stated no person at the ASC was responsible for supervision of nursing services. She stated she could call the Medical Director if there was a problem.</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 10:40 AM. He stated he oversaw all clinical activities at the ASC. The Medical Director lived out of state. He stated he visited the ASC every few months. He stated there was no record of when he visited the ASC.</p>	Q 141			

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Q 141	Continued From page 77 He stated there was no record of his activities in relation to the monitoring and supervision of nursing services. He stated ASCs were not required to provide on site operational supervision. The policy "Duties of Medical Director," not dated, stated the Medical Director would "Oversee all medical and nursing responsibilities at the ASC." The policy also stated the Medical Director would enforce staff rules, regulations, and policies "...where corrective action has been requested against a physician, nurse, or assistant." No policy defined what "Oversee ...nursing responsibilities" meant or specified how nurses activities would be monitored and supervised. Further, the personnel files for the RN and the LPN did not include documentation of orientation, competencies, or evaluations. The Office Manager stated, on 12/18/15 beginning at 8:30 AM, that the RN, who worked on an as needed basis did not have a personnel file. The Medical Director was interviewed on 12/09/15 beginning at 9:45 AM. He confirmed the lack of orientation and competencies in the personnel files. The ASC failed to ensure nursing service policies were developed and implemented necessary to ensure the organization and supervision of the nursing staff.	Q 141			
Q 160	416.47 MEDICAL RECORDS The ASC must maintain complete, comprehensive, and accurate medical records to	Q 160			

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Q 160	Continued From page 78 ensure adequate patient care. This CONDITION is not met as evidenced by: Based on observation, staff interview and review of medical records and facility policies, it was determined the ASC failed to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented. This resulted in the potential for misinterpretation of information and had the potential to negatively impact the quality and safety of patient care. The findings include: 1. Refer to Q162 as it relates to the ASC's failure to ensure medical records were complete and accurate.	Q 160			
Q 162	416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis.	Q 162			

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Q 162	<p>Continued From page 79</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and medical records and staff interview, it was determined the facility failed to ensure medical records were complete and accurate for 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This failure resulted in a lack of clarity in the medical records. The findings include:</p> <p>1. The ASC's policy and procedure manual included Section 2.533, undated, titled "Medical Records." The policy stated "The attending physician/anesthesia provider shall be responsible for preparing a complete medical record for each patient undergoing surgery." The policy listed several items, such as identification data, personal history, dental examinations, etc. which "may" be included in the record.</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13) an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. The nurses' personnel files did not include documentation of orientation or ongoing inservice training, including documentation of training on ASC policies.</p> <p>When asked about documentation of training on 12/08/15, beginning at 9:00 AM, the Office Manager was unable to provide evidence that training had occurred.</p> <p>Patients #1 - #17's medical records were</p>	Q 162		

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Q 162	Continued From page 80 reviewed. The records did not include complete, accurate information, per ASC policy, as follows: a. The "Medical Records" policy stated the record may include the patient's chief complaint and diagnosis. However, the records did not consistently include pre-operative diagnoses. Examples included, but were not limited to, the following: i. Patient #5 was a 2 year old male, admitted to the ASC on 11/30/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified. ii. Patient #6 was a 14 year old female, admitted to the ASC on 11/24/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified. iii. Patient #8 was an 8 year old male, admitted to the ASC on 11/20/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified. iv. Patient #9 was a 24 year old male, admitted to the ASC on 11/18/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified. v. Patient #17 was a 5 year old male, admitted to	Q 162			

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Q 162	<p>Continued From page 81</p> <p>the ASC on 12/10/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified.</p> <p>vi. Patient #12 was a 17 year old male, admitted to the ASC on 12/02/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified.</p> <p>vii. Patient #10 was a 19 year old male, admitted to the ASC on 9/30/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified.</p> <p>viii. Patient #14 was a 13 year old male, admitted to the ASC on 11/04/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The admitting condition was documented as "Tooth Decay and/or Gum Disease." The exact condition was not specified.</p> <p>b. The "Medical Records" policy stated the record may include "...personal history... [and]...physical examination..." The policy stated "A dentist at the ASC will sign the chart stating he has examined the patient and believe [sic] the patient is a good candidate for the procedure, if anesthesia will be provided by a CRNA." The policy also stated "The anesthesia provider will then assess the patient and obtain consent to provide anesthesia."</p> <p>Patient #1 - #17's records included an</p>	Q 162		

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Q 162	<p>Continued From page 82</p> <p>assessment form with a section titled "Dental/Anesthesia Assessment." The assessment stated "I have evaluated the risk of anesthesia/dental procedure and believe the patient is a good candidate for Full Mouth Dental Rehabilitation under GA." The statement in each record was signed by the dentist who performed the procedure.</p> <p>The assessment statement did not include evidence that the patients were examined physically, or evaluated for any changes in the patient's health status that would contraindicate surgery in the ASC.</p> <p>For example, Patient #3 was a 15 year old female admitted to the facility for a dental procedure using general anesthesia. Patient #3's record included an anesthesia record which documented she had asthma and used a Proair rescue inhaler as needed and was last used one week prior to the procedure date. However, in another area of the same section, it was documented Patient #3 had used her inhaler the morning of the procedure.</p> <p>The record did not indicate the dentist or CRNA assessed Patient #3's breath sounds by auscultation with a stethoscope before her procedure.</p> <p>c. The "Medical Records" policy stated the record may include "...A standard operative note by the attending physician/anesthesia provider is to be made immediately after the surgical procedures and completed within forth-eight (48) hours of the surgery. This note will include the names of the physicians/anesthesia provider, diagnosis; surgery performed complications, and</p>	Q 162		

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Q 162	<p>Continued From page 83</p> <p>signed within forth-eight (48) hours of completion of the surgery." However, patient records did not consistently include a standard operative note. Examples included, but were not limited to, the following:</p> <ul style="list-style-type: none"> i. Patient #5's medical record did not include an operative report for an unspecified surgical procedure on 11/30/15. ii. Patient #6's medical record did not include an operative report for an unspecified surgical procedure on 11/24/15. iii. Patient #8's medical record did not include an operative report for an unspecified surgical procedure on 11/20/15. iv. Patient #14's medical record did not include an operative report for an unspecified surgical procedure on 11/04/15. v. Patient #12's medical record did not include an operative report for an unspecified surgical procedure on 12/02/15. vi. Patient #10's medical record did not include an operative report for an unspecified surgical procedure on 9/30/15. <p>Further, procedure start and end times were not documented in Patient #1 - #17's medical records.</p> <p>The ASC failed to ensure operative reports were completed and placed in patient records.</p> <p>d. The "Medical Records" policy stated the record may include a discharge note with the</p>	Q 162		

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Q 162	<p>Continued From page 84</p> <p>patient's condition on discharge. Further, a policy Section 4.500 "Patient Discharge Criteria," undated, stated "The decision to discharge a patient from the ASC will be made by the ASC registered nurse or anesthesia provider based on the following criteria." The discharge criteria in the policy stated the Modified Aldrete scoring system would be used and patients must score 14-16 prior to discharge. The Modified Aldrete is a measurement of recovery after anesthesia that includes gauging consciousness, activity, respiration, and blood pressure.</p> <p>The policy included the scoring table for the Modified Aldrete. A score of 0-2 was assigned for the 8 areas included in the table. The categories listed were: respiration, circulation, skin color, level of consciousness, activity, oxygen saturation measurement, pain, and nausea. Each category included objective patient information, derived from observation and assessment, with a corresponding score. Examples of the scoring include, but were not limited to the following:</p> <p>Respiratory: 2: Respirations adequate, deep breaths, coughs, adequate rate. 1: Dyspnea, limited, or shallow breaths, retractions, grunting, wheezing. 0: Apnea (absence of breathing).</p> <p>Circulation: 2: Blood pressure stable within 20% of patient's pre-anesthetic level, pulse rate stable within +/- 20 points pre-anesthetic level. 1: Blood pressure fluctuating within 50% of patient's pre-anesthetic level, pulse rate fluctuating within 25% of patient's pre-anesthetic level.</p>	Q 162			

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Q 162	<p>Continued From page 85</p> <p>0: Unstable.</p> <p>Activity: 2: Able to move all extremities. 1: Only able to move with assistance. 0: Unable to move, no activity.</p> <p>The documentation in Patient #1 - #17's records did not include a score or number using the Modified Aldrete table, as outlined in the policy. Additionally, the records did not include documentation of all categories in the Modified Aldrete scale included in the ASC policy. Examples included, but were not limited to, the following:</p> <p>i. Patient #1 was a 19 year old male, who was admitted to the ASC on 9/23/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia."</p> <p>Patient #1's record included an anesthesia record. Under the section "CRNA Post-Anesthesia Evaluation" the CRNA documented Patient #1's respirations were unlabored and clear, his blood pressure was normal and his heart rate was stable, his temperature was within normal limits, he was awake and alert, and his pain and nausea were "controlled." The CRNA documented Patient #1 was evaluated and the discharge criteria was met at 12:06 PM.</p> <p>However, there was no documentation of Patient #1's skin color, his activity level, or respiratory rate included in his record. No score was documented in Patient #1's record using the Modified Aldrete scale. Additionally, the post-anesthesia evaluation documented Patient</p>	Q 162		

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Q 162	<p>Continued From page 86</p> <p>#1's pain and nausea was "controlled." The documentation did not indicate if Patient #1 had pain which was relieved by medication or if it was mild, and whether he had experienced nausea and/or vomiting and it was then relieved with medication or absent.</p> <p>ii. Patient #8 was an 8 year old male, admitted to the ASC on 11/20/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia."</p> <p>Patient #8's record included an anesthesia record. Under the section "CRNA Post-Anesthesia Evaluation" the CRNA documented Patient #8's respirations were unlabored and clear, his blood pressure was normal and his heart rate was stable, his temperature was within normal limits, he was awake and alert, and his pain and nausea were "controlled." The CRNA documented Patient #8 was evaluated and the discharge criteria was met at 10:24 AM.</p> <p>However, there was no documentation of Patient #8's skin color, his activity level, or respiratory rate included in his record. No score was documented in Patient #8's record using the Modified Aldrete scale. Additionally, the post-anesthesia evaluation documented Patient #8's pain and nausea was "controlled." The documentation did not indicate if Patient #8 had pain which was relieved by medication or if it was mild, and whether he had experienced nausea and/or vomiting and it was then relieved with medication or absent.</p> <p>The ASC failed to ensure patient records reflected discharge criteria was met per ASC policy.</p>	Q 162		

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Q 162	<p>Continued From page 87</p> <p>2. Patient #3's record was reviewed. Her record documented she was a 15 year old female admitted to the facility for a dental procedure using general anesthesia. Patient #3's medical record included conflicting information, as follows:</p> <p>a. Patient #3's record included a Medical History form, dated 4/16/14. At the bottom of the form was an area for the signature of the patient, parent or guardian. This area was blank. The form documented Patient #3 had no medical problems, medications, or allergies. However, Patient #3's record included an anesthesia record which documented she had asthma and used a Proair rescue inhaler. The anesthesia record also documented Patient #3 had gallbladder issues in 2010.</p> <p>b. Patient #3's record included an anesthesia record, dated 7/02/14.</p> <p>i. The anesthesia record included a section for medical history information signed by the CRNA, but was not dated or timed. The section included documentation Patient #3 used a Proair rescue inhaler as needed and was last used one week prior to the procedure date. However, in another area of the same section, it was documented Patient #3 had used her inhaler the morning of the procedure.</p> <p>ii. A section for recording anesthesia times documented anesthesia began at 7:13 AM and ended at 7:50 AM. However, Patient #3 was transferred by EMS to an acute care facility emergency department at 7:45 AM for declining respiratory status. On the anesthesia record there was an area for documenting complications</p>	Q 162		

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Q 162	<p>Continued From page 88</p> <p>and gave the option of circling "Yes" or "No." Next to these options was a handwritten note which stated "see reverse." On the back side of the form was documentation by the CRNA of the complications Patient #3 experienced during the procedure.</p> <p>At 7:30 AM, the CRNA documented Patient #3's oxygen level dropped and she experienced apnea. The CRNA documented Patient #3's breath sounds were distant and inaudible on the right. The CRNA was unable to ventilate Patient #3 with the LMA and removed it. The CRNA orally intubated Patient #3 with an ETT. The CRNA documented there was good chest movement with breaths given, although Patient #3's breath sounds did not improve.</p> <p>Patient #3's record indicated her oxygen levels continued to decrease down into the 30's and her heart rate went down into the 40's. The CRNA documented due to Patient #3's continued low oxygen level, poor breath sounds, and wheezing, she instructed the staff to contact EMS for transport to a hospital. At 7:45 AM, Patient #3 was transferred to an emergency department by EMS. Patient #3 remained intubated at the time of transfer.</p> <p>c. In the anesthesia record the CRNA documented Patient #3 was extubated and was awake and transferred to the PACU. Additionally, the CRNA documented Patient #3 was in the PACU awake, assessed, and cleared for discharge from PACU. However, Patient #3 did not go to the PACU and was not awake since anesthesia began at 7:13 AM. Patient #3 was transferred to an acute care facility while intubated with a breathing tube.</p>	Q 162			

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Q 162	<p>Continued From page 89</p> <p>The Medical Director was interviewed on 12/08/15 at 1:50 PM. When asked about Patient #3's record, he stated the CRNA had told him about the incident, but he had not reviewed the case and a peer review had not been completed.</p> <p>The ASC failed to ensure Patient #3's record included accurate documentation.</p> <p>3. Refer to Q229 as it relates to the ASC's failure to ensure informed consent was obtained prior to procedures being conducted.</p> <p>4. Refer to Q230 as it relates to the ASC's failure to ensure informed consent was obtained from legally authorized patient representatives prior to procedures being performed.</p> <p>5. Refer to Q261 as it relates to the ASC's failure to ensure a comprehensive H&P was completed within 30 days prior to the scheduled surgery.</p>	Q 162		
Q 200	<p>416.49 LABORATORY AND RADIOLOGIC SERVICES</p> <p>This CONDITION is not met as evidenced by: Based on record review, staff interview, and review of ASC policies, it was determined the ASC diagnostic testing and x-rays were performed in a safe manner for all patients and staff at the ASC. This resulted in potential negative impacts to patient and staff health and safety. The findings include:</p> <p>1. Refer to Q201 as it relates to the ASC's failure to ensure laboratory services were provided in accordance with the CLIA requirements.</p>	Q 200		

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Q 200	Continued From page 90	Q 200			
Q 201	<p>2. Refer to Q203 as it relates to the ASC's failure to ensure radiology services were provided in a safe and effective manner, in accordance with physician orders and conducted by qualified personnel.</p> <p>416.49(a) LABORATORY SERVICES</p> <p>If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter.</p> <p>This STANDARD is not met as evidenced by: Based on interview and review of ASC policies, it was determined the facility failed to ensure procedures for performing urine pregnancy tests met quality standards and were identified as CLIA waived tests for 2 of 2 female patients (Patients #3 and #16) whose records documented pregnancy testing. This failed practice had the potential to negatively impact patient care in the facility. The findings include:</p> <p>1. The Office Manager was interviewed on 12/08/15, beginning at approximately 9:00 AM. When asked if the ASC sent any laboratory tests out to another lab for analysis, she said they did not. When asked if the ASC performed any point of care testing at the ASC, she stated urine</p>	Q 201			

