IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
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BUREAU OF FACILITY STANDARDS
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CERTIFIED MAIL: 2012 3050 0001 2125 5723

July 1, 2016

Rita Kinney, Administrator
Coeur D'Alene Foot & Ankle Surgery
101 Ironwood Drive, Suite 131
Coeur D'Alene, ID 83814

RE: Coeur D'Alene Foot & Ankle Surgery, Provider #13C0001016

Dear Ms. Kinney:

Based on the survey completed at Coeur D'Alene Foot & Ankle Surgery, on June 21, 2016, by our staff, we have determined Coeur D'Alene Foot & Ankle Surgery is out of compliance with the Medicare ASC Condition for Coverage of **Infection Control (42 CFR 416.51)**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused this condition to be unmet, substantially limit the capacity of Coeur D'Alene Foot & Ankle Surgery, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Condition for Coverage referenced above by submitting a written Credible Allegation of Compliance/Plan of Correction.

An acceptable Plan of Correction 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 each form.

Such corrections must be achieved and compliance verified by this office, before August 5, 2016. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than July 26, 2016.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **July 14, 2016**.

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

We urge you to begin correction immediately.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,

GARY GUILES
Health Facility Surveyor
Non-Long Term Care

Dennis Kelly
on behalf of

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

GG/pmt
Enclosures
ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Lynnette Osias, CMS Region X Office

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001016	A. BUILDING _____ B. WING _____	06/21/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COEUR D'ALENE FOOT & ANKLE SUR	101 IRONWOOD DRIVE, SUITE 131 COEUR D'ALENE, ID 83814

(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	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgery center conducted from 6/20/16 to 6/21/16. Surveyors conducting the recertification were: Gary Guiles, RN, HFS, Team Leader Laura Thompson, RN, BSN, HFS Brian Osborn, RN, HFS Acronyms used in this report include: ASC - Ambulatory Surgical Center AORN - Association of periOperative Registered Nurses APIC - Association for Professionals in Infection Control and Epidemiology CDC - Centers for Disease Control and Prevention HIV - Human Immunodeficiency Virus HS - Bedtime mg - milligrams OP - Operative OR - Operating Room PPE - Personal Protective Equipment RN - Registered Nurse STAT - Immediately	Q 000		
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	Q 162	RECEIVED JUL 14 2016 FACILITY STANDARDS	

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

Rita Kinney | Administrator/Manager | 07-11-16

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 162	Continued From page 1 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure medical records were complete for 10 of 11 patients (#1- #10) whose records were reviewed. Incomplete medical records and missing information resulted in lack of clarity and had the potential to result in medication errors and negatively impact patient safety. Findings include: The following medical records contained incomplete information: 1. Patient #1 was a 69 year old male who had surgery to remove a heel spur on 5/31/16. Patient #1's record included a surgical consent which was dated 5/31/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #1's surgery date was 5/31/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 5/31/16, and included	Q 162		

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Q 162	Continued From page 2 preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT" (Cephalexin is an antibiotic). However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #1's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #1's "Post-Op Recovery Record" included vital signs, but they were not timed. The "Post-Surgical Discharge" form included a prescription pain medication for Patient #1 to take but stated no antibiotic was ordered following surgery. However, the form also stated "Keflex 500 mg. Take at HS." (Keflex is another name for Cephalexin). The order did not include the route of administration. 2. Patient #2 was a 48 year old male who had osteotomy surgery on his left foot on 5/05/16. Patient #2's record included a surgical consent which was dated 5/05/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #2's surgery date was 5/05/16, but it did not state the date or time the form was completed.	Q 162		

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Q 162	Continued From page 3 The form titled "Surgical Record" stated Patient #2's surgery date was 5/05/16 and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #2's record included a "Safe Surgery Checklist" which documented the date of the surgery,but was not timed. Patient #2's "Post-Op Recovery Record" included vital signs which were not timed. The "Post-Surgical Discharge" included a prescription pain medication for Patient #2 to take but stated no antibiotic was ordered following surgery. However, the form also stated "Keflex 500 mg. Take at HS." The order did not include the route of administration. 3. Patient #3 was a 77 year old male who had left foot bunion surgery on 4/12/16. Patient #3's record included a surgical consent which was dated 4/12/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #3's surgery date was 4/12/16, but it did not state the date or time the form was completed.	Q 162		

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Q 162	Continued From page 4 The form titled "Surgical Record" stated the surgery date was 4/12/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #3's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #3's "POST-OP RECOVERY RECORD" included vital signs which were not timed. The "Post-Surgical Discharge" included a prescription pain medication for Patient #3 to take, but stated no antibiotic was ordered following surgery. However, the form also stated "Keflex 500 mg. Take at HS". The order did not include the route of administration. 4. Patient #4 was a 60 year old female who had right foot bunion surgery and multiple toe repair and revision on 6/10/16. Patient #4's record included a surgical consent which was dated 6/10/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination. The document stated Patient #4's	Q 162		

