IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RUSSELL S. BARRON– 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 83720-0036
PHONE: (208) 334-6626
FAX: (208) 364-1888
E-mail: fsb@dhw.idaho.gov

May 8, 2018

Clark Brinton, Administrator
Emerald Surgical Center
811 North Liberty
Boise, ID 83704

RE: Emerald Surgical Center, Provider #13C0001017

Dear Mr. Brinton:

On May 2, 2018, a follow-up visit of your facility, Emerald Surgical Center, was conducted to verify corrections of deficiencies noted during the survey of March 21, 2018.

We were able to determine that the Condition of Participation of **Governing Body and Management (42 CFR 416.41) and Assessment and Performance (42 CFR 416.43)** are now met.

Emerald Surgical Center continues to be out of compliance with the Medicare Condition of Participation of **Infection Control (42 CFR COP 416.51).**

Also enclosed is a Statement of Deficiencies/Plan of Correction, Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction.

An acceptable plan of correction (PoC) contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;

- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of the Form CMS-2567.

After you have completed your Plan of Correction, return the original to this office by **May 20, 2018**, and keep a copy for your records.

In our letter to you dated March 29, 2018 we stated: "failure to correct the deficiencies and achieve compliance will result in our recommending that the Centers for Medicare and Medicaid Services (CMS) Region X Office, Seattle, Washington, terminate your approval to participate in the Medicare program."

Because of your failure to correct, we have made that recommendation. CMS will be in contact with you regarding the procedures, timelines, and appeal rights associated with this recommendation that must be followed.

Sincerely,

NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt

ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Patrick Thrift, Survey & Certification Manager Region X
Julius Bunch, Certification & Enforcement Manager Region X

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

IMPORTANT NOTICE – PLEASE READ CAREFULLY

May 16, 2018

Administrator
Emerald Surgical Center
811 North Liberty
Boise, ID 83704

CMS Certification Number: 13C0001017

Re: Notice of Enforcement Action
Recertification Survey completed on March 21, 2018
Revisit Survey completed on May 2, 2018
Conditions for Coverage Remains Not Met
Placed on 90 day termination track

Dear Administrator:

After careful review of the facts, the Centers for Medicare and Medicaid Services (CMS) has determined that Emerald Surgical 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 **June 19, 2018,** (90 days from the exit date of the survey with conditions out) the Secretary of the Department of Health and Human Services intends to terminate its provider agreement with Emerald Surgical Center.

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 1832(a) 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) § 416.35 authorize CMS to terminate Medicare provider agreements when a supplier, such as Emerald Surgical Center no longer meets the Conditions for Coverage for ASCs.

This is an official notice sent electronically or facsimile, pursuant of 42 C.F.R. part 488. No hard copy to follow.

On March 21, 2018, the Idaho Department of Health and Welfare (State survey agency) completed a recertification survey and found that Emerald Surgical Center was not in substantial compliance with federal requirements for ASCs participating in the Medicare and/or Medicaid programs. The following Conditions for Coverage were found not met during the May 2, 2018 revisit survey:

§ 42CFR 416.51 Q-0240 Infection Control

These deficiencies limit the capacity of Emerald Surgical Center to furnish services of adequate level and quality. The details of the above deficiencies were listed on the Statement of Deficiencies and Plan of Correction (Form CMS 2567). Emerald Surgical Center was provided an opportunity to correct the above deficiencies, but failed to provide a credible Plan of Correction in the time specified in your original instructions received from the Idaho Department of Health and Welfare. CMS has determined that if acceptable Plan of Correction is submitted and accepted, CMS will consider authorizing the Idaho Department of Health and Welfare to conduct a second revisit prior to the termination date to confirm compliance.

PUBLIC NOTICE OF TERMINATION

In accordance with 42 CFR 489.53(d) a legal notice of CMS actions will be published on the Survey & Certification (S&C) website at least 2 days prior to termination.