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Q 201	<p>Continued From page 91</p> <p>pregnancy tests were performed on female patients whose menses cycles had begun.</p> <p>a. Patient #3's record documented she was a 15 year old female admitted to the facility for a dental procedure using general anesthesia on 7/02/14. Her record documented she was HCG negative. No additional information related to how the test was administered (e.g. at the ASC or self-administer at home and brought to the ASC) was documented.</p> <p>b. Patient #16's record documented she was an 18 year old female admitted to the facility for a dental procedure using general anesthesia on 8/26/15. Her record documented she had given birth a month prior to the procedure. Her record documented she was HCG negative. No additional information related to how the test was administered (e.g. at the ASC or self-administer at home and brought to the ASC) was documented.</p> <p>The Medical Director was interviewed on 12/08/15, beginning at approximately 1:00 PM. When asked about laboratory testing in the ASC, he stated the only tests that were performed at the ASC were urine pregnancy tests. He stated they were performed on female patients whose menses cycle had begun. He then stated some of the urine pregnancy tests were performed in the patient's home, prior to arriving at the ASC. He said the patient, or patient's parent/guardian, was instructed to bring the pregnancy test results with them to the appointment for verification. When asked if the facility had a process to verify the accuracy of home pregnancy test results, he said they did not. The Medical Director was asked if the ASC had a CLIA waiver for performing urine</p>	Q 201		

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Q 201	Continued From page 92 pregnancy tests. He stated they did not have a waiver.	Q 201			
Q 203	The ASC failed to ensure procedures for performing urine pregnancy tests met quality standards and a CLIA waiver had been obtained. 416.49(b)(1) RADIOLOGIC SERVICES [Radiologic services...] must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter. This STANDARD is not met as evidenced by: Based on observation, review of medical records and ASC policies, and staff interviews, the facility failed to ensure radiology services were provided in a safe and effective manner for 6 of 17 patients (Patients #4 - #9) whose records were reviewed. This resulted in the potential for x-rays to be taken in an unsafe manner by unqualified personnel. The findings include: 1. The ASC's policy Section 11.000 titled "Radiology Services," undated, stated "Dental radiographs may be required prior to the patient's surgical procedure at the ASC. ASC staff that are trained and certified in dental radiographic techniques will perform all radiographic procedures under the direction of the physician." The policy stated the ASC "...will assume all radiological risks" and that "Radiology will be used in the ASC as needed for each patient based on recommendations of the dentist and following the guidelines for dental radiographs, as set forth by the American Dental Association." The policy stated "Radiographs will be exposed	Q 203			

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Q 203	<p>Continued From page 93</p> <p>using the lowest settings and lowest number exposures. Staff and patient safety will be paramount during exposure to x-radiation, including:</p> <p>a. Using properly functioning coned-beam radiation equipment</p> <p>b. Protecting patient and staff, including thyroid, with lead shields</p> <p>c. Staff exposing radiographs at a proper distance from the radiation source (preferably out of the room)."</p> <p>The policy also stated "Dosimetry badges are supplied by the ASC and are to be worn by ASC staff, regardless of whether or not they are assigned the task of taking radiographs. Dosimeters are returned to a contracted monitoring company for evaluation on a quarterly basis."</p> <p>The medical records for Patients #4, #5, #6, #8, and #9, included documentation that x-rays were taken, although orders for x-rays could not be found. Additionally, Patient #7's care was observed on 12/09/15 from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM. Patient #7 was anesthetized at 10:30 AM. The dentist was not in the room. Patient #7 was attended by CRNAA and DA B. Dental x-rays were taken by DA B using a hand held device. Patient #7 was shielded with a vest. However, staff were not observed wearing other protective gear or dosimeters in accordance with ASC policy.</p> <p>When asked about the DAs during an interview</p>	Q 203		

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Q 203	Continued From page 94 with the Office Manager on 12/08/15 beginning at 9:00 AM, the Office Manager stated the ASC did not maintain complete personnel files for the DAs. The Office Manager said the dentists, who had agreements to perform procedures in the ASC, employed their own DAs. She stated the DAs were not considered employees of the ASC, nor were they considered contracted employees, they were employed by each individual dentist and each dentist was responsible for the performance of his or her own DA. The ASC failed to ensure DAs were qualified and trained to safely obtain x-rays. Medical Director was interviewed on 12/09/15, beginning at 10:30 AM. He stated the ASC did a study in 2011 that showed the exposure was so minimal that the DAs did not need to wear protective gear or monitor exposure with dosimeters. However, the Medical Director could not provide evidence of study and stated he had not submitted the study for purposes of a letter of waiver.	Q 203			
Q 219	416.50 PATIENT RIGHTS Condition for Coverage - Patient Rights The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the	Q 219			

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Q 219	Continued From page 95 patient's representative or surrogate, if applicable. This CONDITION is not met as evidenced by: Based on observation, review of policies, record review and staff interview, it was determined the ASC failed to ensure all patients receiving services at the ASC were fully informed of their rights. This failure resulted in the potential for patient rights to be violated. Findings include: 1. Refer to Q221 as it relates to the ASC's failure to ensure patients were provided with verbal and written comprehensive rights information prior to their procedures. 2. Refer to Q224 as it relates to the ASC's failure to ensure patients were provided with information regarding advanced directives. 3. Refer to Q225 as it relates to the ASC's failure to ensure a process was developed to notify patients of the grievance process, including how to file grievance. 4. Refer to Q229 as it relates to the ASC's failure to ensure informed consent was obtained prior to procedures being performed. 5. Refer to Q230 as it relates to the ASC's failure to ensure informed consent was obtained from legally authorized patient representatives prior to procedures being performed. 6. Refer to Q232 as it relates to the ASC's failure to ensure patients' rights to receive care in a safe setting was upheld.	Q 219			
Q 221	416.50(a) NOTICE OF RIGHTS	Q 221			

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Q 221	<p>Continued From page 96</p> <p>An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>This STANDARD is not met as evidenced by: Based on review of medical records and staff interview, it was determined the ASC failed to ensure patients were provided a written notice of their rights for 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This resulted in potential interference with the patients' ability to exercise their rights. Findings include:</p> <p>The records of Patients #1 - #17 all included a form titled "ACKNOWLEDGEMENT CONSENT FOR ANESTHESIA SERVICES." The forms stated "I ALSO ACKNOWLEDGE THAT SOUTHERN IDAHO SURGERY CENTER PLLC HAS PROVIDED ME A COPY, OR ACCESS TO A COPY OF THE PATIENT'S RIGHTS AND RESPONSIBILITIES PRIOR TO MY ADMISSION DATE." However, the records did not include documentation that patients had received a copy of their rights.</p> <p>The Office Manager was interviewed on 12/18/15 beginning at 8:30 AM. She stated patients were offered a copy of patient rights when they checked in for their procedures. She stated if patients did not request a copy of rights at that time, then they were not given a copy.</p>	Q 221			

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Q 221	Continued From page 97	Q 221		
Q 224	<p>416.50(c)(1)(2)(3) ADVANCED DIRECTIVES</p> <p>The ASC must comply with the following requirements:</p> <p>(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.</p> <p>(2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.</p> <p>(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive. This STANDARD is not met as evidenced by: Based on review of policies, record review, and staff interview, it was determined the ASC failed to ensure patients were provided with written information related to the ASC's advanced directives policies for 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This resulted in potential interference with the patients' ability to exercise their rights. The findings include:</p> <p>Policy Section 8.540 "Advanced Directives" undated, stated "In the State of Idaho, all patients have the right to participate in their own healthcare decisions and to make advance</p>	Q 224		

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Q 224	<p>Continued From page 98</p> <p>directives, or to execute power of attorney that authorizes others to make decisions on their behalf based on the patient's expressed wishes when the patient is unable to make decisions or unable to communicate decisions.</p> <p>Unlike an acute care hospital setting, the ASC does not perform 'high-risk' procedures. Most procedures performed at the ASC are considered to be of minimal risk and are performed on pediatric patients with a legal guardian in attendance to execute healthcare decisions at all times.</p> <p>Therefore, it is the policy of the ASC, regardless of the contents of any advanced directive or instructions from a healthcare surrogate or attorney-in-fact, that if an adverse event occurs during treatment at the ASC, we will initiate resuscitative or other stabilizing measures and transfer the patient to an acute care hospital for further evaluation. At the acute care hospital, further treatments or withdrawal of treatment measures already began will be ordered in accordance with the patient's wishes, advanced directive, or healthcare power of attorney. The patient's agreement with this ASC policy will not revoke or invalidate any current healthcare directive or healthcare power of attorney.</p> <p>Patients may be notified of this policy in the 'Notice of Patient Rights and Responsibilities' document that is in the lobby of the ASC.</p> <p>Southern Idaho Surgery Center was built for the purpose of providing surgical services to Pediatric Dental patients only and all of the patients are minors. Surgery can only be performed at SISC if a parent/legal guardian is present at SISC, and if</p>	Q 224			

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Q 224	<p>Continued From page 99</p> <p>any questions/concerns arise about Advanced Directives the guardian may address them accordingly at the correct time.</p> <p>The parent/guardian has the right to exercise their rights without being subjected to discrimination or reprisal from anyone at Southern Idaho Surgery Center..."</p> <p>The records of Patients #1 - #17 were reviewed. None of the records documented the patients had received information concerning advanced directives. Additionally, the records documented Patients #1, #9, #10, and #16 were over the age of 18. However, information related to adult patients was not included in the policy.</p> <p>The Office Manager, interviewed 12/17/15 beginning at 8:30 AM, stated the ASC did not have policies related to advanced directives. She confirmed patients were not provided information regarding advance directives.</p>	Q 224		
Q 225	<p>416.50(d)(4),(5), & (6) SUBMISSION AND INVESTIGATION OF GRIEVANCES</p> <p>The ASC did not provide patients with information concerning advanced directives.</p> <p>The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:</p> <p>(1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p>	Q 225		

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Q 225	<p>Continued From page 100</p> <p>(2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>(3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies, record review, and staff interview, it was determined the ASC failed to ensure a process was developed to notify patients how to file grievances and to inform them of the grievance process for 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This resulted in a lack of information being available and had the potential to prevent patients and their representatives from fully exercising their rights. The findings include:</p> <p>1. The policy "Patient Grievance Process-Submission and Investigation," not dated, stated patients had the right to express complaints to any staff member. The policy outlined a grievance process.</p> <p>The form "Patient Rights," not dated, stated "...Complaint Resolution: Patients are entitled to information about the facility's mechanisms for the initiation, review, and resolution of patient complaints. Patients are entitled to timely resolution of these complaints. Patients may exercise their rights without being subjected to</p>	Q 225			

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Q 225	Continued From page 101 discrimination or reprisal." The form did not explain what the complaint process was or how patients could file a grievance. The records of Patients #1 - #17 included a form titled "ACKNOWLEDGEMENT CONSENT FOR ANESTHESIA SERVICES." The forms stated "I ALSO ACKNOWLEDGE THAT SOUTHERN IDAHO SURGERY CENTER PLLC HAS PROVIDED ME A COPY, OR ACCESS TO A COPY OF THE PATIENT'S RIGHTS AND RESPONSIBILITIES PRIOR TO MY ADMISSION DATE." None of the 17 medical records documented whether patients actually received a copy of their rights. The Office Manager was interviewed on 12/18/15 beginning at 8:30 AM. She stated patients were offered a copy of patient rights when they checked in for their procedures. She stated if patients did not request a copy of rights at that time, then they were not given a copy, including information regarding the ASC's grievance process. The ASC failed to develop a process to ensure patients were informed of their rights to file grievances.	Q 225			
Q 229	416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT [[(1) The patient has the right to the following:] (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, it	Q 229			

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Q 229	<p>Continued From page 102</p> <p>was determined the facility failed to ensure informed consent was obtained from a legally authorized party prior to procedures being conducted for 4 of 4 adult patients (Patients #1, #9, #10 and #16) whose records were reviewed. This resulted in the potential for patient to not be fully informed of procedures and the expected outcomes before they were performed. The findings include:</p> <p>1. The ASC's policies included Section 2.532, titled "Consents," which was undated. The policy stated "A written, signed, informed surgical consent must be obtained prior to all elective procedures...Consents must be completely filled out and must contain, at a minimum, the following:</p> <p>"A statement, in lay person's language, of the condition(s) to be treated."</p> <p>"A statement, in professional and lay language, of the procedures planned."</p> <p>"Signatures in place by:...Physician/anesthesia provider...Patient or the patient's guardian...Witness to the patient's or patient's guardian."</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. The nurses' personnel files did not include</p>	Q 229		

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Q 229	<p>Continued From page 103</p> <p>documentation of orientation or ongoing inservice training, including documentation of training on ASC policies. When asked about documentation of training on 12/08/15, beginning at 9:00 AM, the Office Manager was unable to provide evidence that training had occurred.</p> <p>Patient records were reviewed. The records did not included properly executed consents in accordance with ASC policy. Patients #1, #9, #10 and #16's records documented they were all over the age of 18. The records included a "CONSENT FOR DENTAL SURGERY and ANESTHESIA" form. The form included pre-printed information and was not specific to each individual patient, necessary to ensure each was fully informed, as follows:</p> <p>a. Patient #1 was a 19 year old male, who was admitted on 9/23/15. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form stated "The law guarantees that you have both [sic] the right to make decisions concerning your child's healthcare. Your child's health care providers can provide you with the necessary information and advice, but as a member of the healthcare team, you must enter into the decision-making process..." The consent form was dated 9/23/15, and was signed by Patient #1. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." However, Patient #1's record</p>	Q 229			

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Q 229	<p>Continued From page 104</p> <p>documented he had a surgical procedure to remove 4 impacted wisdom teeth, not the procedure as indicated on the consent.</p> <p>b. Patient #9 was a 24 year old male, who was admitted on 11/18/15. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form stated "The law guarantees that you have both [sic] the right to make decisions concerning your child's healthcare. Your child's health care providers can provide you with the necessary information and advice, but as a member of the healthcare team, you must enter into the decision-making process..."</p> <p>The consent form stated "I acknowledge that I am a legal GUARDIAN and have the power to sign this..." The consent form was dated 10/13/15, and was signed by a representative for Patient #9. The representative documented that she was the LPN for an agency providing care to Patient #9, but did not indicate she was Patient #9's legal guardian or if Patient #9 had a legal guardian. The consent was not signed or dated by a dentist, anesthesiologist, CRNA, or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." However, the specific, planned procedure was not documented.</p> <p>c. Patient #10 was a 19 year old male, who was admitted on 9/30/15. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form stated "The law guarantees that you have</p>	Q 229		

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Q 229	<p>Continued From page 105</p> <p>both [sic] the right to make decisions concerning your child's healthcare. Your child's health care providers can provide you with the necessary information and advice, but as a member of the healthcare team, you must enter into the decision-making process..." The consent form was dated 9/30/15, and was signed. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." However, Patient #10's record documented the planned procedure as surgical removal of 2 erupted teeth, not the procedure as indicated on the consent.</p> <p>d. Patient #16 was an 18 year old female, who was admitted on 8/26/15. Her medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form stated "The law guarantees that you have both [sic] the right to make decisions concerning your child's healthcare. Your child's health care providers can provide you with the necessary information and advice, but as a member of the healthcare team, you must enter into the decision-making process..." The consent form was dated 8/26/15, and was signed by Patient #16. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General</p>	Q 229			

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Q 229	Continued From page 106 Anesthesia." However, the specific, planned procedure was not documented.	Q 229			
Q 230	The ASC failed to ensure facility policy was reflective of adult patients, that staff had been trained and that accurate informed consents were garnered from a legally authorized party. 416.50(e)(2)& (3) EXERCISE OF RIGHTS BY OTHERS (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. This STANDARD is not met as evidenced by: Based on review of policies, record review and staff interview, it was determined the facility failed to ensure informed consent was obtained from legally authorized patient representatives prior to procedures for 13 of 13 minor patients (Patients #2 - #8, #11 - #15 and #17) whose records were reviewed. This resulted in the potential for patient representatives to not be fully informed of procedures and expected outcomes before they were performed. The findings include: 1. The ASC's policies included Section 2.532, titled "Consents," which was undated. The policy stated "A written, signed, informed surgical consent must be obtained prior to all elective procedures...Consents must be completely filled	Q 230			