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Q 162	Continued From page 5 surgery date was 6/10/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 6/10/16, and included preoperative vital signs, but did not state when they were taken. The form stated "Cephalexin 500 mg 1 STAT". However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #4's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #4's "POST-OP RECOVERY RECORD" included vital signs which were not timed. The "Post-Surgical Discharge" form included a prescription pain medication and antibiotic for Patient #4 to take, but the order did not include the route of administration. 5. Patient #5 was a 54 year old female who had left foot surgery on 6/07/16. Patient #5's record included a surgical consent which was dated 6/07/16, but was not timed. The form titled "Surgical Record" stated the surgery date was 6/07/16, and included preoperative vital signs, but did not state a time when they were taken. The form included a	Q 162		

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Q 162	Continued From page 6 section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT". However, the form did not state what time the medication was ordered or given to Patient #5. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #5's record included a "Safe Surgery Checklist" which was not dated or timed. 6. Patient #6 was a 62 year old female who had a bunion removed and right toe surgery on 4/14/16. Patient #6's record include a surgical consent which was dated 4/14/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #6's surgery date was 4/14/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 4/14/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were	Q 162		

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Q 162	Continued From page 7 performed was not documented. Patient #6's record included a "Safe Surgery Checklist" which documented the date of surgery, but was not timed. Patient #6's "Post-Op Recovery Record" included vital signs, but they were not timed. 7. Patient #7 was a 69 year old female who had surgery to remove a heel spur on 5/19/16. Patient #7's record include a surgical consent which was dated 5/19/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #7's surgery date was 5/19/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 5/19/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #7's record included a "Safe Surgery Checklist" which documented the date of surgery, but was not timed.	Q 162		

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Q 162	Continued From page 8 Patient #7's "Post-Op Recovery Record" included vital signs, but they were not timed. 8. Patient #8 was a 57 year old female who had right foot and toe surgery on 5/12/16. Patient #8's record included a surgical consent which was dated 5/12/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #8's surgery date was 5/12/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 5/12/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cipro 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" form stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #8's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #8's "Post-Op Recovery Record" included vital signs, but they were not timed. The "Post-Surgical Discharge" included a prescription pain medication for Patient #8 to take, but stated no antibiotic was ordered following surgery. However, the form also stated	Q 162		

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Q 162	Continued From page 9 "Cipro 500 mg. Take at HS". The order did not include the route of administration. 9. Patient #9 was a 71 year old female who had right toe surgery on 5/17/16. Patient #9's record included a surgical consent which was dated 5/17/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," included a brief history and a physical examination and stated Patient #9's surgery date was 5/17/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 5/17/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cipro 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" form stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #9's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #9's "Post-Op Recovery Record" included vital signs, but they were not timed. The "Post-Surgical Discharge" included a prescription pain medication for Patient #9 to take, but stated no antibiotic was ordered following surgery. However, the form also stated	Q 162		

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Q 162	Continued From page 10 "Keflex 500 mg. Take at HS". The order did not include the route of administration. 10. Patient #10 was a 54 year old female who had right foot toe surgery on 6/09/16. Patient #10's record included a surgical consent which was dated 6/09/16, but was not timed. The document "Pertinent History/Physical and Order Sheet," contained a brief history and a physical examination. The document stated Patient #10's surgery date was 6/09/16, but it did not state the date or time the form was completed. The form titled "Surgical Record" stated the surgery date was 6/09/16, and included preoperative vital signs, but did not state when they were taken. The form included a section "Pre-Op Medication" which stated "Cephalexin 500 mg 1 STAT." However, the form did not state what time the medication was ordered or given. Also, the form did not list the route of administration. The "Surgical Record" stated laboratory tests, including hemoglobin and blood glucose levels, were performed. The time the tests were performed was not documented. Patient #10's record included a "Safe Surgery Checklist" which documented the date of the surgery, but was not timed. Patient #10's "Post-Op Recovery Record" included vital signs, but they were not timed. The "Post-Surgical Discharge" form included a prescription pain medication for Patient #10 to take, but stated no antibiotic was ordered	Q 162		

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Q 162	Continued From page 11 following surgery. However, the form also stated "Keflex 500 mg. Take at HS." The order did not include the route of administration. The Nurse Manager reviewed the medical records of Patients #1 - #10 with surveyors on 6/20/16, beginning at 2:00 PM. She confirmed the lack of times and incomplete documentation. The ASC failed to ensure medical records were accurate and complete.	Q 162		
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, review of administrative documents, 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: 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 and nationally recognized guidelines. 2. Refer to Q242 as it relates to the ASC's faileure to ensure there was ongoing monitoring and evaluation of the program to ensure there was adherence to infection control policies and	Q 240		7/26/16

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COEUR D'ALENE FOOT & ANKLE SURGERY	101 IRONWOOD DRIVE, SUITE 131 COEUR D'ALENE, ID 83814

(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 240	Continued From page 12 guidelines. 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. This STANDARD is not met as evidenced by: Based on observation, review of administrative documents, policy review, and staff interview, it was determined the ASC failed to maintain a sanitary and functional environment for patients receiving care at the facility. This directly impacted 1 of 1 patient (Patient #11) whose procedure was observed and had the potential to impact all patients receiving services at the ASC. This resulted in patients being placed at an increased risk for infections. Findings include: A tour of the ASC was conducted on 6/20/16, beginning at 10:30 AM with the Nurse Manager. During the tour, 2 procedure rooms, a bathroom, waiting room, and reprocessing area were observed. The reprocessing area was in an open area in the center of the ASC. The reprocessing area included a double sink with a counter on the right side. The Nurse Manager stated the right side of the sink was designated as dirty and the left side was designated as clean. She stated this was the only sink in the ASC, besides the one in the bathroom. The counter next to the sink	Q 241		7/28/16