All correspondence and questions should be directed to CMS_RO10_CEB@cms.hhs.gov Attn: Renae Hill.

Sincerely,

Julius P. Bunch Jr.

Julius P. Bunch, Jr., Manager
Division of Certification and Enforcement Branch
CMS Regional Office - Seattle

cc: Idaho Department of Health and Welfare

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

PRINTED: 05/07/2018
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001017	A. BUILDING _____ B. WING _____	R 05/02/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EMERALD SURGICAL CENTER	811 NORTH LIBERTY BOISE, ID 83704

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{Q 000}	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification follow-up survey of your ASC conducted on 5/01/18 to 5/02/18. Surveyors conducting the follow-up survey were: Brian Osborn, RN, HFS - Team Leader Laura Thompson, RN, BSN, HFS Acronyms used in this report include: AORN - Association of periOperative Registered Nurses ASC - Ambulatory Surgery Center CI - Chemical Indicator CST - Certified Scrub Technician GB - Governing Body IFU - Instructions For Use OR - Operating Room QAPI - Quality Assessment Performance Improvement	{Q 000}	RECEIVED MAY 17 2018 FACILITY STANDARDS	
{Q 041}	CONTRACT SERVICES CFR(s): 416.41(a) 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 the ASC plan of correction review, review of governing body meeting minutes, and staff interview, it was determined the governing body failed to ensure oversight of contracted services for the ASC. This resulted in a lack of contract development and monitoring of services provided to the ASC. Findings include: A Medicare recertification survey was conducted	{Q 041}	A governing body meeting was held on 5-8-2018. The contracts were reviewed and approved without changes to the contracts. Nurse Director will now include on all future agenda's, the topic of contract review. This will help the GB monitor and track the Contracts on an annual basis. This plan of correction was completed on 5-16-2018	

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

Clara Clark | Nurse Director | 5-11-2018

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

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{Q 041}	Continued From page 1 at the ASC from 3/19/18 to 3/21/18. The ASC was cited at Q41 due to the governing body's failure to have oversight of contracted services. The ASC submitted a plan of correction, dated 4/06/18, signed by the Nurse Director. The submitted plan of correction included: "We will review all contracts from outside services and also update any contracts that require updating and/or new contracts. Develop a method to evaluate said contracts annually by the Governing Body and on an ongoing basis as contracts are changed or renewed by 4/25/18 by Governing Body 4/25/18 [sic] Nurse Director initiated [sic]." The ASC's submitted plan of correction was not implemented. The governing body meeting minutes, dated 4/18/18, signed by the members of the governing body, included 14 topics which were discussed: 1. "Centers policy and Procedures" 2. "Centers Plans Approved" 3. "Medical Staff Credentials Review and Privileges" 4. "Positions approved" 5. "Important problems and concerns to be studied" 6. "Staff concerns" 7. "Incidents Reviewed" 8. "Patient Satisfaction / Complaints" 9. "Clinical record reviewed" 10. "Transfers" 11. "Facility & Environmental issues" 12. "Infections" 13. "Pharmacy, Radiology & Laboratory" 14. "Benchmarking"	{Q 041}	see page 1	

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{Q 041}	Continued From page 2 Review of the ASC's contracts by the governing body was not included in the meeting minutes. The Nurse Director was interviewed on 5/01/18, beginning at 11:35 AM, and the governing body meeting minutes were reviewed in his presence. When asked how many governing body meetings had taken place since the exit of the previous survey on 3/21/18, he stated 1, on 4/18/18. When asked if the ASC contracts were reviewed by the governing body, as outlined in their plan of correction, the Nurse Director stated no. The Nurse Director confirmed the ASC's plan of correction was not implemented. The governing body failed to review and evaluate the ASC's contracted services.	{Q 041}	See page 1	
{Q 084}	GOVERNING BODY RESPONSIBILITIES CFR(s): 416.43(e) 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 review of the ASC's plan of correction,	{Q 084}	A GB meeting was conducted on 5-8-2018 and the 2018 QAPI program was presented to the G.B. by the M.D. The current data collection method and the 2 QI studies were approved and have been implemented. The QAPI data will continue to be evaluated and analyzed Quarterly and also reviewed by the GB Quarterly. * 5/17/18 ADDENDUM: Pg. 4.	