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Q 230	<p>Continued From page 107 out and must contain, at a minimum, the following:</p> <p>"A statement, in lay person's language, of the condition(s) to be treated."</p> <p>"A statement, in professional and lay language, of the procedures planned."</p> <p>"Signatures in place by:...Physician/anesthesia provider...Patient or the patient's guardian...Witness to the patient's or patient's guardian."</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. The nurses' personnel files did not include documentation of orientation or ongoing inservice training, including documentation of training on ASC policies. When asked about documentation of training on 12/08/15, beginning at 9:00 AM, the Office Manager was unable to provide evidence that training had occurred.</p> <p>Patient records were reviewed. The records did not included properly executed consents in accordance with ASC policy. Patients #2 - #8, #11 - #15 and #17's records documented they were all under the age of 18. The records included a "CONSENT FOR DENTAL SURGERY and ANESTHESIA" form. The form included pre-printed information and was not specific to</p>	Q 230		

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Q 230	Continued From page 108 each individual patient, necessary to ensure patient representatives were fully informed. Examples included, but were not limited to, the following: a. Patient #8's medical record documented an 8 year old male, admitted to the ASC on 11/20/15, for an unidentified dental procedure. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form was dated 12/10/15, but was not signed by a parent/guardian. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The specific, planned procedure was not documented. b. Patient #5's record documented a 2 year old male, admitted to the ASC on 11/30/15, for an unidentified dental procedure. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form was dated 11/30/15 and was signed by a parent/guardian. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA, or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." However, the specific, planned procedure was not documented.	Q 230			

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Q 230	<p>Continued From page 109</p> <p>c. Patient #6's medical record documented a 14 year old male, admitted to the ASC on 11/24/15, for an unidentified dental procedure. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form was dated 11/24/15 and was signed by a parent/guardian. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The specific, planned procedure was not documented.</p> <p>d. Patient #17's medical record documented a 5 year old male, admitted to the ASC on 12/10/15, for an unidentified dental procedure. His medical record contained a "CONSENT FOR DENTAL SURGERY and ANESTHESIA." The consent form was dated 12/10/15 and was signed by a parent/guardian. The dentist was not identified, and the consent was not signed or dated by a dentist, anesthesiologist, CRNA, or other witness. The admitting condition was documented as "Tooth Decay and/or Gum Disease." The specific condition was not identified. The planned procedure was documented as "Full Mouth Dental Rehabilitation Requiring General Anesthesia." The specific, planned procedure was not documented.</p> <p>The ASC failed to ensure staff were trained and accurate informed consents were garnered prior to procedures being performed in accordance with ASC policy.</p>	Q 230			

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Q 232 Q 232	Continued From page 110 416.50(f)(2) SAFETY [The patient has the right to -] (2) Receive care in a safe setting This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to develop, implement, and monitor systems to ensure patients' rights to receive care in a safe setting was upheld. These failures directly impacted 1 of 2 patients (Patient #7) whose care was observed and had the potential to impact all patients receiving care at the facility. These systemic failures resulted in the inability of the facility to ensure patients received safe nursing care and that their risk of infection was minimized. The findings include:	Q 232 Q 232			
Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, ASC policy review, record review and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented, and monitored for all facility staff and patients receiving care at the facility. This resulted in the potential for increased risk of patient infections.	Q 240			

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Q 240	Continued From page 111 Findings include: 1. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 2. Refer to Q242 as it relates to the ASC's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained. 3. Refer to Q243 as it relates to the ASC's failure to ensure the IP provided sufficient direction over the infection control program and activities. 4. Refer to Q244 as it relates to the ASC's failure to ensure infection control was addressed as an integral part of the ASC's QAPI program. 5. Refer to Q245 as it relates to the ASC's failure to ensure a comprehensive action plan to prevent, identify and manage infections and communicable diseases within the ASC was developed and implemented. The cumulative effect of these systemic deficient practices resulted in the inability of the facility to ensure patient risk of infections and communicable diseases was minimized.	Q 240			
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.	Q 241			

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Q 241	<p>Continued From page 112</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to adhere to professionally accepted standards of infection control practices. These failures directly impacted 1 of 2 patients (Patient #7) whose care was observed and had the potential to impact all patients receiving care at the facility. These systemic failures resulted in a lack of hand hygiene, a lack of appropriate reprocessing of instruments and a lack of appropriately cleaned laundry being provided, necessary to minimize the risk of patient infections and communicable diseases. The findings include:</p> <p>1. Patient #7 was a 6 year old male who had 2 teeth extracted and other dental work performed under general anesthesia on 12/09/15. His procedure was observed from his admission at 9:55 AM until his discharge from the operating room at approximately 11:35 AM.</p> <p>During the observation of Patient #7's care on 12/09/15, CRNA A and DA B were not observed to adhere to standard infection control practices, as follows:</p> <p>Patient #7 was anesthetized at 10:30 AM. The dentist was not in the room. Patient #7 was attended by CRNA A and DA B. Dental x-rays were taken by DA B. After taking the x-rays, DA B changed her gloves but did not perform hand hygiene. She suctioned Patient #7, then cleaned and put sealants on his teeth. During this procedure, the suction catheter slipped off the table and came to rest on her scrub pants. It stayed there for approximately 1 minute. She used it again to suction the child without cleaning it. She then removed her gloves and left the</p>	Q 241		

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Q 241	<p>Continued From page 113 room. She did not perform hand hygiene.</p> <p>While DA B was applying the sealants, CRNA A took her gloves off, attached an IV to a pump, then donned new gloves. She did not perform hand hygiene during this time. CRNA A wrote on a paper chart, touched her face multiple times, then sat with her gloved hands folded. At 10:58 AM, CRNA A charted on paper and then dropped her pen on the floor. She picked up the pen, charted again, and touched her face. At 11:03 AM, CRNA A was observed to sit on her gloved hands. Dentist B and DA B entered the room at 11:05 AM. CRNA A charted and touched her face. She removed her gloves, adjusted the IV pump, drew up Propofol (an IV anesthetic) and placed the syringe on the blanket on top of Patient #7. She then sat with her hands between her legs. At 11:14 AM she got a bottle of an inhalation anesthetic and placed it on the anesthesia machine. She replaced the Propofol syringe on the IV pump and sat on her hands. At 11:18 AM, CRNA A picked up her cell phone and touched the screen. She picked up a rag and wiped at something below waist level. At 11:22 AM, CRNA A picked up a small computer from a handbag and typed on it. At 11:27 AM, she adjusted the pump on the anesthesia machine. She then put on gloves and sat with her hands between her legs.</p> <p>The procedure ended at 11:29 AM. CRNA A got a wet wipe from a container on her cart and began wiping down monitor cables and tubes. CRNA A then suctioned Patient #7 and removed his breathing tube. She removed the positioning blocks from under Patient #7, wiped them down and turned Patient #7 on his side. She wrote on Patient #7's chart and made a phone call. After</p>	Q 241			

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Q 241	<p>Continued From page 114</p> <p>the call, CRNAA removed the Propofol from the IV pump and cleaned the cable and tubing. Then she removed her gloves and cleaned her hands with an alcohol based product.</p> <p>CRNAA was interviewed on 12/09/15 beginning at 11:40 AM. She stated she did not know if the ASC had a hand hygiene policy or not. She stated she had performed hand hygiene once following the intubation of Patient #7. She stated she typically performed hand hygiene 2 times, after intubating the patient and when the procedure was over. She stated she did not touch patients during a procedure, only their blankets and tubes.</p> <p>The ASC's July 2011 Infection Prevention Manual was reviewed. Section 6 of the manual, titled "Patient Care Policies" included a policy, dated July 2011 which was titled "Hand Hygiene." The policy stated "Handwashing [sic]/hand hygiene is generally considered the most important single procedure for preventing healthcare-associated infections." The policy stated hand washing was to occur "When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, and in case of a patient with a spore-forming organism (e.g., C. difficile), after going to the restroom, and before eating, perform hand hygiene with either a non-antimicrobial soap and water or an antimicrobial soap and water."</p> <p>The policy also stated waterless hand washing products could be used. The policy stated "If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under 'Handwashing' [sic] above."</p>	Q 241			

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Q 241	Continued From page 115 The policy did not include information related to other time points or circumstances in which hand hygiene was to be performed. The CDC "Guidelines for Hand Hygiene in Health-Care Settings" and "Hand Hygiene Basics" information accessed via the CDC website www.cdc.gov on 12/11/15 stated "Healthcare providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients including: before patient contact; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before invasive procedures; and after removing gloves (wearing gloves is not enough to prevent the transmission of pathogens in healthcare settings)." The guidelines stated hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, was recommended including when hands were not visibly soiled, after contact with patient's intact skin, when moving from a contaminated body site to a clean body site, and after contact with inanimate objects in the immediate vicinity of the patients. The ASC failed to ensure its hand hygiene policy was sufficiently developed, implemented and monitored. 2. During a tour of the ASC on 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed about dental instrument reprocessing/sterilization in the ASC and those responsible for the procedure. She stated the ASC's RN and LPN, and the DAs were responsible for reprocessing instruments. The Office Manager said the dentists, who had	Q 241			

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Q 241	<p>Continued From page 116</p> <p>agreements to perform procedures in the ASC, employed their own DAs and that DAs processed instruments only for the dentist by whom they were employed. The Office Manager said the DAs used the ASC's equipment and supplies to reprocess instruments, then packaged and stored instruments in carts assigned to each, individual dentist.</p> <p>When asked about the credentialing process used to determine the DAs acceptable scope of practice in the facility, the Office Manager stated the ASC did not maintain credentialing files for the DAs. She stated each dentist was responsible for the performance of his or her own DA.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. The ASC's infection control program, as it related to the instrument sterilization process, was discussed. The Medical Director stated he was responsible for infection control in the ASC. He stated the ASC nurses were responsible for reprocessing only two small pieces (blades) of the laryngoscopes (a tubular scope equipped with a light and mirrors used for examination of the larynx) used by the CRNAs when intubating patients. The Medical Director also said each DA reprocessed/sterilized instruments only for the dentist by whom they were employed.</p> <p>Observations of reprocessing were conducted on 12/09/15 and 12/10/15. Reprocessing was not completed in accordance with manufacturer's instructions and ASC policies, as follows:</p> <p>The ASC used a SciCan STATIM 2000/5000 G4</p>	Q 241			

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Q 241	<p>Continued From page 117</p> <p>Cassette Autoclave for reprocessing instruments. The manufacturer instructions for the autoclave stated the autoclave was designed to provide complete sterilization for unwrapped and wrapped instruments using steam sterilization.</p> <p>a. The autoclave manufacturer's instructions stated it included a "Process Enforced Usage" mechanism which, when activated, required employees to enter a personal identification number at the beginning and at the end of each cycle. The instructions stated "Any user can stop a cycle and remove the cassette even with Process Enforced usage ON [sic]. However, the cycle data will record that an unauthorized user has stopped the cycle and/or removed the cassette."</p> <p>During observations of reprocessing conducted on 12/09/15, beginning at approximately 11:15 AM, and on 12/10/15, at approximately 1:00 PM, personal identification numbers were not observed to be used.</p> <p>Section 6 titled "Patient Care Policies," of the ASC's Infection Prevention Manual, included a July 2011 "Monitoring of Sterilizers" policy. The policy stated the facility shall "Monitor each load with mechanical (e.g. time, temperature, pressure) and chemical (internal and external) indicators."</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a sterilization log that included documentation of each item autoclaved, a lot number, duration, temperature, the date, the results of the autoclaving, and the name of the staff who had run the load, the RN stated she was not aware of</p>	Q 241			

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Q 241	<p>Continued From page 118</p> <p>such a log. She stated she was only aware of a log which was used to document the use of biologic indicators.</p> <p>b. The autoclave instructions included a section for "Preparing and Loading Instruments." The instructions stated "Before loading any instruments into the STATIM, consult the manufacturer's reprocessing instructions."</p> <p>The ASC's dentists used various instruments from various manufacturers. For example, when asked, on 12/11/15 at approximately 9:00 AM, the Office Manager stated Dentists A and B used Hu-Friedy instruments and Dentist C used Henry Schein Instruments.</p> <p>The instrument manufacturers' instructions were accessed and reviewed, on 12/11/15, via the Hu-Friedy manufacturer website, www.hu-friedy.com, and the Henry Schein manufacturer website, www.henryschein.com. Both sets of instructions included information related to reprocessing the instruments.</p> <p>i. The Hu-Friedy instrument instructions stated before processing the instruments they must be pre-treated to remove impurities and organic matter. The Hu-Friedy instrument instructions stated a detergent was to be selected that was compatible with the instruments and to "Use an enzymatic cleaner...or precleaning product ... For other cleaning agents and disinfectants the instructions of the manufacturer must be observed."</p> <p>The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a</p>	Q 241			

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Q 241	<p>Continued From page 119</p> <p>tepid or lukewarm water or detergent bath for at least 10 minutes...Note: The use of enzyme detergents is preferred as they help to break up organic soil more readily and rapidly than do conventional detergents."</p> <p>Section 6 titled "Patient Care Policies," of the ASC's Infection Prevention Manual, included a July 2011 "Approved Sterilizing, Disinfecting and Hand Hygiene Agents" form. The form stated "The following agents have been approved for use in this facility. Note: Follow manufacturer's instructions in use of all products." The form included sections for approved sterilizing agents, high level disinfectants for instruments/equipment, disinfectants for environmental cleaning, etc. The form was blank. No documentation of approved products was present on the form. However, the ASC's policy and procedure manual, dated July 2013, included a "Cleaning Agents Approved by the ASC" policy which stated "Instrument cleaners: A specific cleaner/decontaminate shall be used to wash dirty instruments, such as Enzy-Clean."</p> <p>The policy did not include information related to ensuring cleaning agents were compatible with and used per the dental instrument manufacturers' instructions.</p> <p>Reprocessing was observed on 12/09/15 beginning at approximately 11:15 AM. DA B, the DA for Dentist B, who used Hu-Friedy instruments, was interviewed and observed while preparing dental instruments for reprocessing.</p> <p>A large container of liquid detergent, McKesson Low Suds Liquid Instrument Detergent, was observed on the counter top beside the sink.</p>	Q 241			

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Q 241	<p>Continued From page 120</p> <p>When asked when the detergent was used, DA B stated the detergent was used for pre-soaking. She said the nurses in the ASC prepared the soaking solution in the morning, before surgical cases began.</p> <p>During a second reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated she placed the dirty instruments in a tub of detergent solution that had been prepared by the ASC nurses. When asked, DA C stated she had never seen any manufacturer's guidelines for any of the cleaning solutions. She said she thought most of the cleaning solutions were "ok to use on any manufacturer's dental instruments, but the cleaning process might be different."</p> <p>During an interview with the ASC RN on 12/09/15 at approximately 2:00 PM, she stated she had not received any type of training specific to infection control or education about the manufacturer's guidelines for any of the chemicals used in the instrument sterilization process. She stated she prepared the detergent solution for pre-soaking dirty instruments. She stated "I use 2-3 pumps of the detergent, in the tub, and then I add some water." When asked, she confirmed she did not measure the amount of detergent or water that was added to the soaking tub.</p> <p>The McKesson Low Suds Liquid Instrument Detergent label stated "Pour product into basin or sink at a dilution of 1/8 ounce to 2 ounces of product per 1 gallon of water." Further, the Material Safety Data Sheet for the McKesson Low Suds Liquid Instrument Detergent stated the pH concentrate was 9.0 to 10.0.</p>	Q 241			