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Q 241	Continued From page 13 was the designated dirty area for reprocessing of surgical instruments, which included an ultrasonic cleaner. To the right of the dirty counter, along another wall, was the designated clean area for reprocessing. The Nurse Manager stated this was the area where she would wrap the clean instruments in preparation for sterilization. Directly across from the clean counter was a small room with an autoclave for sterilization of surgical instruments. The ASC's Infection Control Program binder was reviewed after the tour of the ASC. Included in the binder were guidelines from the CDC, manufacturer instructions, and administrative documents. A document titled "Infection Management Program," revised 10/2015, stated the facility followed CDC guidelines for their infection control program. The facility's Infection Control binder included the printed guidelines from the CDC "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008." Additionally, the document stated other guidelines which were reviewed were from the AORN and APIC. The Infection Control binder included an administrative document "Governing Body Approved Germicidal Solutions," dated 3/18/00, which stated Madacide or Citriguard were to be used for cleaning the ASC, including surgical spaces. Additionally, the document stated Jobmaster disinfectant was to be used for cleaning of the surgical floors and walls. There were no other cleaning agents approved for use in the ASC.	Q 241		

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Q 241	Continued From page 14 1. The ASC practices were not consistent with the CDC guidelines and the germicidal solutions approved by the Governing Body were not used. Examples include: a. During an interview on 6/20/16 at 1:00 PM, the Nurse Manager was asked about the process for terminal cleaning (a thorough cleaning then disinfection and sterilization of an area) of the procedure rooms. She stated the procedure rooms were terminally cleaned every evening after the procedure day was completed and the evening prior to procedure days. The Nurse Manager stated the RNs performed the terminal cleaning and cleaning of the procedure rooms between procedures. She stated she trained the staff how to terminally clean the procedure rooms. The Nurse Manager stated a check list was used by staff to ensure all surfaces and equipment in the procedure rooms were terminally cleaned. The check list included a policy, undated, which stated "The OR rooms are to be terminally cleaned and check list completed by the ASC staff every night proceeding surgeries." The Nurse Manager was asked how the procedure rooms were terminally cleaned by staff. She stated the product used for terminal cleaning was Clorox Hydrogen Peroxide, which was sprayed on all surfaces and allowed to sit for 3 minutes. After 3 minutes had passed, staff would then wipe off the spray from surfaces. The Nurse Manager stated this was a new product the ASC had switched to about 4 months ago. When asked how the floors of the procedure rooms were terminally cleaned, the Nurse Manager stated a Swiffer WetJet mop system was used.	Q 241		

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Q 241	Continued From page 15 She stated if blood or other fluid had dropped onto the floor after a procedure, the Clorox Hydrogen Peroxide spray would be used to clean the floor. The manufacturer instructions for the Clorox Hydrogen Peroxide were reviewed in the presence of the Nurse Manager. The instructions stated "This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument ... This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection." Additionally, the manufacturer instructions stated for cleaning and disinfection of hard, nonporous surfaces the surface should be thoroughly wet and allowed to remain wet for a contact time of 1 to 4 minutes, depending on the microorganism to be killed. The manufacturer instructions stated when using this product to clean and decontaminate against Hepatitis B or C and HIV on surfaces soiled with blood or body fluids, the blood and body fluids must be cleaned from the surface prior to applying the product. The 2008 CDC guidelines stated when cleaning and disinfecting environmental surfaces, an Environmental Protection Agency registered hospital disinfectant must be used. The guidelines also stated to follow the manufacturer instructions for proper use for disinfecting surfaces. The Nurse Manager stated she was not aware of the Clorox Hydrogen Peroxide manufacturer instructions prior to the review with the surveyors. She stated the Swiffer WetJet was labeled as antibacterial and she believed that would be	Q 241		

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Q 241	Continued From page 16 sufficient for use in the ASC. The Nurse Manager confirmed the Swiffer WetJet was not labeled for medical grade cleaning or healthcare use. The ASC failed to follow nationally recognized guidelines and approved germicidal solutions for terminal cleaning. b. An observation was conducted on 6/21/16, beginning at 11:45 AM. RN A was observed performing cleaning of the procedure room following the surgical procedure of Patient #11. Patient #11 had correction of her big toe and 2 hammer toes on her right foot. The procedure room was not cleaned following nationally recognized guidelines, or ASC procedures, as follows: A facility document "Facility Cleaning Surgical Spaces," dated 6/2009, was reviewed. The document stated, "Counter tops, tables, carts, stands, trays, etc., will be cleaned with a center approved germicidal solution before each surgical case." RN A was observed using 50% isopropyl alcohol on horizontal surfaces prior to spraying Clorox Hydrogen Peroxide. RN A stated "I'm not sure if this helps, but we do it anyway." Additionally, RN A was observed spraying Clorox Hydrogen Peroxide onto hard, nonporous surfaces. However, the amount used did not saturate the surfaces per the manufacturer's instructions. RN A was also observed spraying hydrogen peroxide directly onto blood on the floor prior to it being precleaned as per manufacturer's instructions. She then wiped the specific area, but did not clean the remainder of the floor.	Q 241		