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{Q 084}	Continued From page 3 review of governing body meeting minutes, and staff interview, it was determined the governing body failed to define and approve the ASC's QAPI program. This resulted in a lack of documented QAPI program oversight by the governing body. Findings include: A Medicare recertification survey was conducted at the ASC from 3/19/18 to 3/21/18. The ASC was cited at Q84 due to its failure to ensure the governing body implemented and maintained the QAPI program. The ASC submitted a plan of correction, dated 4/06/18, signed by the Nurse Director. The plan of correction included: "The governing body will reconvene quarterly and ensure the QAPI is approved to implemented [sic] and maintained. GB will evaluated [sic] for effectiveness and specify data collection methods, expectations, etc. [staff's name] will oversee the schedule at meetings [sic] Nurse Director + GB will meet by 4/25/18." The ASC's plan of correction was not implemented. The governing body meeting minutes, dated 4/18/18, signed by members of the governing body, did not include approval or evaluation of the ASC's QAPI program or approval of the QAPI program's method of data collection. The Nurse Director was interviewed on 5/01/18, beginning at 11:35 AM, and the governing body meeting minutes were reviewed in his presence. When asked how many governing body meetings had taken place since the exit of the previous survey on 3/21/18, he stated 1, on 4/18/18. The Nurse Director stated the governing body	{Q 084}	See page 3 Q 084 * ADDENDUM: 5/17/18 MEETING OF THE GOVERNING BODY: PARTICIPANTS CONCLUDED IT WOULD BE PRUDENT TO INCLUDE 'INFECTION CONTROL (IC) ASSESSMENTS IN OUR QAPI & GUIDELINES. AN ASSESSMENT TOOL PREPARED BY THE DEPT. OF HHS/CDC / VERSION 2.3 /9/2016 WAS APPROVED AND ADDED TO QAPI: EFFECTIVE 'IMMEDIATELY': TO BE MONITORED MONTHLY AND REVIEWED FOR INCONSISTENCIES. ASSESSMENT TOOL 'INCLUDES: - INFECTION CONTROL PROGRAM - ENVIRONMENTAL CLEANING - IC TRAINING - HAND HYGIENE - PERSONNEL SAFETY - STERILIZATION OF REUSABLE DEVICES - POINT OF CARE TESTING - DEVICE REPROCESSING - PERSONAL PROTECTIVE EQUIPMENT - INJECTION SAFETY - RESPIRATORY HYGIENE	

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{Q 084}	Continued From page 4 discussed the ASC's overall QAPI program at length during this meeting, but confirmed the governing body's approval and definition of the QAPI program was not documented. He confirmed the ASC's plan of correction was not implemented. The governing body failed to define and approve the ASC's QAPI program.	{Q 084}	See page 3 Q 084	
{Q 240}	INFECTION CONTROL CFR(s): 416.51 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, policy review, review of manufacturer instructions, review of national guidelines, 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 the potential for increased risk of patient infections. Findings include: Refer to Q241 as it relates to the ASC's failure to ensure a sanitary environment for patients receiving care at the ASC and failure to follow manufacturer instructions and nationally recognized guidelines for disinfection and sterilization of surgical instruments. 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}	The 2018 infection control plan was completed 5-4-2018 by the I.C. nurse and ~~HSD~~ Nurse Director This plan included a revision in the instrument decontamination policy and the sterilization policy. The items were completed may 7th 2018 and presented to the GB by nurse director on 5-8-2018 the IC plan and revised policies were approved by GB * ADDENDUM: 5/17/18 MONITORED MONTHLY USING: QAPI (HHS/CDC ASSESSMENT TOOL) = STERILIZATION OF REUSABLE DEVICES / DEVICE REPROCESSING.	