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Q 241	Continued From page 121 The Hu-Friedy instrument manufacturer's instructions stated "Detergents or disinfectants containing the following substances must not be used: strong alkalines (> pH 9), strong acids (< pH 4)..." Without appropriate mixing and testing, the ASC could not ensure the pH level of the cleaning solution was compatible with the Hu-Friedy instruments. The ASC failed to ensure the cleaning detergent was used in accordance with the manufacturer's instructions and that chemical concentration was monitored. ii. The Henry Schein manufacturer's instructions stated "Recommended procedures for manual cleaning are to first soak the instruments in a tepid or lukewarm water or detergent bath for at least 10 minutes..." During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, stated the instruments would remain in the tub of solution prepared by the ASC nurse until she had time to scrub them with a brush under running water. The ASC failed to ensure the soak time was monitored to ensure soaking was completed in a manner consistent with the Henry Schein instrument instructions. iii. During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was observed to scrub all instruments in accordance with the Hu-Friedy	Q 241			

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Q 241	<p>Continued From page 122</p> <p>instrument manufacturer instructions. She then sprayed the instruments with a disinfectant (CaviCide), and placed the instruments in soft, pliable packages. DA B then placed the packages containing the instruments on a tray and placed the tray in the autoclave.</p> <p>When asked how long the instruments would process in the autoclave, DA B stated the sterilizer could be set to run with instruments that had been covered, as she had done by placing the instruments in packages, or set to run for a shorter period of time when instruments were processed uncovered. DA B said when instruments were processed uncovered, the processing time was shorter. She said the covered method was preferred, and that she only processed uncovered instruments when the dentist did not have sufficient instruments to conduct the next case.</p> <p>However, the Hu-Friedy instructions stated the instruments were to be "...packaged for sterilization in material suitable for steam sterilization. The material must be sufficient to protect the instruments and the packaging against mechanical damage."</p> <p>The Hu-Friedy instrument manufacturer's instructions did not include information related to the placement of unwrapped instruments into an autoclave.</p> <p>Further, the McKesson Low Suds Liquid Instrument Detergent label stated "Wrap instruments and proceed with further processing." Additionally, the ASC's Infection Prevention Manual included Section 7, titled "Department Policies." Section 7 included a July 2011 policy</p>	Q 241			

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Q 241	<p>Continued From page 123</p> <p>titled "Central Sterile Processing." The policy stated items were to be "...cleaned, rinsed and wrapped for sterilization."</p> <p>The ASC failed to ensure instruments were packaged for sterilization in accordance with the instrument manufacturers' instructions, the cleaning detergent instructions and the ASC's policy.</p> <p>iv. The Hu-Friedy instructions stated once sterilization and drying was completed, sterilization could only be maintained if the instruments remained packaged or wrapped to prevent exposure to micro-organisms, and if stored in a dry and dust free clean area.</p> <p>On the morning of 12/10/15 at approximately 8:00 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, asked the surveyor to review her method of storing instruments. In one of the procedure rooms, sterilized instruments had been prepared for an early morning procedure on 12/10/15. The sterilized instruments were unpackaged, arranged on trays and covered with a paper drape. DA B stated if there were early morning procedures scheduled it was her practice to prepare the instruments the prior evening, leaving them as viewed, overnight. DA B confirmed that housekeeping staff cleaned the building, including procedure rooms, after hours each evening. DA B agreed she had no way to verify that the instruments remained sterile until the following morning. She indicated she would no longer use the practice and planned to store the sterilized, packaged instruments in Dentist B's cart and set them up the following morning.</p>	Q 241			

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Q 241	<p>Continued From page 124</p> <p>The ASC failed to ensure sterilized instruments were not compromised prior to use.</p> <p>c. The autoclave manufacturer's instructions included a section for "Routine Monitoring." The instructions stated "Chemical process indicators [a means to assess physical conditions, such as temperature, during the sterilization process] suitable for steam sterilizers should be included in or on each package or load being sterilized. In addition, the weekly use of biological indicators, [a means of monitoring the sterilization process for the presence of resistant microorganisms] which allows you to ascertain whether instruments have been exposed to sterilization condition, is recommended..."</p> <p>During the reprocessing observation on 12/09/15 beginning at approximately 11:15 AM, DA B, the DA for Dentist B, who used Hu-Friedy instruments, was asked how often she ran biologic indicators and chemical indicators. She stated she did not do so because the ASC nurses were responsible for running indicators.</p> <p>During the reprocessing observation on 12/10/15 at approximately 1:00 PM, DA C, the DA for Dentist C, who used Henry Schein instruments, was asked if she used biological or chemical indicators. She stated she did not and indicated the ASC nurses were responsible for running indicators.</p> <p>When asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a chemical and biological indicator log, the RN stated she ran biological indicators one time per month. She then presented a notebook that contained pages titled "STERILIZER." The pages</p>	Q 241			

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Q 241	<p>Continued From page 125</p> <p>contained a column for the date and a column for the person's initials. The last 10 dates, accompanied by a nurse's initials, were as follows: 1/23, 3/23, 4/23, 5/23, 6/22, 7/22, 8/31, 9/28, 10/22 and 11/23. The month of February was missing, and the year was not included on the dates.</p> <p>Biological and chemical indicators were not used in accordance with the autoclave manufacturer's instructions.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. He stated the nurses were responsible for running biologic indicators once monthly. When asked whether chemical indicators were included with each tray of instruments, the Medical Director stated chemical indicators were not necessary.</p> <p>However, the ASC's Patient Care Policies, dated July 2011, included a policy titled "Monitoring of Sterilizers." The policy stated the facility shall "Monitor each load with...chemical (internal and external) indicators." The policy also stated "Use biological indicators to monitor the effectiveness of sterilizers at least weekly..."</p> <p>The ASC failed to ensure biological and chemical indicators were used in accordance with the ASC's policy.</p> <p>d. The ASC's July 2011 policy titled "Central Sterile Processing" stated "For safety reasons, only an adequately instructed person may operate sterilizer [sic]."</p> <p>On 12/09/15 at approximately 11:15, AM DA B</p>	Q 241			

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Q 241	<p>Continued From page 126</p> <p>was asked if the ASC provided training related to instrument reprocessing/sterilization and/or other infection control training. She stated she was not aware of any training. She said she used similar equipment and cleaning solutions in the dentist office where she was employed and was therefore comfortable with the process at the ASC.</p> <p>On 12/10/15 at approximately 1:00 PM, DA C was asked whether the ASC had provided any training related to instrument reprocessing, or other infection control related training. She stated she had not received any training from the ASC.</p> <p>On 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed. When asked about the ASC's employee training program related to the use of the instrument reprocessing/sterilization equipment (autoclave) and necessary supplies, the Office Manager stated she was unaware of any training and was unable to provide evidence that training had occurred.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. When asked about training, the Medical Director confirmed the ASC had not provided training specific to instrument reprocessing/sterilization to the ASC nurses or the DAs.</p> <p>The ASC failed to ensure staff were trained and reprocessing was completed in accordance with the autoclave, instrument, and detergent's manufacturer's instructions and in accordance with ASC policies.</p>	Q 241			

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Q 241	<p>Continued From page 127</p> <p>The ASC failed to ensure patients were provided with trained staff and appropriate equipment and supplies, necessary to ensure patient risk of serious infection was minimized.</p> <p>3. The 2015 Edition AORN Guidelines for Perioperative Practice state "All individuals who enter the semi-restricted and restricted areas should wear scrub attire that has been laundered at a health care-accredited laundry facility or disposable scrub attire provided by the facility and intended for use within the perioperative setting. Using health care accredited laundry facilities is recommended because they meet industry standards. Reusable scrub attire should be left at the health care facility for laundering."</p> <p>However, an undated ASC policy, titled "Washing of Scrubs and Patient Gowns, Blankets, etc., " stated "All linen will be washed in the ASC washing machine in warm water (>120 degrees F)... Either the dental assistant or the registered nurse will be responsible for laundry, depending on the workload."</p> <p>During a tour of the ASC on 12/08/15, beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program as it related to laundering of ASC linens. The laundry room was observed during the tour, which contained a household style washer and dryer. The Office Manager stated patient gowns, blankets and staff scrubs were laundered at the ASC. She stated the contracted housekeeping staff performed laundry duties, but that other ASC staff helped with laundry duties as well. When asked if a log was maintained that included temperature monitoring of water and the washing machine and dryer temperature, she stated she</p>	Q 241			

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Q 241	Continued From page 128 was not aware of such a log. When asked what type of laundry detergent was used, she stated "regular laundry detergent." When asked if training for how to launder ASC linens was provided, the Office Manager stated she was not aware of any such training.	Q 241			
Q 242	Without appropriate equipment, detergent, temperature monitoring, and staff training, the ASC would not be able to ensure all linens were appropriately laundered. 416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on staff interview, policy review and review of infection control documentation and employee inservice/education documents, it was determined the ASC failed to ensure that an explicit, ongoing infection control program based on nationally recognized guidelines was developed, implemented and monitored to ensure the health and safety of all patients receiving care in the ASC. This resulted in a lack of direction and training being provided to staff necessary to ensure patient risk of infection and communicable diseases was minimized. The findings include: 1. The ASC's "Infection Prevention Manual SISC	Q 242			

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Q 242	<p>Continued From page 129</p> <p>2011" was reviewed. The manual contained 10 sections, with multiple policies included in each section. Various policies (e.g. "Infections Waste Management," dated March 2010, "Bloodborne Pathogens Model Exposure Control Plan," undated, the "Infection Prevention Orientation Outline," dated July 2011, etc.) referenced OSHA regulations and CDC recommendations. However, the Infection Prevention Manual did not include evidence that the ASC had considered and selected nationally recognized infection control guidelines for use in its infection control program.</p> <p>The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked which nationally recognized infection control guidelines the ASC was following, he stated the facility did not follow any specific, nationally recognized infection control guidelines.</p> <p>2. Section 1 of the ASC's Infection Control Manual was titled "Infection Prevention Program." Section 1 included a policy titled "Infection Prevention Program Overview," dated July 2011. The policy stated "Policies and procedures for infection prevention are reviewed on a regular schedule and updated as needed." The last sentence of the policy stated "The Infection Prevention Committee will review the Infection Prevention Plan annually." Beyond the annual Prevention Plan review, no other information related to the "regular schedule" review and updates was present in the policy.</p> <p>A corresponding July 2011 "Infection Prevention Plan" policy, which was also included in section 1 of the Infection Prevention Manual, stated "A</p>	Q 242			

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Q 242	<p>Continued From page 130</p> <p>current written infection prevention plan will be written." The policy stated the plan was to include an assessment of risk, services provided, and population served, prioritized strategies to decrease risk, an evaluation of the effectiveness of the strategies and a surveillance plan based on analysis of previous data. The policy stated the plan would be updated at least annually and more often as needed.</p> <p>Section 2 of the Infection Prevention Manual, titled "Surveillance," also included a policy titled "Infection Prevention Plan." The top of the policy stated "Infection Prevention Manual for [name of another Idaho ASC]" and was dated March 2010. The policy stated the mouth was considered a "Class II/Clean-Contaminated Wound" and that dentistry had a very low incidence of infection. The policy stated the primary reason for the procedure was to repair infected teeth and prophylaxis antibiotics would not be administered. The policy further stated all postoperative infections would be documented and followed and the plan would be updated at least annually.</p> <p>Immediately following the policy was a form titled "Infection Prevention Plan," which was not dated. The form included a column titled "Risk Assessment." Factors listed in the "Risk Assessment" column included Boise, Idaho, Medicaid patients, oral hygiene, dental care only. The Risk Assessment column also included "Population characteristics" of pediatric, lower income and poor oral health.</p> <p>The form included 2 additional columns, one titled "Characteristics that increase risk" and one titled "Characteristics that decrease risks." No information had been entered in either column.</p>	Q 242		

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Q 242	Continued From page 131 The ASC failed to ensure a comprehensive infection prevention plan was developed, implemented and monitored. 3. Section 3 of the ASC's Infection Control Manual was titled "Infection Prevention Education." Section 3 included a policy titled "Infection Prevention Orientation Outline." The outline included general infection prevention principles (hand hygiene), employee health (work restrictions for communicable diseases, reporting exposure to infectious diseases, vaccines and TB skin tests), patient infections (prevention of infections, recognition and reporting), standard precautions and other barrier precautions (Employee protection against bloodborne pathogens, OSHA regulations, and CDC recommendations), standard precaution policy, components of standard precautions (barriers for protection, safe sharps devices, biomedical waste, linen handling), transmission-based precautions (airborne, droplet and contact), and additional infection concepts (standard precautions/transmissions based precautions, principles of asepsis including clean and sterile technique, and separation of clean and dirty procedures). The policy also included "Compliance Monitoring," which included staff self-evaluations and observation of practices. Immediately following the policy was a corresponding "Orientation Checklist," a policy titled "OSHA Bloodborne Pathogens Standard Employee Training Outline," and a policy titled "Tuberculosis Employee Training Outline."	Q 242			

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Q 242	<p>Continued From page 132</p> <p>Further, Section 4 of the "Infection Prevention Manual" titled "Isolation" included a policy titled "Compliance Monitoring." The policy stated "Each new employee providing direct patient care will be observed during orientation. Specific items related to compliance with infection prevention policies will be included on the evaluation form. Specific compliance issues will be discussed with the individual employee involved..."</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. None of the nurses' files included documentation of orientation training and there was no evidence that observations had been conducted during the staffs' orientation period as specified in the ASC's policies. Personnel files for the DAs could not be found.</p> <p>On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide evidence of any infection control training.</p> <p>When asked about the DAs, the Office Manager stated the ASC did not maintain personnel files for the DAs. The Office Manager said the dentists, who had agreements to perform</p>	Q 242			

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Q 242	Continued From page 133 procedures in the ASC, employed their own DAs. She stated the DAs were not considered employees of the ASC, nor were they considered contracted employees, they were employed by each individual dentist and each dentist was responsible for the performance of his or her own DA. The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked about staff infection control training and monitoring, he stated there was no infection control training program for staff. When asked, he stated each dentist had their own DA who assisted them with procedures and performed other duties, such as caring for that dentist's instruments. He stated the ASC did not have a formal relationship with the DAs. He stated they were not employees and they had not been granted privileges by the Governing Body. He stated the dentists who employed them were responsible for their actions. He stated the ASC was not responsible for their actions.	Q 242			
Q 243	The ASC failed to ensure staff were trained in professionally accepted standards of infection control practices. 416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION The program is - Under the direction of a designated and qualified professional who has training in infection control.	Q 243			

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Q 243	<p>Continued From page 134</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interviews, it was determined the ASC failed to ensure the IP provided sufficient monitoring over the infection control program for all staff and all patients receiving care at the facility. This resulted in a lack of direction to staff and inadequate infection control practices being implemented. Findings include:</p> <p>1. On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide evidence of any infection control training.</p> <p>However, the "Infection Prevention Manual SISC 2011" was reviewed. The manual contained 10 sections. Section 1 "Infection Prevention Program" included a policy titled "Infection Prevention Program Overview." The Infection Prevention Program Overview policy stated "The Governing Body is ultimately responsible for the Infection Prevention Program...Responsibility is delegated to the Infection Preventionist (IP) to carry out the daily functions of the Infection Prevention Program. Those functions are described in the IP job description..." The policy stated one of the 2 ASC owners was the IP.</p> <p>The Medical Director was interviewed on 12/08/15 beginning at 1:50 PM. He stated he</p>	Q 243			