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Q 241	Continued From page 17 During the post procedure clean of Procedure Room 1, RN A did not use governing body approved Madacide or Citriguard for cleaning of surgical spaces. Additionally, she did not follow the manufacturer instructions for the Clorox Hydrogen Peroxide. RN A was interviewed on 6/21/16, at 12:00 PM. When asked if she had received formal training for cleaning and terminal cleaning, she stated "No we've learned by what the Nurse Manger has taught us." During an interview on 6/20/16 at 1:00 PM, the Nurse Manager confirmed Clorox Hydrogen Peroxide spray, Swiffer WetJet Antimicrobial solution, and 50% isopropyl alcohol were not approved for use by the governing body. She stated there was no formal education and training for cleaning and terminal cleaning of the procedure rooms, as that function was previously performed by a Medical Assistant who no longer worked for the facility. The facility failed to provide a sanitary environment for surgical services. 2. Instrument reprocessing was observed on 6/21/16 beginning at 11:00 AM. Reprocessing was not completed in a manner consistent with nationally recognized standards of practice, as follows: a. The reprocessing area was an open area in the middle of the ASC. The area in which the instruments were decontaminated, cleaned, and sterilized included a double sink with a counter, a separate counter, and a small closet area with the autoclave. Decontamination and cleaning were	Q 241		

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Q 241	Continued From page 18 performed on the counter next to the double sink and the drying and wrapping of instruments was performed on the longer counter. The Nurse Manager was observed to fill the right side of the sink a quarter full with water from the faucet. She then placed the contaminated instruments in the water and began to scrub them with a disposable plastic scrub brush, while wearing gloves and no other PPE. After scrubbing the instruments, the Nurse Manager placed the instruments into a metal tub. The metal tub was then placed into an ultrasonic cleaning machine. The sink was not cleaned or sanitized after being used. When asked about the sink, the Nurse Manager stated the ASC only had the one sink. She stated it was used for the decontamination and cleaning of instruments, as well as, hand hygiene and the physician's presurgical scrub. According to AORN 2015 Guidelines for Perioperative Practice "Instruments should not be cleaned or decontaminated in scrub or hand sinks. Cleaning soiled instruments in a scrub or hand sink can contaminate the sink and faucet, which are intended to be used for clean activities (e.g., hand washing, surgical hand antisepsis)." The guidelines also stated "Personnel working in the decontamination area and handling contaminated instruments must wear PPE." PPE which must be worn includes a gown, gloves, a mask and eye protection, and shoe covers. The ASC failed to follow nationally recognized guidelines for instrument cleaning and decontamination.	Q 241		

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Q 241	Continued From page 19 b. The Nurse Manager removed the metal tub of instruments from the ultrasonic cleaning machine and dumped them onto a paper cloth on the designated clean counter. She then proceeded to dry individual instruments with 4 x 4 gauze and placed them on a surgical towel, which was sitting open next to the paper towel. The Nurse Manager was not observed performing hand hygiene after removing her gloves, after scrubbing the instruments, or before drying the instruments with the gauze. She was not wearing a head cover during this part of the process. While observing the Nurse Manager during reprocessing, she was questioned about her sterile reprocessing training. She stated "It was several years ago, but the principles haven't changed." AORN 2015 Guidelines for Perioperative Practice stated a head cover is required when wrapping clean instruments for sterilization. When asked about not wearing gloves or a head cover, the Nurse Manager stated she did not usually wear a head cover when wrapping instruments, and stated her hands were "clean." The ASC failed to follow nationally recognized guidelines for wrapping surgical instruments. 3. An ASC document "Bloodborne Pathogen Exposure Control Plan," undated, was reviewed. The document stated, "As soon as feasible after removal of gloves or other personal protective equipment, employees shall wash their hands." An observation was conducted on 6/21/16, beginning at 8:40 AM, of Patient #11. The observation was conducted from the time Patient #11 entered the procedure room and ended after	Q 241		

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Q 241	Continued From page 20 the cleaning of the procedure room upon Patient #11's discharge. The "Bloodborne Pathogen Exposure Control Plan" was not followed by ASC staff. Examples include: a. Patient #11 was a 65 year old female who had correction of her big toe and 2 hammer toes on her right foot on 6/21/16. An observation of Patient #11's procedure was conducted beginning at 8:40 AM. During the observation RN A was in the procedure room assisting the physician. RN A stepped out of the room several times while preparing for the surgical procedure to retrieve supplies. RN A did not perform hand hygiene consistently when leaving the procedure room, after removing gloves, or upon re-entering the room. b. RN A was observed cleaning Procedure Room 1 after Patient #11's procedure on 6/21/16 beginning at 11:45 AM. During the observation RN A did not perform hand hygiene prior to donning gloves, in between glove changes, before or after leaving Procedure Room 1, or after final glove removal. c. The Nurse Manager was observed performing reprocessing of surgical instruments on 6/21/16 beginning at 11:00 AM. The Nurse Manager did not perform hand hygiene after decontaminating and cleaning the surgical instruments and removing her gloves. She also did not perform hand hygiene prior to handling the surgical instruments after they were cleaned. During an interview on 6/21/16 at 12:00 PM, the Nurse Manager stated her hands were clean during reprocessing.	Q 241		