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{Q 241}	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, policy review, review of manufacturer instructions, review of national guidelines, and staff interview, it was determined the ASC failed to ensure a sanitary environment for patients receiving care at the ASC and failed to follow manufacturer instructions and nationally recognized guidelines for disinfection and sterilization of surgical instruments. This resulted in patients being placed at an increased risk for infections. Findings include: An ASC policy "Instrument Decontamination Policy," revised 4/2018, stated the procedure for preparation of surgical instruments for sterilization included directions to place dirty instruments in a sink with enzymatic cleaner, germicidal solution, and hot water and allowed to soak. The policy included a reference to AORN guidelines. The policy did not state these procedures followed manufacturers' instructions for use regarding mixing of the 2 chemicals and whether the surgical instruments IFUs included the use of these chemicals when cleaning them. An observation was conducted on 5/01/18 beginning at 1:30 PM, to watch disinfection and sterilization of surgical instruments. CST A and CST B were in the reprocessing area and adjacent OR. CST B performed the disinfection of the surgical instruments and prepared them for	{Q 241}	The use of germacidal solution in combination with the enzymatic cleaner was stopped immediately on 5/1/2018 The germacidal Cleaner was removed from the process of Instrument decontamination The instrument decontamination + sterilization policies were revised and updated after reviewing the enzymatic cleaners instructions and reviewing the surgical instruments manufactors guidelines for decontamination + sterilization of instruments and consulting AAMI National standard ST79 for Steam Sterilization. Thes guidelines and instructions were placed in a binder and placed in the decontamination room and guidelines were posted on the Cupboard above the Cleaning Sink. to allow easy access and reference to the guidlines. The CST's will follow	

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{Q 241}	Continued From page 6 sterilization in the autoclave. Manufacturer instructions and nationally recognized guidelines were not followed. Examples included: 1. The AORN 2015 Guidelines for Perioperative Practice in the "Sterilization and Disinfection" section under the "Guideline for Cleaning and Care of Surgical Instruments" included "Instrument Cleaning: Recommendation VIII" which stated "Surgical instrument, cleaning product, and cleaning equipment manufacturers' validated, written IFU should be reviewed for compatibility during selection and followed during use of cleaning products and equipment for cleaning and decontaminating surgical instruments." This was not done. Upon entrance into the decontamination and sterilization area CST B stated the surgical instruments were already soaking in the stainless-steel double sink. On the right side of the sink surgical instruments were soaking in water. When asked about the soaking of the instruments CST B stated after each procedure all instruments were soaked in water which included an enzymatic cleaner and a disinfecting agent. She stated instruments which were used during the procedure soaked in the water mixture for 3 minutes, and instruments which were not used soaked for 1 minute. When asked how much enzymatic and how much disinfectant was in the water CST B stated 2 pumps of each were added to the water. When asked how much water was in the sink CST B stated there was 2 gallons, and showed where the sink was marked on the backside with a small line to indicate the level.	{Q 241}	AAMI and Manufacturers guidelines for decontamination and sterilization of the Surgical instruments and follow enzymatic cleaners instructions for correct expose time, temperature, water quality, and concentration. The GB Approved the Revised policies on 5-8-18 * ADDENDUM: 5/17/18 MONITORED MONTHLY. USING QAPI (HHS/CDC) ASSESSMENT TOOL: STERILIZATION OF REUSABLE DEVICES/ DEVICE REPROCESSING	