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Q 243	<p>Continued From page 135</p> <p>lived out of state. He stated he came to the ASC every few months. He said he spoke to ASC personnel all of the time. He stated he served as the ASC's Medical Director, IP, Director of Nursing, and Director of Quality.</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 10:40 AM. He stated there was no record of his visits to the ASC to perform administrative functions. The Medical Director was interviewed again on 12/10/15 beginning at 11:15 AM. He stated he provided direct oversight to clinical personnel. He confirmed there was no documentation of oversight activities. He stated he provided supervision by telephone. He stated onsite supervision of staff was not required. When asked how much time he spent on directing the infection control program, the Medical Director estimated half an hour each week.</p> <p>The Infection Prevention Manual included the IP job description. The job description stated the IP had multiple responsibilities which included, but were not limited to, the following:</p> <ul style="list-style-type: none"> - Does on-going monitoring of healthcare-associated infections. - Identifies infection prevention problems and makes recommendations for corrective action. - Prepares the agenda for the Infection Prevention Committee. - Serves as a resource for all departments and personnel. - Initiates, reviews and revises infection prevention policies and procedures. - Provides educational offerings for orientation and on-going in-services. - Participates in quality improvement activities. 	Q 243		

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Q 243	<p>Continued From page 136</p> <p>- Participates in short and long range planning for the infection prevention department.</p> <p>The policy and job description did not include information regarding how sufficient oversight of the Infection Control Program could be accomplished through off-site monitoring. Further, ASC documentation did not support IP responsibilities were being upheld in accordance with the Infection Prevention Program Overview policy and the IP job description, as follows:</p> <p>a. The IP job description stated the IP was responsible for monitoring healthcare-associated infections, identifying infection prevention problems and making recommendations for corrective action. The Infection Prevention Program Overview policy stated the IP was to monitor patient infection cases, complete the line listings of infections, and the monthly report forms.</p> <p>When asked on 12/08/15 beginning at approximately 1:50 PM, the IP stated he had discontinued completing the forms because there were no infections in the ASC.</p> <p>b. The Infection Prevention Program Overview policy stated the IP was to report to the Infection Prevention Committee ..." A corresponding "Infection Prevention Committee" policy, dated July 2011, listed the 2 ASC owners as the Infection Prevention Committee members. The "Infection Prevention Committee" policy also stated "The Infection Prevention Committee meets on a regular basis. The committee may meet as part of the Quality Assurance Committee." The policy stated the IP "Prepares infection reports and presents them to the</p>	Q 243		

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Q 243	<p>Continued From page 137</p> <p>committee. Areas for improvement are identified and actions are planned for resolution." The IP job description stated the IP was responsible for preparing the agenda for the Infection Prevention Committee and participating in short and long range planning for the infection prevention department.</p> <p>Infection Control Committee meeting minutes were requested for review. The ASC provided meeting minutes dated 3/28/12, 6/1/12, 4/13/13, 12/26/13, and 1/12/15. Meeting minutes dated 2014 were not submitted for review. However, the 1/12/15 meeting minutes stated "During the year 2014, NO [sic] infection cases have been reported to SISC from the DDS offices. SISC continues to grow in the number of DDS that are utilizing our facility, and yet no infections are noted. A new STERUS machine was purchased during 2014. The RNs are familiar with how it works. Test strips are done weekly, and all the equipment is running correctly."</p> <p>The meeting minutes did not include other information related to infection control monitoring, action plans, or infection control goals, and the meeting minutes did not include information related to the training the RNs received regarding the STERUS machine or additional information related to the weekly test strips.</p> <p>Additionally, when asked, during an interview on 12/10/15 at approximately 2:00 PM, if the ASC had a chemical and biological indicator log, the RN stated she ran biological indicators one time per month. She then presented a notebook that contained pages titled "STERILIZER." The pages contained a column for the date and a column for the person's initials. The last 10 dates,</p>	Q 243		

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Q 243	<p>Continued From page 138</p> <p>accompanied by a nurse's initials, were as follows: 1/23, 3/23, 4/23, 5/23, 6/22, 7/22, 8/31, 9/28, 10/22 and 11/23. The month of February was missing, and the year was not included on the dates.</p> <p>On 12/08/15, beginning at approximately 1:00 PM, the ASC's Medical Director, who was also the ASC's IP, was interviewed. He stated the nurses were responsible for running biologic indicators once monthly.</p> <p>c. The Infection Prevention Program Overview policy stated "Policies and procedures for infection prevention are reviewed on a regular schedule and updated as needed." The IP job description stated the IP was responsible for initiating, reviewing and revising infection prevention policies and procedures.</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>d. The IP job description stated the IP was responsible for providing "educational offerings for orientation and on-going in-services."</p> <p>The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked about staff infection control training, he stated there was no infection control training program for staff.</p> <p>e. The Infection Prevention Program Overview policy stated the IP was responsible for ensuring "Compliance with infection prevention practices is monitored and documented by...Staff</p>	Q 243		
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Q 243	<p>Continued From page 139</p> <p>evaluation...Observation of Practices." The policy stated "The IP/Medical Director will review the compliance monitoring and initiate appropriate action."</p> <p>Further, Section 4 of the "Infection Prevention Manual" titled "Isolation" included a policy titled "Compliance Monitoring." The policy stated "Each employee providing direct patient care may be given self-evaluation forms to be completed annually. These forms will be reviewed by the Infection Preventionist and any problems will be discussed with the individual employee." The policy stated "Each new employee providing direct patient care will be observed during orientation. Specific items related to compliance with infection prevention policies will be included on the evaluation form. Specific compliance issues will be discussed with the individual employee involved. Any problems will be evaluated by the Infection Preventionist and incorporated into the infection prevention report..."</p> <p>Immediately behind the policy was a "Staff Self-Evaluation Of Infection Control Practices" which stated it was "To be done yearly when job appraisal is done." Section 4 also included a checklist titled "Monitoring Compliance with Infection Prevention Policies by Observation" which also stated it was to "To be done yearly when job appraisal is done."</p> <p>The ASC contracted with 2 CRNAs (CRNA A contracted on 10/23/12 and CRNA B contracted on 7/15/13) and employed 1 RN (hired on 1/26/12), and 1 LPN (hired on 11/12/14). The nurses' personnel files were reviewed. None of the nurses' files included documentation of</p>	Q 243			

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Q 243	Continued From page 140 orientation training and there was no evidence that observations had been conducted during the staffs' orientation period as specified in the ASC's policies. Personnel files for the DAs could not be found. On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide evidence of any infection control training. The ASC failed to ensure the IP provided direction over the infection control program in accordance with ASC policy.	Q 243		
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -] An integral part of the ASC's quality assessment and performance improvement program This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and QAPI records, it was determined the ASC failed to ensure the infection control program was incorporated into the facility QAPI program for all patients receiving services at the ASC. This resulted in the inability of the ASC to	Q 244		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001069	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 12/10/2015
NAME OF PROVIDER OR SUPPLIER SOUTHERN IDAHO SURGERY CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 3235 N TOWERBRIDGE WAY, SUITE 100 MERIDIAN, ID 83646		
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Q 244	<p>Continued From page 141</p> <p>evaluate its infection control processes necessary for improving the quality of patient care. Findings include:</p> <p>1. The ASC's Policy and Procedures Manual included an undated policy "Section 8.000 Quality Assurance." The policy stated "The Governing Body has formed a QA Committee with the sole intention of conducting an ongoing, comprehensive self-assessment of the quality of care provided." The policy listed multiple areas, including infection control, which were to be monitored through the Quality Assurance program.</p> <p>However, the ASC's undated Section 8.120 "Quality Assurance & Performance Improvement (QAPI) Program" only included 6 quality indicators. The policy stated "Measure, analyze, and track quality indicators: ...Data collection." The data collection section listed adverse patient events, patient complaints and staff suggestions and complaints. Patient satisfaction surveys was also listed, but had been lined through. Patient feedback at post-op visit was listed, but post-op visit had been lined through and "pacu" had been written in.</p> <p>Quality indicators specific to infection control were not identified.</p> <p>Section 8.121 of the policies was titled "Quality Performance Improvement Form," which was undated. The form included areas which were to be completed to document an "event." Under the "Description Of Incident Section" the form included a place for staff to document the type of event, and included adverse patient events, safety issues, patient care issues and infection</p>	Q 244		

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Q 244	Continued From page 142 control. Section 8.15 of the policies was titled "Risk Management," which was undated. The policy stated "...all actual and potential infection occurrences and breaches, surgical site infections, and other health-care acquired [sic] infections will be analyzed with a detailed plan of action." Section 8.200 of the policies was titled "Quality Assurance Program," which was undated. The policy stated "post-op infections" would be reviewed. The policy stated "If a patient is seen in clinic for post-op infection, the Medical Director will be notified and the chart reviewed." The performance improvement program would be reviewed quarterly by the Governing Body and the Medical Director. However, the word quarterly was lined through and yearly was written in. Section 8.201 of the policies was titled "Post-Operative Questionnaire," which was undated. The form included information which was to be garnered from the patient, including "Any signs of Infection." A large handwritten X was written across the form. Further, the ASC's Infection Prevention Manual, Section 2 "Surveillance," included a policy titled "Infection Prevention Surveillance, dated July 2011. The policy stated the IP "...does surveillance of infections among patients and employees." The policy stated "Healthcare-associated infections in ambulatory care are those associated temporally with an ambulatory care visit or with the care provided during the visit...Targeted surveillance may be	Q 244			

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Q 244	<p>Continued From page 143 done in the ambulatory setting with a focus on high-risk areas and those with a potential to reduce risk."</p> <p>The policy stated "Ambulatory surgery centers shall develop a system for post-discharge surveillance." The policy stated the IP "...does surveillance of healthcare-associated infections by:"</p> <ul style="list-style-type: none"> - "Review of culture reports and other pertinent lab data." - "Medical record review." - "Patient examinations." - "Personal consultation by employees." - "Follow-up on communicable disease exposure." - "Review of employee's physical assessments." - "Maintenance of the employee infection record." - "Physician consultation." <p>Section 8.202 of the policies was titled "BenchMarking [sic]," which was undated. The policy stated "SISC has a fairly unique purpose; there are not many Pediatric Dental only ASC that exit [sic]. Fortunately, there are two nearby ASCs that perform the same procedures. SISC will yearly review its complications rates (see below) and compare the results to the two (2) other Pediatric Dental only Surgery Centers below." The policy stated performance measures which were to be compared were hospital admissions,</p>	Q 244		

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Q 244	Continued From page 144 wrong site surgery, and post-operative infection rates. Additionally, Section 10 of the Infection Prevention Manual titled "Performance Improvement" included a policy titled "Supervisory Review," dated July 2011. The policy stated "Supervisory review will be conducted to assess compliance with infection prevention standards. The frequency and type of review will be determined based on the scope of problems identified and the effectiveness of corrective measures. Section 10 included multiple forms to assess infection control practices in various areas including, but not limited to hand hygiene, environmental cleanliness, sharps disposal, and standard precautions. The ASC's QAPI documents were reviewed. The documentation did not include any of the above mentioned forms or checklists, data, including bench marking data, or data analysis. Further, no potential areas of improvement related to infection control were identified. The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies. However, he stated the ASC did not complete post-operative questionnaires, chart review check lists were not used and record reviews were not done. The ASC failed to ensure the infection control program was an integral part of the ASC's QAPI program.	Q 244			
Q 245	416.51(b)(3) INFECTION CONTROL PROGRAM	Q 245			

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Q 245	<p>Continued From page 145</p> <p>The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and record review, it was determined the ASC failed to ensure a system for the prevention and identification of infection and communicable diseases was developed, implemented and monitored for all staff and patients of the ASC, including 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This resulted in a lack of ongoing staff and patient training in infection control and an ineffective infection control surveillance system. The findings include:</p> <p>1. The "Infection Prevention Manual SISC 2011" was reviewed. The manual contained 10 sections.</p> <p>a. The Infection Control Manual's Section 1 "Infection Prevention Program" included a July 2011 policy titled "Infection Prevention Plan." The policy stated "A current written infection prevention plan will be written." The policy stated the plan was to include an assessment of risk, services provided, and population served, prioritized strategies to decrease risk, an evaluation of the effectiveness of the strategies and a surveillance plan based on analysis of previous data. The policy stated the plan would be updated at least annually and more often as needed.</p>	Q 245		

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Q 245	<p>Continued From page 146</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>b. The July 2011 "Infection Prevention Program" policy stated the IP "...will conduct one-on-one training with personnel as practices are observed and corrections or changes in practice are needed."</p> <p>The policy stated records were to be maintained which included, the date and time of training, the instructor and their qualifications, a content outline and the participants and their department."</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. None of the nurses' files included documentation of orientation training and there was no evidence that observations had been conducted during the staffs' orientation period as specified in the ASC's policies. Personnel files for the DAs could not be found.</p> <p>On 12/08/15 beginning at 9:00 AM, the Office Manager was interviewed about the ASC's infection control program. She said there was not a specific person overseeing infection control in the facility. She stated all ASC employees were responsible for infection control in the ASC. When asked to describe any infection control related training or inservices that the ASC had provided to employees and contracted employees, the Office Manager was unable to recall any such training and could not provide</p>	Q 245		

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Q 245	<p>Continued From page 147 evidence of any infection control training.</p> <p>When asked about the DAs, the Office Manager stated the ASC did not maintain personnel files for the DAs. The Office Manager said the dentists, who had agreements to perform procedures in the ASC, employed their own DAs. She stated the DAs were not considered employees of the ASC, nor were they considered contracted employees, they were employed by each individual dentist and each dentist was responsible for the performance of his or her own DA.</p> <p>The Medical Director, who was also the IP, was interviewed on 12/08/15 beginning at approximately 1:00 PM. When asked about staff infection control training and monitoring, he stated there was no infection control training program for staff.</p> <p>c. Section 4 of the Infection Prevention Manual titled "Isolation" included a policy titled "Compliance Monitoring." The policy stated "Each employee providing direct patient care may be given self-evaluation forms to be completed annually. These forms will be reviewed by the Infection Preventionist and any problems will be discussed with the individual employee." The policy stated "Each new employee providing direct patient care will be observed during orientation. Specific items related to compliance with infection prevention policies will be included on the evaluation form. Specific compliance issues will be discussed with the individual employee involved. Any problems will be evaluated by the Infection Preventionist and incorporated into the infection prevention report. The infection prevention report is prepared by the</p>	Q 245		

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Q 245	<p>Continued From page 148</p> <p>Infection Preventionist and presented quarterly to the Infection Prevention Committee."</p> <p>Immediately behind the policy was a "Staff Self-Evaluation Of Infection Control Practices" which stated it was "To be done yearly when job appraisal is done." Section 4 also included a checklist titled "Monitoring Compliance with Infection Prevention Policies by Observation" which also stated it was to "To be done yearly when job appraisal is done."</p> <p>Documentation of staff self-evaluations and documentation related to the observations of staff compliance could not be found.</p> <p>d. Section 3 of the Infection Prevention Manual titled "Infection Prevention Education," included a policy titled "Patient and Family Education for Infection Prevention and Infectious Diseases." The policy stated "It is the intent of this facility to identify educational and teaching opportunities for patients and/or family members relating to infection prevention and infectious diseases.</p> <p>However, the facility recognizes that not all patients are capable of participating in educational activities. The professional staff should determine individual patient's educational needs for infection prevention.</p> <p>Infection prevention teaching may be provided in a variety of ways (verbal, written, etc.) and based on individual needs may include..." The policy then gave examples which included personal hygiene, hand hygiene, PPE and barrier precautions used by staff, transmissions of infections, specific infectious diseases, antibiotic treatment, and care of a wound.</p>	Q 245		