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Q 241	Continued From page 21 The ASC failed to follow their "Bloodborne Pathogen Exposure Control Plan" to prevent transmission of pathogens.	Q 241		
Q 242	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 observation, staff interview, review of administrative documents, and review of infection control documents, it was determined the agency failed to ensure there was ongoing monitoring and evaluation of the Infection Control Program to ensure there was adherence to infection control policies and guidelines. This had the potential to result in patient infection due to poor infection control practices. Findings include: The ASC's Infection Control Program binder was reviewed. A document titled "Infection Management Program," revised 10/2015, stated the ASC followed CDC guidelines for their infection control program. The document stated in order to have an effective infection control program, ASC policies and procedures for asepsis (the absence of bacteria, viruses, and other microorganisms) and the surgical environment, as well as, a universal precaution program, must be monitored. Additionally, the document stated the CDC guidelines were	Q 242		7/15/16

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Q 242	Continued From page 22 primarily followed as part of their infection control program. During an interview on 6/20/16 at 1:00 PM, the Nurse Manager was asked about the Infection Control Program for the ASC. She stated she was the designated Infection Control Nurse. The Nurse Manager stated she was employed part-time with the ASC and she spent about half of her time on infection control. She confirmed the CDC guidelines were the primary source selected for their program, but they also reviewed guidelines from the AORN and APIC. The guidelines and procedures, which were selected for the ASC's Infection Control Program, were not followed by staff and were not monitored or evaluated for compliance. Examples include: 1. The 2008 CDC guidelines stated when cleaning and disinfecting environmental surfaces, an Environmental Protection Agency registered hospital disinfectant must be used. The guidelines also stated to follow the manufacturer instructions for proper use for disinfecting surfaces. The Nurse Manager was asked how the procedure rooms were terminally cleaned by staff during the above interview. She stated the product used for terminal cleaning was Clorox Hydrogen Peroxide, which was sprayed on all surfaces and allowed to sit for 3 minutes. After 3 minutes had passed, staff would then wipe off the spray from surfaces. The Nurse Manager stated this was a new product the ASC had switched to about 4 months ago. When asked how the floors of the procedure rooms were terminally cleaned, the Nurse Manager stated a Swiffer WetJet mop	Q 242		

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Q 242	Continued From page 23 system was used. She stated if blood or other fluid had dropped onto the floor after a procedure, the Clorox Hydrogen Peroxide spray would be used to clean the floor. The manufacturer instructions for the Clorox Hydrogen Peroxide were reviewed in the presence of the Nurse Manager. The instructions stated "This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument ... This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection." Additionally, the manufacturer instructions stated for cleaning and disinfection of hard, nonporous surfaces the surface should be thoroughly wet and allowed to remain wet for a contact time of 1 to 4 minutes, depending on the microorganism to be killed. The manufacturer instructions stated when using this product to clean and decontaminate against Hepatitis B or C and HIV on surfaces soiled with blood or body fluids the blood and body fluids must be cleaned from the surface prior to applying the product. An observation was conducted on 6/21/16 beginning at 11:45 AM. RN A was observed performing cleaning of the procedure room following the surgical procedure of Patient #11. Patient #11 had correction of her big toe and 2 hammer toes on her right foot. The procedure room was not cleaned following nationally recognized guidelines or ASC procedures. A facility document "Facility Cleaning Surgical Spaces," dated 6/2009, was reviewed. The document stated, "Counter tops, tables, carts, stands, trays, etc., will be cleaned with a center	Q 242		

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Q 242	Continued From page 24 approved germicidal solution before each surgical case." RN A was observed using 50% isopropyl alcohol and Clorox Hydrogen Peroxide to clean the procedure room. RN A stated "I'm not sure if this helps, but we do it anyway." During the post procedure cleaning of Procedure Room 1, RN A did not use governing body approved Madacide or Citriguard for cleaning of surgical spaces. Additionally, she did not follow the manufacturer instructions for the Clorox Hydrogen Peroxide. 2. According to the AORN 2015 Guidelines for Perioperative Practice "Personnel working in the decontamination area and handling contaminated instruments must wear PPE." PPE which must be worn include a gown, gloves, a mask and eye protection, and shoe covers. During observation of reprocessing of surgical instruments on 6/21/16, beginning at 11:00 AM. The Nurse Manager did not wear the appropriate PPE for decontamination, cleaning, or wrapping of the surgical instruments. 3. AORN guidelines stated "Instruments should not be cleaned or decontaminated in scrub or hand sinks. Cleaning soiled instruments in a scrub or hand sink can contaminate the sink and faucet, which are intended to be used for clean activities (e.g., hand washing, surgical hand antisepsis)." During a tour of the ASC conducted on 6/20/16, beginning at 10:30 the Nurse Manager stated the ASC only had one sink. She stated the one sink was used for the physician's presurgical scrub, hand hygiene, and for reprocessing the surgical	Q 242		