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{Q 241}	Continued From page 7 The manufacturer IFU for the enzymatic stated "DO NOT add other chemicals such as bleaches, peroxides, or other detergents which could destroy the effectiveness of McKesson Multi-Enzymatic Spring Fragrance Cleanser." The manufacturer IFU for the disinfectant stated "TO CLEAN, DECONTAMINATE, AND DISINFECT: Remove gross dirt and soil. Thoroughly wet the surface with DisCide ULTRA Disinfecting Spray and allow to remain wet for the required contact time." The IFU did not include instructions for dilution or mixing with other chemicals. CST A and CST B were asked how long they had been mixing the enzymatic cleanser with the disinfectant to soak and clean the instruments. CST A stated they had been doing that for 5 weeks. When asked who made the decision to begin mixing the 2 chemicals CST A stated they, CST B and herself, made the decision after the recertification survey which occurred on 3/21/18. During an interview with the Nurse Director beginning at 2:20 PM on 5/01/18, he was informed of the observation and asked about the use of both the enzymatic cleanser and the disinfectant for disinfecting and cleaning the surgical instruments. He stated CST A and CST B did come to him and discuss the process change, using both chemicals simultaneously in the sink with water, and the policy was changed to reflect the use of both chemicals as part of the process. When asked whether they researched the process change, for use of both chemicals simultaneously, by reviewing manufacturers' IFUs or nationally recognized guidelines, the Nurse Director stated he did not do any research or	{Q 241}	See page 6+7.	

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{Q 241}	Continued From page 8 review of the IFUs or nationally recognized guidelines for disinfection and sterilization. A request was made for the number of procedures performed between 3/22/18 and 5/01/18. An additional request was made for the manufacturer names of the surgical instruments used at the ASC. During a subsequent interview with the Nurse Director beginning at 3:35 PM on 5/01/18, he reported 76 procedures were performed from 3/22/18 to 5/01/18. The Nurse Director stated he had called CST A to find out the names of the manufacturers for the surgical instruments. He stated the surgical instruments came from 4 different manufacturers. When asked for the manufacturers' IFUs for the instruments he called CST A, during the interview, to ask where they were located. The Nurse Director stated CST A informed him they were not present in the ASC, they did not have them. The website for one of the surgical instrument manufacturers was accessed on 5/02/18, www.depuysynthes.com, and the instructions for "Processing Synthes Reusable Medical Devices - Instruments, Instrument Trays and Cases," was reviewed. The instructions, under the section "Cleaning - Manual Method," stated "Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration." These instructions were not followed. The website for another surgical instrument manufacturer used in the ASC was accessed on	{Q 241}	See page 6+7.	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001017	A. BUILDING _____ B. WING _____	R 05/02/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EMERALD SURGICAL CENTER	811 NORTH LIBERTY BOISE, ID 83704

(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 241}	Continued From page 9 5/02/18, www.teleflex.com, and the instructions "General Instrument Sourcebook," was reviewed. The instructions, under the section "Manual Cleaning and Soaking," stated "If instruments have been exposed to blood, tissue, saline or other foreign matter, you must rinse them in warm (not hot) water before the substances are allowed to dry. After rinsing, immerse them in a cleaning and disinfecting solution...Follow the manufacturer's instructions for the preparation of the cleaning solutions." These instructions were not followed. The ASC failed to ensure staff followed nationally recognized guidelines and manufacturers' IFUs for disinfection and sterilization of surgical instruments. 2. During the observation beginning at 1:30 PM on 5/01/18, CST B was observed while preparing a tray for sterilization in the autoclave. After cleaning, rinsing, and drying the instruments CST B laid out a surgical towel on the counter and placed a stainless-steel container next to the towel. CST B placed instruments on the surgical towel and then rolled the towel with the instruments and placed it in the stainless-steel container. She did not place a chemical indicator inside the surgical towel with the instruments. CST B then sorted through the instruments and began placing them next to the rolled surgical towel inside the stainless-steel container. She then stated she would place a chemical indicator in the bottom of the container prior to wrapping it for sterilization. When asked why a chemical indicator was not placed inside the rolled surgical towel CST A	{Q 241}	the CI usage was revised 5-3-18 from the AORN 2015 guideline/Recommendation V that stated "a chemical indicator should be placed on the outside and inside of every package to be processed unless the internal indicator is readable through the package material" to the AAMI guideline 13.5222 "that a chemical indicator will be located in the least accessible area to steam penetration. CST's have been putting CI's inside the towel wraps within the outer wrap since 5-3-2018. * ADDENDUM: MONITORED MONTHLY: QUALITY (THIS/ODC) ASSESSMENT TOOL: DEVICE REPROCESSING: STERILIZATION OF RESUSE DEVICES	