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Q 245	<p>Continued From page 149</p> <p>The policy stated "Documentation of teaching may be found in the medical record."</p> <p>The medical records of Patients #1 - #17 were reviewed. Documentation of teaching was not evident in the records.</p> <p>The ASC failed to ensure staff and patients received ongoing infection control education in accordance with ASC policy.</p> <p>2. The ASC's Infection Prevention Manual, Section 2 "Surveillance," included a policy titled "Infection Prevention Surveillance," dated July 2011. The policy stated the IP "...does surveillance of infections among patients and employees." The policy stated "Healthcare-associated infections in ambulatory care are those associated temporally with an ambulatory care visit or with the care provided during the visit... Targeted surveillance may be done in the ambulatory setting with a focus on high-risk areas and those with a potential to reduce risk."</p> <p>a. The policy stated "Ambulatory surgery centers shall develop a system for post-discharge surveillance."</p> <p>The policy stated the IP "...does surveillance of healthcare-associated infections by:"</p> <ul style="list-style-type: none"> - "Review of culture reports and other pertinent lab data." - "Medical record review." - "Patient examinations." 	Q 245			

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Q 245	Continued From page 150 - "Personal consultation by employees." - "Follow-up on communicable disease exposure." - "Review of employee's physical assessments." - "Maintenance of the employee infection record." - "Physician consultation." However, surveillance documentation as indicated in the ASC's policy could not be found. The ASC failed to ensure an effective infection control surveillance system was maintained in accordance with ASC policy.	Q 245			
Q 261	416.52(a)(1) ADMISSION ASSESSMENT Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records and ASC policy, it was determined the ASC failed to ensure a comprehensive H&P was completed within 30 days prior to the scheduled surgery for 17 of 17 patients (Patients #1 - #17) whose records were reviewed. This had the potential to interfere with assessment of the patient's readiness for surgery. The findings	Q 261			

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Q 261	<p>Continued From page 151 include:</p> <p>1. The ASC's policies included Section 2.533 titled "Medical Records," undated. The policy stated "A complete history and physical examination must be recorded for all surgical patients and made part of the medical record prior to the surgery...This report should include all pertinent findings resulting from an assessment of all systems of the body."</p> <p>The Medical Director was interviewed on 12/09/15 beginning at 8:45 AM. He stated since they were adopted, the Governing Body had never reviewed the ASC's policies.</p> <p>The personnel files of 2 CRNAs (CRNA A, contracted on 10/23/12 and CRNA B contracted on 7/15/13), an RN (hired on 1/26/12), and an LPN (hired on 11/12/14) were reviewed. The nurses' personnel files did not include documentation of orientation or ongoing inservice training, including documentation of training on ASC policies.</p> <p>When asked about documentation of training on 12/08/15, beginning at 9:00 AM, the Office Manager was unable to provide evidence that training had occurred.</p> <p>Patient #1 - #17's records were reviewed. The records included an assessment performed prior to their procedures, signed by the CRNA. The assessments were on a pre-printed form, and included check marks in boxes. One area that was checked as completed, stated "Patient seen, H/P performed, drug/allergy/anesthesia history noted." However, documentation of a complete H&P, in accordance with ASC policy, was not</p>	Q 261			

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Q 261	Continued From page 152 included in the patients' records. Examples included, but were not limited to, the following: a. Patient #10 was a 19 year old male, admitted to the ASC on 9/30/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." Patient #10's medical record included a "Health History Form," dated 7/29/15, and a "Pre-Anesthesia Questionnaire," dated 9/22/15, and a cardiologist's report based on a visit date of 4/09/14 (greater than a year prior to surgery). Patient #10's medical record did not include documentation of a current medical history or a physical examination as part of a complete H&P. b. Patient #12 was a 17 year old male, admitted to the ASC on 12/02/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." Patient #12's medical record included documentation of completion of a pre-anesthesia questionnaire, dated 10/14/15; a "Health History Form," dated 10/12/15, and "Medical Information," dated 11/12/15. There was no documentation of a physical examination, as part of a complete H&P. c. Patient #13 was a 22 year old male, admitted to the ASC on 10/07/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." Patient #13's medical record included a "Pre-Anesthesia Questionnaire," dated 9/09/15, and a medical history, dated 6/19/15. Patient #13's medical record did not include documentation of a physical examination as part of a complete H&P. d. Patient #14 was a 13 year old male, admitted to the ASC on 11/04/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia."	Q 261			

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Q 261	<p>Continued From page 153</p> <p>Patient #14's medical record included a "Health History Form," dated 10/20/15, and a "Pre-Anesthesia Questionnaire," dated 10/20/15. Patient #14's medical record did not include documentation of a physical examination as part of a complete H&P.</p> <p>e. Patient #6 was a 14 year old male, admitted to the ASC on 11/24/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." Patient #6's medical record included a past medical history. It did not include documentation of a physical examination as part of an H&P.</p> <p>f. Patient #8 was an 8 year old male, admitted to the ASC on 11/20/15, for "Full Mouth Dental Rehabilitation Requiring General Anesthesia." Patient #8's medical record included a "pre-anesthesia questionnaire." It did not include an H&P.</p> <p>g. Patient #5's record stated he was a 2 year old male, admitted to the ASC on 11/30/15, for an unidentified dental procedure. There was no documented H&P included in Patient #5's medical record.</p> <p>The ASC failed to ensure staff were trained and a comprehensive H&P was completed in accordance with ASC policy.</p>	Q 261			

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Plan of Correction

FEB 22 2016

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CMS Certification 13C0001069

FACILITY STANDARDS

3235 N. Towerbridge Way, Suite #100
Meridian, ID 83646

Q 040 Condition ~

The Governing Body will monitor the ASC through the Medical Director, Office Manager, Clinical Coordinator, Director of Nursing and Infection Control Specialist. The day to day monitoring of the ASC as a whole will be done by the Office Manager as a member of the Governing Body. The other members of the GB will be kept informed of potential situations that could escalate through email or phone. The OM will make modifications within the scope set by the GB to assure compliance.

The Clinical Coordinator, Infection Control Coordinator, and the Director of Nursing will write up quarterly reports that will be emailed to the Medical Director. The reports will summarize any incidents that took place and what was done to resolve them, any questions that may have arisen and how they were resolved, any training or observations that were done other than those within the scope of the day to day. A printed out copy of these reports will be kept in a binder in the OM office. They will be reviewed at the GB biannual meeting

There will be biannual meetings of the GB as a whole, but 2 or more members can meet as need dictates. At the biannual GB meeting, that will include all members of the GB, there will be a standard agenda that will be used to ensure that there are no overlooked aspects of the ASC. Meeting notes will be typed up by a member of the GB and kept in a binder to be maintained by the OM.

We feel the changes made in Section 1 of the Policy and Procedure Manual will ensure that there is sufficient GB oversight and operational direction over the ASC.

Refer to Q 41 as it relates to the Governing Body's ability to ensure that contracted staff provides services in a safe manner.

Refer to Q 60 as it relates to the Governing Body's ability to ensure the ASC's systems related to nursing care and infection control are implemented, and monitored to ensure a safe and healthy environment for all patients.

Refer to Q 80 as it relates to the Governing Body's ability to ensure a comprehensive, data-driven QAPI program is developed and implemented.

Refer to Q 84 as it relates to QAPI oversight of Governing Body

Refer to Q 100 as it relates to the Governing Body's ability to ensure a safe and sanitary environment is provided and maintained.

Refer to Q 120 as it relates to the Governing Body's ability to ensure that all credentialed personnel are accountable to the GB.

Plan of Correction

Refer to Q 140 as it relates the Governing Body's ability to ensure the nursing staff is provided with sufficient direction and supervision.

Refer to Q 160 as it relates to the Governing Body's ability to ensure complete, comprehensive, and accurate medical records system is developed and implemented.

Refer to Q 200 as it relates to the Governing Body's ability to ensure that all diagnostic and x-rays are performed in a safe manner.

Refer to Q 219 as it relates to the Governing Body's ability to ensure that all patients are informed of their rights and that they are upheld.

Refer to Q 240 as it relates to the Governing Body's ability to ensure a comprehensive infection control program is developed and monitored.

Completed 02/22/2016

Echo Williams

Q 41 Standard ~

Refer to Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to credentialing of dental assistants in addition:

The ASC has and will continue to credential all dental and medical staff that work. The files on each dentist, dental assistant, physician, CRNA, RN and LPN will be maintained by the OM. They will be reviewed as needed to maintain current copies of licensure and proof of insurance. 30 days prior to an expiration date the credentialed personnel will be notified via letter by the OM, or a member of the front office staff, and a request for updated information will be sent in writing via email or a letter given to the Dentist. If the requested items are not received within 30 days of expiration date, giving the provider 60 days to correct the deficiency, the provider will be suspended until the deficiency has been corrected.

Each new credentialed personnel will be trained on the policies and procedures of the ASC. There will be follow-up observations made quarterly with corrections made by ASC staff as needed. If there are corrections made they will be documented by the ASC staff. If multiple corrections are made to a credentialed staff member and that staff member continues to make the same mistake, the situation will be referred to the Medical Director for disciplinary action. See Section 2 of P & P Manuel

Completed 02/22/2016

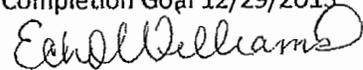
Echo Williams

Q 064

The CRNA's that are contracted with the ASC through MDA did not have documentation of training in their personnel files (pg.7). This documentation was requested from MDA and was received and put into their files (Appendix C, D). There was some concern about CRNA A and her failure to listen perform a hands on physical per SISC policy. This failure has been discussed with MDA and the CRNA. Per SISC policy there will be a hands on physical performed prior to anesthesia. The CRNA will examine the patient per ASA standard. Currently there is no specific policy detailing the CRNA responsibility toward SISC. One is being created. It will outline the CRNA duties, including the health and physical of patient, how this will be monitored by SISC's Director of Nursing, and how it will be documented. The Director of Nursing will enforce all SISC policy with CRNA and document any failures or deficiencies to the Medical Director and the OM. The OM will document the incident for her quarterly report to the Governing Body.

Further monitoring of the CRNA will be from the OM where the paperwork is concerned. The CRNA's general anesthesia forms, that include the H&P, are to be completed during the procedure will be reviewed by OM for completion and accuracy. After the standard is met there will be five (5) patient charts per month reviewed by the OM. Until this standard is met all patient charts will be reviewed. After five (5) days of 100% file reviews will be a random three (3) a day. After five (5) days of 100% we will revert to the normal standard of review. The daily reviews the OM will only document the patient files where an error is found. After that the OM will document the names of the three (3) files chosen and if any deficiencies were found in that patient chart until 100% correction is met. After that has been met it will only be the five (5) charts a month that will be logged. The OM will report any and all deficiencies found by the Director of Nursing and by him /herself concerning chart completion, to the head of MDA and the CRNA.

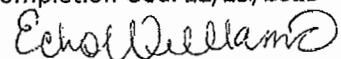
Completion Goal 12/29/2015



Q 064

The current RN/LPN had training at time of employment but there were no records kept so they will be retrained on all aspects of the ASC and this training will be documented and evaluated. This training and documentation will be done and proof of completion will be in their personnel files.

Completion Goal 12/29/2015



Q 064

The hand hygiene concern has and will be addressed through training and documentation of said training (Appendix E). Because of the time constraints on all of our providers and the immediate need to rectify this oversight of hand hygiene training, a CDC power point will be /has been emailed out to all our dentists and assistants to watch. There will be a form stating they watched it and took the accompanying quiz. This form is to be sent back to SISC prior to December 28, 2015. We recognize that there are some individuals out of town or the country for the holidays so there has been an exception made for them and they will be expected to complete the training on their next scheduled date here at SISC. Those who have completed the form will be required to demonstrate their knowledge to our CC before being allowed to see patients at SISC. The CC will observe the washing of hands for proof of understanding. If at any point in the hand hygiene the CC notices a lapse in the process, the CC will make immediate corrections. The CC or DN will observe the DA and dentist assigned to their OR, by using the ASC Quality Collaboration form for hand hygiene, on a daily basis until the standard has been met. After five (5) observations where the standard has been met the observations will revert back to quarterly observations by the ICC. If during the observation they need to suggest a correction the DN or CC will the make note of it in the appropriate section of the Incident log book. If the DA has not completed the hand hygiene training their privileges will be suspended until they are in compliance with SISC policy.

Partial Completion 12/29/2015

Echol Williams

Q 064

The new Hand Hygiene policy is in the process of being clarified. It is in section 13.4 of the Policy and Procedure manual. It will detail the when and how of hand hygiene as it pertains SISC (pg.10)

Completion Goal 12/29/2015

Echol Williams

Q 064

The laundering of the scrubs, blankets and towels at SISC will continue to be done here in the facility. You stated that the AORN 2015 edition stated that everyone entering semi-restricted areas "...should wear scrub attire that has been laundered..." "...or disposable scrubs attire provided by the facility..." policies are being written to clarify this to our credentialed medical staff. Further it states that "reusable scrub attire should be left at health care facility for laundering." According to the CDC's *Laundry: Washing Infected Material*, (Appendix F) commercial laundry facilities use a temperature of 160 to remove "microorganisms from grossly contaminated linen." It further states that "satisfactory reduction of microbial contamination can be achieved at temperatures lower than 160. It goes on to say that "...normal washing and drying cycles including "hot" or "cold" cycles are adequate to ensure patient safety." The scrubs, blankets and towels used at our facility are not considered "grossly

contaminated" they are considered "soiled". The washer and dryer used at our facility have a "sanitize" setting. According to the manufactures manual, during the sanitize setting, water reaches a temperature of 150 (Appendix G). This meets the standard for "grossly contaminated" as well as "soiled". All loads are washed and dried on the sanitize setting. Signs have been posted in laundry room to remind everyone to run ALL cycles on "sanitize". All laundry is washed per the manufactures suggested HE laundry detergent to maximize the washers' efficiency. All personnel that will be responsible for the laundry will be instructed by the ICC on the correct PPE to wear during the process of loading and switching the laundry. Section 6.345 will be rewritten to say "Any employees of SISC will be responsible for laundry depending on the workload" SISC employee is defined as anyone who receives a paycheck from SISC.

Completion Goal 12/29/2015

Erol Williams

Q 064

As stated previously, our infection control program is being re-written to include the concerns of ongoing training and orientation of new employees or providers (pgs.12-14). This will be handled like the Hand Hygiene situation. Videos will be sent out to all the dental offices with a request to watch attached videos on OSHA Infection Prevention guidelines and the proper use of personal protective equipment with a form to complete at the completion of the video and then at their next scheduled date the ICC or CC will review what they watched and have the provider demonstrate their knowledge (Appendix E). The providers have been told that we must have all paper work in place prior to their seeing patients at our facility.

On pg. 14 you quoted the Prevention Manual Section 4 on Isolation, it states "...may be given self-evaluation forms..." this will be re written to say "will be given" since the word "may" implies there 'is a possibility of' and to ensure patient safety there will need to be documentation of employees understanding of SISC's Infection Control and Patient Care policies and a compliance to. When this policy is in place, the documentation will be in the personnel file. These files will be reviewed yearly by the Office Manager who will report a summary of file reviews to the Governing Body.