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Q 242	Continued From page 25 instruments. 4. An ASC document "Bloodborne Pathogen Exposure Control Plan," undated, was reviewed. The document stated, "As soon as feasible after removal of gloves or other personal protective equipment, employees shall wash their hands." Staff, including the physician, were observed not performing hand hygiene consistently as outlined in the plan. During an interview on 6/20/16 at 2:15 PM, the Nurse Manager stated she had not done surveillance on hand hygiene "In a long time." She stated because the ASC was so small, with only 3 RNs and the physician, she did not feel it was necessary. The Nurse Manager stated "We can just talk with each other if we notice something." When asked about policies for the Infection Control Program and infection prevention practices, the Nurse Manager stated there were no written policies regarding the Infection Control Program or infection prevention. She stated only a couple of written procedures and guidelines printed from the CDC were included in the Infection Control Program binder. The ASC failed to evaluate and identify breeches in their Infection Control Program.	Q 242		

Q162 FORM AND CONTENT OF RECORD 416.47 (b)

Pages 1 – 12 Plan of Correction for Medical Records being incomplete with missing information

Action that will be taken to correct specific deficiency:

The Coeur d'Alene Foot & Ankle Surgery Center is committed to having patient care information within the perioperative practice that is complete, accurate and comprehensive. Towards that end, the Policy and Procedure of the Coeur d'Alene Foot & Ankle Surgery Center has been changed to stipulate that all documents in the surgical record shall be dated and the time of completion noted, including the Surgical Consent Form, the Safe Surgery Checklist, and the Pertinent History / Physical and Order Sheet.

Many procedure times on the Surgical and Postop Recovery and Discharge Record are already annotated, such as anesthetic times, surgery start and end times, discharge time, etc. In addition to these times noted, however, the Surgical Record and the Postop Recovery and Discharge Record, shall also note the times on the following:

1 Pre operative Vital Signs
2 Intra operative Vital Signs
3 Post operative Vital Signs
4 Medication Order and Medication Administration
5 Laboratory Tests

To eliminate any confusion and promote accuracy, Post operative antibiotic prescriptions will be more specific, differentiating between the dispense of 1) a Prescription OR 2) the dispense of an antibiotic pill or tablet to be taken orally (route of administration will be noted) at a designated time as ordered by the surgeon (usually at HS /bedtime) OR 3) the dispense of both OR 4) the dispense of neither the RX and/or antibiotic pill or tablet.

The Policy and Procedure of the Coeur d'Alene Foot & Ankle Surgery Center has also been changed to stipulate that the route of administration of all medications given must be noted. Accepted abbreviations include standard pharmaceutical abbreviations and as designated by the USA FDA Route of Administration Short Name / Abbreviations.

Description of how the actions will improve the processes that led to the deficiency:

The actions of recording the date and times of completion of all documents, and the annotating of the times when certain procedures are performed in the surgical chart, will ensure the records are complete. Because more detail is provided, the record will also be more comprehensive, adding to patient safety in evaluating a patients' response to treatments.

Specifying the route of administration of a medication also adds to the completeness of the surgical chart and makes the surgical record more comprehensive. Patient safety is enhanced, enabling the medical staff to better assess the patents' response to the medication by knowing the route administered as well as the time given.

Procedure for implementing the acceptable plan of correction:

The Coeur d'Alene Foot & Ankle Surgery Center surgical forms, including the Surgical Consent Form, the Safe Surgery Checklist, and the Pertinent History / Physical and Order Sheet were all modified to include an entry slot for date and times of completion data to be entered by the appropriate medical staff. The Surgical Record and the Postop Recovery and Discharge Records were also modified to include entry slots for times of completion data for specific procedures such as Pre operative Vital Signs, Intra operative Vital Signs, Post operative Vital Signs, Medication Order and Medication Administration, and Laboratory Tests. The Postoperative antibiotic prescription or medication dispense description formats were also changed for greater clarity.

Completion date for correction of deficiency: Policy is currently in effect and changes were implemented **July 2, 2016**.

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 Coeur d'Alene Foot & Ankle Surgery Center medical records are subject to internal and external audits. The ASC has a contract with another ambulatory surgery center for medical records review and peer review. The physician / surgeon of this Spokane Ambulatory Surgery Center has been advised of this deficiency correction. He was asked that upon his future evaluation of the records, to verify that the Coeur d'Alene Foot & Ankle Surgery Center is in compliance, eliminating the deficiency of the Form and Content of Medical Records deficiency.

Also the Quality Assurance Review Committee of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the medical staff of the Surgery Center in addition to the owner) meets quarterly to insure that problem identification and assessment techniques are effective and that resolution actions are indeed eliminating said problems. The QA Committee examines the Quarterly Log, as seen by the ASC Surveyors 07/21/16, which documents a "Summary of Review & Problems / Actions" for each category including Medical Records. This log will document the medical record audits, determining that in the record the compliance actions to eliminate this deficiency are being observed and achieved.

The QA Committee will note on the Committee of the Whole report, done quarterly, that compliance with Medical Record Standards are being performed, or identify problems and implement a plan of resolution if this is found not to be the case. Tracking compliance may also be part of a future QAPI Project.

Title of the Person responsible for implementing the acceptable plan of correction: Rita Kinney, Administrator. Upon her retirement within the next year, Michelle Kopriva, RN, Infection Control Manager, will be assuming the Administrator position. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the medical staff of the Surgery Center in addition to the owners) will be monitoring the compliance as detailed above.