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{Q 241}	Continued From page 10 stated it was not necessary because the chemical indicator they used was a "Class V" indicator. When asked what that meant, CST A stated the chemical indicator would identify if the container reached the appropriate time and temperature for sterilization. When asked again why it was not necessary to place the chemical indicator inside the rolled towel CST A stated because it was a Class V indicator, it was able to determine if sterilization occurred throughout the container, including the rolled towel. The AORN 2015 Guidelines for Perioperative Practice in the "Sterilization and Disinfection" section under the "Guidelines for Cleaning and Care of Surgical Instruments" included "Packaging Systems: Recommendation V" which stated, "A CI [chemical indicator] should be placed on the outside and inside of every package to be processed unless the internal indicator is readable through the package material." The guideline stated internal CIs are used to demonstrate that packages have been exposed to the physical conditions of the sterilizer. The ASC failed to follow nationally recognized guidelines for the use of chemical indicators. 3. The AORN 2015 Guidelines for Perioperative Practice in the "Sterilization and Disinfection" section under the "Guideline for Cleaning and Care of Surgical Instruments" included "Sterilization: Recommendation VII" which stated, "Immediate use steam sterilization (IUSS) should be kept to a minimum and should be used only in selected clinical situations and in a controlled manner." The recommendation stated IUSS may be associated with an increased risk of infection	{Q 241}	Emerald Surgical Center Immediately purchased an additional set of Knee arthroscopy Instruments. That will in effect make IUSS/ Flash sterilization use always to very infrequently. effective 5-9-2018 + Additionally: QAPI Assessment: monitored monthly: Sterilizer / Device Reprocessing	

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{Q 241}	Continued From page 11 to patients. Additionally, the recommendation stated time constraints may result in pressure on personnel to eliminate or modify 1 or more steps in the cleaning and sterilization process. Immediately after observing the disinfection and cleaning process for surgical instruments, beginning at 1:30 PM on 5/01/18, a request was made to review the log for IUSS. CST A stated they do not perform IUSS frequently at the ASC. However, entries in the log documented the ASC was performing IUSS several times a month. A request was made for copies of the IUSS log for the previous 6 months. The IUSS log documented a specific tray, which contained knee trocars and biters, underwent IUSS 2 to 5 times a day at least 2 procedure days a month. Examples include: - November 2017: Knee Trocars and biters 2 times on 11/01/17, 5 times on 11/15/17, and 4 times on 11/29/17 - December 2017: Knee Trocars and biters 4 times on 12/13/17 and 4 times on 12/27/17 - January 2018: Knee Trocars and biters 3 times on 1/24/18 - March 2018: Knee Trocars and biters 2 times on 3/07/18 and 3 times on 3/21/18 - April 2018: Knee Trocars and biters 4 times on 4/04/18 and 2 times on 4/18/18 When asked why this set underwent IUSS frequently each month, CST A stated the ASC had only the 1 set for use by a specific physician. When CST A asked whether this was brought to the attention of management or the physicians, she stated she had discussed it.	{Q 241}	The CST's participated in the AAMI Standards Update Webinar on 5-9-2018 to become familiar with the updated guidelines. Nurse Director approved. * ADDENDUM: 05/23/18 QAPI ASSESSMENT TOOL: MONITORING DEVICE REPROCESSING/ STERILIZATION OF REUSABLE DEVICES. MONTHLY MONITORING FOR UPDATES.	

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{Q 241}	Continued From page 12 The ASC failed to use IUSS on an infrequent basis.	{Q 241}	See page 11-12	