Completion Goal 12/28/2015

Erol Williams

Q 064

Previously all of the dental assistants that accompanied dentist to our facility were approved under the dentist, and the dentist was responsible for bringing competent assistants (pg.15, 16). This will no longer be the case. All Dental Assistants and Hygienist will need to be credentialed through SISC's Governing Body and approved by the Medical Director (Section 2.424 (Appendix H), Section 2.427 (Appendix I), and Section 2.430 (Appendix J)). There will be an application, appointment and reappointment process. The DA/DH's will be trained on all SISC policies where infection control is concerned. Proof of completion will be in personnel files. These files will be

review yearly for maintenance purposes by the Office Manager. The OM will submit a report of findings to the Governing Body.

Accordingly, the credentialing of the DA/DH will not remove the dentist responsibility for his or her assistant's competency. SISC staff will train and monitor infection control aspects and the dentist will remain responsible for the actual work done by the DA/DH. SISC has delivered an application to the appropriate personnel at the dental offices that use our facility. They have been informed that as of December 28, 2015 any assistant who has not been approved by the Medical Director will not be permitted to assist the dentist at SISC until they have been credentialed and approved (Appendix K). There have been several applications submitted and approved (see Appendix L). They will get the Statim, NOMAD and practical application of the emailed videos and ppt's done here at SISC on their next day scheduled at SISC before being allowed to provide services.

Completion Goal 12/29/2015

Echo Williams

Q 064

SISC will follow all CDC and OSHA standards for infection control. All Infection Prevention and Control and Hand Hygiene training material that has, and will be presented, is based on OSHA and CDC standards. Daily Hand Hygiene and Re Processing procedural observation will be done by the RN/LPN to ensure the standard is met. The hand hygiene observation standard has previously been outlined. These observations will take place during the natural progression of the work day and by per the ADA standards, an observation checklist currently being written up. The RN/LPN will observe at least one reprocessing a day per DA. If during that observation they notice a mistake they will take appropriate responsive action and then report to the OM the name of the DA and the action corrected. It will be noted in the DA's file by DA or RN/LPN. The DA will then be observed by a SISC employee for the next reprocessing done. After three (3) correct observations, it will only be done quarterly by the CC. All practices will be monitored via logbooks, observation, as outlined in another section, and updated training as needed at time of infraction.

The Infection Control Coordinator and the Clinical Coordinator will provide ongoing training. The Office Manager will oversee the documentation of all training to maintain a current and up to date personnel file on all SISC employees and credentialed medical staff and report to Governing Body

Completion Goal 12/29/2015

Echo Williams

Q 064

The sterilization of all dental instruments will be addressed per Center for Disease Control (CDC) guidelines as provided to the American Dental Association (ADA). As there has been no specific, uniform process here at SISC one will be created per manufactures and CDC recommendations. This process shall be included in the policies that will be rewritten concerning this procedure. Reminders will be posted in both 'dirty' and 'clean' rooms. Logs will be created to track sterilization. All dental assistants will be

trained on SISC's procedure for re-processing to ensure that both ADA and CDC infection control standards are met. DA /DH will be trained, their first day scheduled at SISC. There will need to be proof of completion of training and a statement of understanding in their personnel file prior to their being allowed in the 'dirty' and 'clean' rooms. If they are not trained they will not be allowed to run their own sterilization of instruments. It will be ran by SISC's RN/LPN or ICC when they have time to do it between patient care and SISC duties. As previously stated the OM will be responsible for the monitoring of personnel files on a yearly basis and will report to the Governing Body of anything found lacking.

Completion Goal: 12/29/2015

Echoll Williams

Q 064

In the current Policy and Procedure Handbook, Section 6, Patient Care, has sterilization policies. These are to be rewritten per CDC and ADA guidelines. As per the new policies, when they are approved, the sterilization of dental instruments will include the use of the Statim. SISC has chosen to not activate the "Process Enforced Usage" on our Statim. We feel that with the number of dental offices and assistants from each office, assigning each individual a code is not feasible. SISC will instead place log books that require all personnel running loads through the Statim to document the load number, items being processed, person running load and the office they are from and the reading from the sterilization strip that will be included in each load. There is a comment section to document any "out of the ordinary" situations ie: when they forgot the strip and have to re-run the load, or it didn't run properly because of water levels etc. Each pre-soak bucket, timer, Statim and logbook have been assigned to an OR so that whomever is working in that OR will know which equipment is for them to run their instruments through without the mixing of instruments and contaminants. This will be addressed during the Statim training. Proof of this training will be included with the sterilization of dental instruments.

All sterilization training and cleaning agents if needed, will be per CDC and ADA recommendations as the ADA recommendations address all manufactures of dental instruments, this will be our standard. As stated previously this observation check list is still being created as we are still gathering all the needed data to ensure CDC and manufacturer requirements are met. All instruments will be divided into three (3) categories per CDC standard as: 1) Critical, 2) Semi-critical, and 3) Non-critical. Our policy will be written to reflect these categories as they all need processed differently. The RN/LPN on staff will be trained by the CC and ICC on the proper procedure so they can watch the credentialed staff to ensure that the standards are maintained. As stated previously if corrective action is needed they will do it and then notify the OM and it will be documented in incident log.

Completion Goal 12/29/2015

Echoll Williams

Q 064

In response to the claim that states the "ASC failed to ensure sterilized instruments were not compromised prior to use." DA B will no longer be leaving anything out for the next day. All equipment will be sterilized and locked up until the next day when she will set up. OM will follow up before assistant leaves building to ensure all dental instruments are sterilized and locked up.

Completion Goal 12/18/2015

Echoll Williams

Q 064

The Statim will go through weekly biological and chemical testing per CDC standard. There is a log book assigned to each Statim that will document this testing and by whom the testing was performed. This logbook will also contain any and all maintenance performed on the Statim and by whom that work was completed. Once the standard of care has been met these log books will be reviewed monthly by the ICC who will report findings to the IP and OM. Until the standard has been met the log will be reviewed weekly by the ICC to ensure that the biological monitoring has been performed. The ICC will report to the IP via OM throughout this process. If there is a failure to test discovered the ICC will perform the Biological Indicator test and then report the failure to test to the OM who will address this failure with the appropriate staff member and then notify the IP.

Completion Goal 12/29/2015

Echoll Williams

Q 064

SISC will ensure that all staff and credentialed staff are trained and compliant with policies and procedures pertaining to Infection Prevention and Control. We will provide documentation of training and completion of training. Any and all visiting providers will not be allowed to see patients at SISC until there is appropriate documentation in their personnel file. As stated previously, the OM will manage the documentation of training completion and personnel files. There will be yearly audits done on all personnel files with findings reported to the Governing Body.

Completion Goal 12/29/2015

Echoll Williams

RECEIVED

FEB 17 2016

FACILITY STANDARDS

Plan of correction for SISC's Immediate Jeopardy

Response to Q 060

Policy and Procedure Handbook reviewed for deficiencies

Completed 12/29/2015

Echo Williams

Individual policies reviewed and modified where found lacking or incomplete in accordance with CMS, CDC, ADA, or OSHA guidelines. They will be submitted to Governing Body for approval See Q 064

Completed 12/29/2015

Echo Williams

Put into practice a Clinical Coordinator (CC) (Appendix A) and an Infection Control Coordination (ICC) (Appendix B)

See Q 064

Completed 12/29/2015

Echo Williams

Created a Checks and Balance system to support policy compliance. See Q 064

Completed 12/29/2015

Echo Williams

Q064

In response to the claim that "No policy specified how oversight of the medical and nursing services would occur" we created a Director of Nursing (DN). (Section 3.320, Appendix A) The Director of Nursing will report to the Medical Director (MD) by email a minimum of once a month. There may be phone conversations that need to take place. All conversations will be logged in a log book. This log book will include all conversations concerning medical issues between the MD and DN. It will be reviewed by the office manager quarterly. If there is a deficiency discovered by the OM, the OM will discuss it with the DN for clarification if needed or for actual correction of deficiency. If the deficiency is medically related the OM will immediately call the MD so the MD can take corrective action if needed. The deficiency will be documented in the incident log and the personnel file, it will then be reported to the Governing Body. The Medical Director will visit a minimum of two (2) times a year to evaluate the competency of the Director of Nursing and participate in training and emergency drills.

Completed 12/29/2015

Echo Williams

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FEB 17 2016

FACILITY STANDARDS

Plan of correction for SISC's Immediate Jeopardy

Response to Q 060

Policy and Procedure Handbook reviewed for deficiencies

Completed 12/29/2015

Echo Williams

Individual policies reviewed and modified where found lacking or incomplete in accordance with CMS, CDC, ADA, or OSHA guidelines. They will be submitted to Governing Body for approval See Q 064

Completed 12/29/2015

Echo Williams

Put into practice a Clinical Coordinator (CC) (Appendix A) and an Infection Control Coordination (ICC) (Appendix B)

See Q 064

Completed 12/29/2015

Echo Williams

Created a Checks and Balance system to support policy compliance. See Q 064

Completed 12/29/2015

Echo Williams

Q064

In response to the claim that "No policy specified how oversight of the medical and nursing services would occur" we created a Director of Nursing (DN). (Section 3.320, Appendix A) The Director of Nursing will report to the Medical Director (MD) by email a minimum of once a month. There may be phone conversations that need to take place. All conversations will be logged in a log book. This log book will include all conversations concerning medical issues between the MD and DN. It will be reviewed by the office manager quarterly. If there is a deficiency discovered by the OM, the OM will discuss it with the DN for clarification if needed or for actual correction of deficiency. If the deficiency is medically related the OM will immediately call the MD so the MD can take corrective action if needed. The deficiency will be documented in the incident log and the personnel file, it will then be reported to the Governing Body. The Medical Director will visit a minimum of two (2) times a year to evaluate the competency of the Director of Nursing and participate in training and emergency drills.

Completed 12/29/2015

Echo Williams

Plan of Correction

Q 060 Condition ~

The ASC will ensure that all procedures are performed by qualified physicians who have been granted privileges at our ASC.

Refer to Q 061 as it relates to the ASC's ability to ensure that a comprehensive patient assessment is complete prior to anesthesia.

Refer to Q 064 as it relates to the ASC's ability to ensure personnel are trained on equipment and sanitary practices to ensure a safe environment.

Completed 02/22/2016

Echo Williams

Q 061 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the review of patient files to assure that everything is completed and documented as such. This will be documented and completed by the OM and Medical Director with a summary verbally reported to the Governing Body.

Completed 02/22/2016

Echo Williams

Q 064 Standard ~

Refer to Q64 of the Immediate Jeopardy abatement plan submitted 12/23/2015 and abated on 12/29/2015 as it refers to the credentialing of personnel and documentation of training on ASC's policies.

Completed 02/22/2016

Echo Williams

Plan of Correction

Q80 Condition ~

The ASC will maintain a regular ongoing QAPI program through regular patient file reviews as spelled out in Section 8 of the Policy and Procedure Manual to ensure appropriate documentation and charts, by running patient account summary reports of off Open Dental on a monthly basis to ensure timely filing/billing/payment of all accounts. The ASC will keep and review log books that will document disgruntled parents, patients that arrive but are not on the schedule, parents that come out of recovery requesting a nurse or an update, patients who have had an extended wait past the reasonable wait time, patients that are canceled due to NPO, injury's sustained on ASC property, post op phone calls are they ASC (anesthesia) related or dental related and need to be referred to the dentist office to resolve. This data will be collected to ensure patient quality of care has been met and collection of data on potential areas for improvement between the patients or the referring dentist office. The ASC will maintain an observation program of hand hygiene and policy and procedure enforcement on a quarterly basis. Through the data collected via observation a yearly training will be chosen. The GB will decide which programs to focus on and the appropriate training to present to staff.

Refer to Q 081 as it relates to the ASC's ability to ensure a comprehensive, data-driven QAPI program that measures, analyzes, and tracks quality indicators is maintained.

Refer to Q 082 as it relates to the ASC's ability to ensure quality indicator data, including the negative, is collected, analyzed, and reviewed.

Refer to Q 083 as it relates to the ASC's ability to ensure PIP's are conducted.

Refer to Q 084 as it relates to the Governing Body's ability to oversee the QAPI program.

Completed 02/22/2016

Echo Williams

Q 081 Standard ~ Program Scope

The ASC will maintain a fully functional QA Committee as outlined in Section 8 of the Policy and Procedure Manual. The GB has changed Section 8.100 GA Committee, by adding more members and amending the policy to allow for meetings with only partial committee available with the stipulation that the rest of the committee be informed of the meeting, and the notes be made available to them. The OM will maintain a binder with the meeting notes.

Plan of Correction

The QA Committee will meet as a whole two (2) times a year. At this meeting they will review incident reports, machine/equipment maintenance reports, discuss the need for different or new equipment, safety report, file review, doctor/patient charts reviewed, charts reviewed on any emergencies or unusual occurrence cases, and anything else that needs to be discussed. The QA Committee will break down all the information into specific indicators that include, but are not limited to, Process of Care Indicator, Physical Facility Indicator, Outcome Indicators, Financial Performance Indicators and Infection Control Indicators. At the end of the meeting there will be a summary made with recommendations to suggest to the GB. These reports will be maintained by the OM to be presented in the GB at their meeting.

The QAPI program set up by the ASC will be maintained by the QA Committee. It will include, but is not limited to, the following quality indicators: patient charts, credentialed staff, employees of the ASC, (under the direction of the GB) creating and caring out PIP's and the review maintenance of PIP's, facility maintenance being performed when needed, emergency equipment up to date, Rx safety (locked up, logged, accounted for, ordering practices), billing of insurance and Medicaid, infection control, renewal of transport agreement done by MD, renewal of CLIA waiver and maintaining x-ray registration, internet safety and HIPPA compliance, and patient care pre and post-operative. The QA members will each be assigned different aspects of the QAPI to be responsible for and will answer to the committee as a whole two (2) times a year.

The ASC, through the QA, will develop and maintain a comprehensive QAPI program that will be developed and implemented to measure and analyze all the quality indicators mentioned. They will focus on the data directed high volume and problem-prone areas.

Completed 02/22/2016

Echall Williams

Q 082 Standard ~ Program Data

The ASC has incident log books that will be used to collect data. These log books will be maintained by various ASC personnel. The Clinical Coordinator, Infection Control Coordinator, and the Director of Nursing have logbooks where they will maintain documentation of incidents that are brought to their attention within the scope of their responsibilities. The front desk has an incident log book that will be maintained by the front desk personnel and the OM that include incidents within the scope of their responsibilities. The log books are designed to identify problems and document how they were resolved or need to be resolved. There are specific areas of interest in each log book with room for additional

Plan of Correction

topics and data to be added. Quarterly, these logbooks will be reviewed and summarized by the OM or whomever the OM assigns. These summaries will be reviewed by the QA Committee to interpret the data. Refer to Q 81 as refers to the QA oversight. This data will be sent to the GB with a recommendation.

There will be monthly patient account summary reports printed off of Open Dental to ensure that all patients have been billed in a timely manner, and that the accounts remain up to date. This will be done by the OM or whomever the OM assigns. It will be reviewed for deficiencies by the OM. Any deficiencies will be documented in the patients file with a note made in the Incident log book. These will be included in the quarterly reports sent to the QA Committee for data interpretation. This will be included in the QA reports to the GB.

The OM will review five (5) patient charts a month for completion. The OM will check for a current H&P, Pre-admission order sheet, Pre-Anesthesia Questionnaire, Notice of Patients' Rights received, completed treatment form, and proof of billing and payment. If there are any charts noted to be deficient, it will be documented in the appropriate log book and the patient file and if applicable action will be taken to ensure the chart is corrected. See Section 8.212 of the Policy and Procedure Manual (Appendix E). These will be included in the quarterly summaries done by the QA that are sent to the GB.