Q 240 416.51 INFECTION CONTROL Sanitary Environment Q241

Q241 SANITARY ENVIRONMENT

The Coeur d'Alene Foot & Ankle Surgery Center used a compilation of nationally recognized guidelines as sources for use in its infection control program. For the most part, these sources were gathered on line and accessible for no cost, being somewhat general in nature. These factors make the guidelines inherently limited in terms of being current, specific, and complete, leaving them subject to interpretation as evidenced by no deficiencies being cited by surveyors in the 2012 survey regarding many of the same practices that were observed by the surveyors of the most recent survey.

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Therefore the Coeur d'Alene Foot & Ankle Surgery Center considered a number of nationally recognized guidelines, including AAMI, AORN, APIC, and WPRO to name a few. It was noted that while costly, AORN, being evidence based, seemed to incorporate many of the standards from each of the previously named organizations and seemed very specific in scope to the Operating Room environment. Therefore, the Coeur d'Alene Foot & Ankle Surgery Center selected AORN as its' nationally recognized guidelines for complying with generally accepted infection control standards of practice. The Coeur d'Alene Foot & Ankle Surgery Center purchased membership to the Association of periOperative Registered Nurses and also purchased the AORN's Guidelines for Perioperative Practice via eSubscription.

Plan of Correction for failing to provide a sanitary environment for surgical services with an open reprocessing area and no separate sinks for decontamination of instruments and hand washing.

The Coeur d'Alene Foot & Ankle Surgery Center was originally designed to meet the specifications and conditions for coverage set forth by the Department of Health and Human Services Centers for Medicare & Medicaid Services and the design included a large single basin sink with the reprocessing area in an open area, which received approval upon original inspection by CMS July 20, 1995 and again at the survey completed June 28, 2001. The Health Facility Surveyors of the recertification survey on September 24, 2012 stated that "the regulations had changed" and said separate sinks were needed, even though the surgeries performed at the surgery center are minimally invasive with a small numbers of instruments used, and that the ASC has a very low surgical site infection rate. Researching this problem, we were able to find medical / surgical stainless steel sink product lines designed for use in hospitals and surgery centers, which offered design solutions without compromising function,

relative to our particular situation. The sink design features sloped bottom surfaces that will prevent splashing and over spill providing effective separation of clean from dirty activities to ensure that the inadvertent transmission of infectious agents does not occur. Such a sink was installed and was in use at the time of this current survey per approval of the previous Health Care Facility Surveyors via phone calls and as stated in our 2012 Plan of Correction.

Action that will be taken to correct this specific deficiency:

With the deficiency of the double sink and open processing area by the most recent surveyors, the Coeur d'Alene Foot & Ankle Surgery Center has begun remodeling the facility, and most specifically, the instrument reprocessing area.

The Coeur d'Alene Foot & Ankle Surgery Center joined the Association of Operating Room Nurses and also purchased the AORN Guidelines for Perioperative Practice and will be following these guideline recommendations for the remodel.

Recommendation V of the AORN Guideline for Cleaning and Care of Surgical Instruments, states that "Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled". [10,45,46] Therefore, the Coeur d'Alene Foot & Ankle Surgery Center will be creating a separate room for the decontamination area which will be separate from where clean items are handled. Also per Recommendation V of the AORN Guideline for Cleaning and Care of Surgical Instruments, the decontamination and clean spaces will be separated by a wall and the decontamination room will have a bi-fold door as the limited space allows, containing the room. There will be separate sinks for washing instruments and for hand hygiene, decontaminating equipment (e.g., ultrasonic cleaner); and storage space for PPE and cleaning supplies in the decontamination area.

Description of how the actions will improve the processes that led to the deficiency:

Cross-contamination can result when soiled items are placed in close proximity to clean items or are placed on surfaces upon which clean items are later placed. Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces. Therefore the physical separation of decontamination areas from areas where clean items are handled will minimize the risk of cross-contamination and provide a sanitary environment in accordance with acceptable standards of practice and nationally recognized guidelines, ensuring patient risk of infections and communicable diseases are minimized.

Completion date for correction of deficiency: **July 26, 2016**

The Coeur d'Alene Foot & Ankle Surgery Center is coordinating the remodel of the ASC with Parkwood, the Facility Management Company of the complex wherein the Coeur d'Alene Foot & Ankle Surgery Center rents space. The owners have met with the plumber and contractor and the contractor has to get permits from the city of Coeur d'Alene and cannot start the work until these permits are obtained. The applications for these permits have been filed and the sinks have been ordered and the remodel is in process, pending permits granted. In speaking with the contractor this week, it was confirmed that the remodel separating dirty and clean spaces and sinks installed will be completed by **July 26, 2016**. (Bifold door to be installed later since delivery date is three weeks out, during which time traffic in area will be limited during cleaning / reprocessing).

Staff training and competency validation in regards to reprocessing procedures within the newly closed reprocessing area with separate sinks will also be completed by **July 26, 2016.**

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 infection control manager will be monitoring the remodel to eliminate the open reprocessing area and eliminate the single divided sink set up previously used for decontamination of instruments and hand washing. The infection control manager will also be tracking procedure practices, ensuring that the bi-fold door containing the room be closed during the reprocessing and that appropriate PPE is available as well as cleaning supplies in the new decontamination area and that such items are used appropriately and if applicable, in accordance to manufacturer instructions. Employees will be educated and trained in these procedures. The training and competency validation will be noted on the new Infection Control Staff Training and Competency Verification log. This tracking may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project to gather data regarding adherence to policy in this area.