The MD will also pull five (5) random charts to review. The MD will be reviewing the charts for the same content as the OM. If there are any deficiencies noted they will be documented in the log book and the patient chart. (See Section 8.212 of the Policy and Procedure Manual) These will be included in the quarterly summary of the log books that is sent to the QA committee for review then on to the GB. There will be training if necessary and continued observations of compliance performed by the appropriate staff.

Completed 02/22/2016

Echo Williams

Q 083 Standard ~ Performance Improvement Projects

The ASC has poor records of the past Performance Improvement Projects. To rectify this refer to Q 81 as it refers to more committee members added and documentation of all meetings held.

The ASC's GB has currently undertaken a project that was brought to our attention through the CMS audit. The ASC is reviewing what information is in patient charts and if it meets the CMS standard. The purpose of this PIP is twofold. First is to bring all our current and future patient charts up to CMS

Plan of Correction

standard. Secondly, to identify dental offices that are consistently late providing us the required information, not getting us the correct information, or not providing any information.

As the ASC works with multiple dental offices there has not been a uniformity of information received. After reviewing what CMS requires in each patient chart the GB has been requesting specific information from all offices prior to their patient being seen at our facility. There have been forms revised and or created for this purpose. The patient may be denied services at our facility if we do not receive the requested information in a timely manner.

To complete history part of the H & P there is the Pre-Anesthesia Questionnaire (PAQ) (Appendix A) that we receive from the offices on all patients scheduled. If there are any "yes" circled the dental office must send it via fax or email to the ASC contracted CRNA for Medical Clearance prior to being scheduled. The CRNA will review the PAQ, and after getting clarification on any of the yes answers from either a parent or current doctor's notes, the CRNA will either clear the patient or refer them to the dentist as a hospital case. If the patient has been medically cleared by our CRNA then they can be scheduled here.

A Pre-Admission Orders (PAO) form (Appendix B) has been created for all dentist to complete on each patient and deliver to us prior to the day of surgery. The PAO includes the treatment planned and a notice of consents signed through the dental office stating that the patient or patients' guardian understands all that the dentist plans to do while the patient is under general anesthesia.

With the information from the PAO, our office completes our consent for Dental Work Under Anesthesia (Appendix H) that the patient or patients' guardian and the dentist both sign prior to surgery. This consent is time and date stamped.

As this project is still underway we do not have all the documentation and results available. After the data is collected it will be turned over to the GB so decisions can be made concerning the content of the patients' charts and if it meets CMS standards. The GB will decide if more charts need to be reviewed and if the forms we required from the dental offices is sufficient. The data will help determine the offices that need to be addressed individually.

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 084 Standard ~ Governing Body responsibilities

The GB will ensure that the QAPI program is defined and maintained by ASC employees. After reviewing data sent to the GB by the QA Committee, the GB will focus on the data specifically directed at the high volume and problem-prone areas to decide on the appropriate PIP.

Refer to Q 40 as it relates to the GB responsibilities and how it will carry them out.

Refer to Q 82 as it relates to the data collected by the GB for QAPI data.

Refer to Q 83 as it relates to the GB choosing PIP's and monitoring their oversight.

Completed 02/22/2016

Echo Williams

Q 100 Condition ~

The ASC will provide a sanitary and safe environment for surgery and patient health, safety and care.

Refer to Q 101 as it relates to the ASC's ability to ensure equipment reprocessing is done according to manufactures guidelines.

Refer to Q 106 as it relates to the ASC's ability to ensure the staff is trained on emergency equipment.

Completed 02/22/2016

Echo Williams

Q 101 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to training personnel on the correct use of equipment and sterilization

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 106 Standard ~

The training of staff in the use of the emergency equipment will be documented and will be reviewed yearly (Appendix N). The Director of Nursing (DON) will be responsible for maintaining the equipment and keeping it in safe, current, functioning condition through regular checks on expiration dates

Completed 01/19/2016

Echo Williams

Q 120 Condition ~

The GB will require anyone working in an OR to go through the credentialing process (See Section 2 of the Policy and Procedure Manual), or be an employee of the ASC.

Refer to Q 121 as it relates to the ASC's ability to ensure medical staff privileges are granted by qualified personnel.

Refer to Q 123 as it relates to the ASC's ability to ensure oversight of personnel is monitored to ensure appropriate patient care

Completed 02/22/2016

Echo Williams

Q 121 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the credentialing of personnel.

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 123 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the adding of credentialing the dental assistants as well as the dentist and quarterly observations

Completed 02/22/2016

Echo Williams

Q 140 Condition ~

The ASC will employ a Director of Nursing and Clinical Coordinator

Refer to Q 141 as it relates to the ASC's ability to ensure nursing staff policies are enforced.

Completed 02/22/2016

Echo Williams

Q 141 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the adding of a Director of Nursing and Clinical Coordinator

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 160 Condition ~

The ASC will complete the patients H&P with the completed PAQ. If the PAQ was filled out by the patient or patients' guardian longer than 30 days, during check in, prior to the surgery, the patient or guardian will be asked to review the PAQ for any changes and then sign and date the bottom of the sheet. The physical to confirm patient is cleared for surgery will be performed by the nursing staff and CRNA as they will review the patients' medical history and other aspects of the pre-op as outlined on the GA sheet (Appendix D). This will be signed off by the physician prior to surgery.

Refer to Q 162 as it relates to the ASC's ability to regulate medical records

Completed 02/22/2016

E. Williams

Q 162 Standard ~

Prior to the date of service front office personnel will review all patient information sent to the ASC from the dental office to ensure that all of patients' vital information, pre-anesthesia questionnaire (Appendix A), and pre-admission orders (Appendix B) are complete. Pre-admission order form includes treatment plan, x-rays requested, dental office consents and review of allergies. Refer to Q83 as it refers to the use of the PAQ and the PAO

On the date of service the front desk will review the PAQ with patient or guardian if the PAQ is older than 30 days. The patient or guardian will be given a patient information sheet to fill out, the Patients' Rights and Responsibilities which include the Advance Directive Notification, patient Complaint or Grievance information and the Disclosure of Ownership (Appendix G), the Acknowledgement of Receipt of Notice of Privacy Practice and Advance Directive (Appendix P) that includes a section that identifies if parent, guardian or patient representative. If it is a guardian or patient representative we must have court or notarized documents to support their statement. Refer to Q 230 as it relates to other situations beyond the parent, guardian or patient representative.

They will also be given a copy of the Anesthesia Consent (Appendix H), Consent for Dental Surgery and Anesthesia (Appendix H cont.) (Refer to Q 83 as it relates to the Consent for Dental Surgery and Anesthesia), and Patients Financial Responsibility (Appendix H cont.) After the paperwork is filled out and the consents read, the patient or patient parent/guardian will be asked to sign digitally for the consents. The digital consent includes a date and time stamp (Appendix I). Before the patient is taken back to the room the front office staff will fill out a checklist to ensure that everything is in order for surgery (Appendix Q)

Plan of Correction

The patient H&P within 30 days of surgery documentation will include but is not limited to: the Pre-Anesthesia Questionnaire and Medical Clearance form if required, and a completed top right side section of the GA sheet filled out. The Physician will sign after he has reviewed the notes and visited with the patient prior to surgery.

At the completion of the dental procedure the nursing staff and front office personnel will review the file to ensure all the proper information is completed by credentialed staff prior to them leaving the facility. The completed treatment plan (Appendix C) will be filled out by the dentist or dental assistant that attended to the procedure but it must be signed off by the dentist. The CRNA will fill out the GA sheet, and the RN/LPN will complete the discharges post-op. On the GA sheet (Appendix D) there will be three signatures consisting of the doctor, anesthesia provider, and discharging nursing staff.

Refer to Q 82 as it refers to the patient chart review for completion.

Completed 02/22/2016
Echo Williams

Q 200 Condition ~

The ASC's MD will ensure that the ASC maintains a current CLIA Waiver from the State

Refer to Q 201 as it relates to the ASC's ability to ensure that laboratory services are provided in accordance with CLIA requirements.

Refer to Q 203 as it relates to the ASC's ability to ensure that radiology services are provided in a safe effective manner, in accordance with physician orders and conducted by qualified personnel.

Completed 02/22/2016
Echo Williams

Q 201 Standard ~

The ASC will obtain and maintain CLIA certificate of waiver (Appendix F) that allows the medical staff to perform HCG testing on females that have begun menses.

Plan of Correction

The only HCG test that will be recognized for surgery approval is to be done at the ASC with a urine sample provided by the patient when patient presents for surgery. The ASC's nursing staff will perform the test and read the results prior to surgery according to quality standards.

Completed 02/22/2016

Echoll Williams

Q 203 Standard ~

The ASC will register all x-ray taking equipment with Idaho Bureau of Laboratories per Idaho Code Section 39-3006 (Appendix M).

Refer to Q 162 as it relates to the doctors' orders concerning the taking of X-rays.

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the credentialed staff being "trained and compliant with the policies and procedures...providers not allowed to see patients at SISC until there is appropriate documentation in their files." (Appendix L of IJ)

Completed 02/22/2016

Echoll Williams

Q 219 Condition ~

The ASC will ensure that all patients are informed of their rights and have proper consents in place prior to the surgery.

Refer to Q 221 as it relates to the ASC's ability to ensure the patient is provided with a written and verbal comprehensive rights information prior to their procedure.

Refer to Q 224 as it relates to the ASC's ability to ensure patients are provided with information regarding advance directives.

Refer to Q 225 as it relates to the ASC's ability to ensure that the patient is notified of the grievance process, including how to file a grievance.

Refer to Q 229 as it relates to the ASC's ability to ensure that informed consents are obtained prior to procedures being performed.

Refer to Q 230 as it relates to the ASC's ability to ensure that informed consents are obtained from legally authorized patient representatives prior to procedure.

Plan of Correction

Refer to Q 232 as it relates to the ASC's ability to ensure that the patients' rights to receive care in a safe setting is being upheld

Completed 02/22/2016

Echo Williams

Q 221 Standard ~

Refer to Q 162 as it pertains to the patient's receipt of a copy of their Patients' Rights and Responsibilities (Appendix G). After they have read through the Consents and Patients' Rights they will be asked if there is anything they need clarification on before they are asked to sign. After it is clear the person signing has had all their questions answered then they will be asked to sign a digital copy of the consents. While having them sign digitally the front desk personnel will give a brief summary of the consent they are signing as a way of giving a reminder as to what they are signing. The digital signature has a date and time stamp that has been added (Appendix I).

Completed 02/22/2016

Echo Williams

Q 224 Standard ~

Refer to Q 162 as it applies to the receipt of Advance Directive.

The patient or parent, guardian or patient representative will be given a copy of the Patients' Rights (Appendix G). There will also be a box on the GA sheet to be marked for Patients' Rights and Advance Directive having been provided to patient (Appendix D).

Completed 02/22/2016

Echo Williams

Q 225 Standard ~

Refer to Q 162 as it relates to the patient's rights to file a complaint or grievance and informed of how and where (Appendix G)

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 229 Standard ~

Refer to Q 162 as it relates to the date and time stamp on digital consents (Appendix I).

Refer to Q 162 as it relates to the Pre-Admission Orders (Appendix B) which include "Risk, benefits and alternatives" being discussed with patient, parent, guardian or patient representative in dental office and the consent date of papers signed.

Refer to Q 162 as it relates to identifying relationship to patient to ensure consents are obtained by a legal representative. (Appendix P)

Completed 02/22/2016

Echo Williams

Q 230 Standard ~

Refer to Q 162 as it relates to identifying relationship to patient.

The ASC will ensure the relationship to the patient in two (2) different documents that come from our office. The first will be on the Pre-Anesthesia Questionnaire (refer to Q 162 Appendix A) where it asks for relationship to patient, which is filled out prior to the patient coming to the ASC and then a second time on the New Patient Form (Appendix J) that will be filled out in the office the day of the procedure. Also, a letter was sent out in September of 2015, to all the Dental offices that bring patients to our facility concerning the need for the legal guardian to be the one filling out the consents and a detailed process to follow in case of foster care or guardianship.

In the cases where there is not an appointed guardian we as an ASC are referring to Idaho Statutes, Title 39 *Health and Safety*, Chapter 45 *The Medical Consent and other Natural Death Act*. 39-4503 where it states "Any person who comprehends the need for, the nature of, and the significant risks ordinarily inherent in any contemplated hospital, medical, dental, surgical or other health care, treatment or procedure is competent to consent thereto on his own behalf." "...may provide such health care and services in reliance upon such a consent if the consenting person appears...to possess such requisite comprehension at the time of giving the consent" as it applies to those patients signing for themselves.(Appendix K)

39-4504 (g) "Any relative of such person who represents himself or herself to be an appropriate, responsible person to act under the circumstances;" (h) "Any other competent individual representing himself or herself to be responsible for the health care of such a person" (Appendix L)

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 232 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it relates to the sterilization process

Completed 02/22/2016

Echo Williams

Q 240 Condition ~

The ASC will maintain an infection control program that will actively strive to minimize infections and communicable diseases.

Refer to Q 241 as it relates to the ASC's ability to ensure that patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice.

Refer to Q 242 as it relates to the ASC's ability to ensure that there is an ongoing program to control and prevent infections and communicable diseases.

Refer to Q 243 as it relates to the ASC's ability to ensure the Infection Preventionist provides sufficient direction over the infection control program.

Refer to Q 244 as it relates to the ASC's ability to ensure infection control is addressed as an integral part of the ASC QAPI program.

Refer to Q 245 as it relates to the ASC's ability to ensure that there is a comprehensive action plan to prevent, identify, and manage infections and communicable diseases within the ASC.

Refer to Q 261 as it relates to the ASC's ability to ensure a comprehensive H & P is completed within 30 days prior to surgery.

Completed 02/22/2016

Echo Williams

Q 241 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the standard of hygiene

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 242 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to ongoing observations and training of personnel

Completed 02/22/2016

Echo Williams

Q 243 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers to the Infection Control Coordinator.

Completed 02/22/2016

Echo Williams

Q 244 Standard ~

Refer to Q 083 and Q 84 as they relate to GB oversight of PIP's

Completed 02/20/2016

Echo Williams

Q 245 Standard ~

Refer to Q64 in Immediate Jeopardy abatement plan submitted 12/23/2015 abated on 12/29/2015 as it refers documentation of sterilization tests that are ran weekly and ongoing training and observations.

There will be continued quarterly observations done on staff and credentialed personnel to ensure continued compliance to hand hygiene, PPE's and sterilization of instruments. The observations will be done by the Clinical Coordinator, Infection Control Coordinator, Director of Nursing or the Medical Director. These observations will be placed in their personnel file. If deficiencies are found, they will be addressed by the ICC. If continued failure to comply is observed, the person will be referred to the GB for dismissal.

Completed 02/22/2016

Echo Williams

Plan of Correction

Q 261 Standard ~

In the patient's chart, a completed Pre-Anesthesia Questionnaire (PAQ) will be filled out prior to surgery. If the surgery day occurs more than 30 days after completion of the PAQ the patient or parent, guardian, or patient representative will be asked to review the information for any changes and then sign and date the bottom. The front office personnel will review the patient charts the day before the procedure and highlight the charts that need an 'updated' PAQ. The PAQ will also be reviewed by ASC personnel during the exam prior to surgery. The Physician will sign the chart after his examination of the patient to confirm patient has been cleared for surgery.

Refer to Q 162 as it applies to the H&P

Charts will be reviewed by the Office Manager a minimum of five (5) charts a month and the Medical Director five (5) charts per quarter to ensure that all forms are being completed correctly and that there are no missed steps. See Section 8.212 of the Policy and Procedure Manual (Appendix E) and Section 8.2131 (Appendix O)

Completed 02/20/2016