Also the Coeur d'Alene Foot & Ankle Surgery Center Governing Body (which consists of the administrator RN, medical staff and owners) will be meeting monthly in addition to the regular quarterly meeting during this transition period of remodel to ensure the remodel is in accordance with AORN guideline recommendations as well as staff adherence to these guidelines in regards to reprocessing procedures within the newly closed reprocessing area with separate sinks.

Title of the Person responsible for implementing the acceptable plan of correction:
Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the ASC Administrator, Rita Kinney, the medical staff of the Surgery Center in addition to the owners) will be monitoring the compliance as detailed above.

Q241 SANITARY ENVIRONMENT

Plan of Correction for failure to use approved germicidal solutions for terminal cleaning and to follow the manufacturer instructions for proper use for disinfecting surfaces.

Action that will be taken to correct this specific deficiency:

Per AORN recommendation, The Coeur d'Alene Foot & Ankle Surgery Center will select cleaning chemicals for use in the perioperative setting by evaluating several factors, including the Environmental Protection Agency (EPA) registration, targeted microorganisms, dwell times, chemical manufacturers' instructions for use, compatibility with surfaces, cleaning materials, and equipment, patient population, cost, safety and effect on the environment. Alcohol will not be used to disinfect large environmental surfaces since alcohol is not an EPA-registered disinfectant.

Likewise the Coeur d'Alene Foot & Ankle Surgery Center will evaluate the selection of cleaning materials, tool and equipment regarding manufacturer's instructions for use on surfaces to be cleaned, manufacturer instructions for use for cleaning materials and equipment, compatibility with detergents and disinfectants, effect on environmental conditions in the OR, cost, personnel ergonomics and safety and effect on the environment. Reusable or single-use disposable cleaning materials (e.g., mop heads, cloths) may be used, including Mops that dispense cleaning solutions, and microfiber or low-linting cotton cleaning materials (e.g., mop heads, cloths).

Manufacturer instructions for proper preparation, handling, use, storage and disposal will be followed for all ASC approved disinfectant / germicidal solutions, including but not limited to enzymatic instrument cleaner, instrument cleaner prep enzyme, germicidal disinfecting wipes, and general disinfectants. Education (which will be ongoing) of staff on these afore mentioned instructions will be conducted detailing this policy and procedure and these practices will be monitored for compliance.

Description of how the actions will improve the processes that led to the deficiency:

The Coeur d'Alene Foot & Ankle Surgery Center, per AORN recommendation on product selection, approved Clorox Germicidal Disinfecting Wipes which are EPA registered. Advised use is for Terminal cleaning, Environmental service, and Cleaning and the disinfecting of large surfaces. Wipes are pre-moistened to ensure proper concentration, safe for stainless steel, glass, plastic, synthetic rubber, and aluminum, strong and heavy for thorough cleaning without tearing, kills 51 microorganisms in 3 minutes or less, disposable, to help reduce risk of cross-contamination and ready to use to reduce labor and time costs. Wipes are Pre-moistened to ensure proper concentration at 5500 ppm, equal to a 1:10 dilution of liquid bleach, are a controlled application that protects EVS from spills, more cost- and time-effective, with a refillable bucket that reduces the waste stream and tested for 12-month shelf life.

Per AORN / CDC recommendation, Floors will be terminally cleaned with a single-use mop and an ASC and EPA approved disinfectant. The floor will be wet with the disinfectant for the dwell time indicated on the manufacturer instructions for use. The entire floor surface will be disinfected and will progress from the cleanest to dirtiest areas of the floor which is usually the center of the room.

By selecting and using these products per manufacturer instructions, the ASC is in compliance using an EPA approved germicidal solution for terminal cleaning.

Completion date for correction of deficiency: **July 8, 2016**

Clorox Healthcare Germicidal Disinfecting Wipes, which are EPA registered and designated for terminal cleaning, are currently being used by staff who received education on instructions of use with verification of competency documented for terminal cleaning.

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 Infection Control Manager will ensure proper training of staff and evaluate perioperative personnel in their understanding, and proper use of ASC approved germicidal solutions and cleaning equipment in accordance with manufacturer's instructions for use. The training and competency validation will be noted on the new Infection Control Staff Training and Competency Verification log. This tracking of adherence of staff to ASC / AORN procedure may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction:
Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as described more under the Quality Management Section.

Q240 Infection Control and Sanitary Environment Q241

Plan of Correction for failure to perform hand hygiene as stipulated by nationally recognized infection control guidelines to prevent transmission of pathogens

Action that will be taken to correct this specific deficiency:

As detailed before, the Coeur d'Alene Foot & Ankle Surgery Center selected AORN as its' nationally recognized guidelines for complying with generally accepted infection control standards of practice. Therefore, the medical staff at the ASC will be using the AORN recommendations on Hand Hygiene. Education, training and competency validation regarding these practices will be conducted.

Description of how the actions will improve the processes that led to the deficiency:

Because Hand washing remains one of the most important measures in maintaining patient and health care personnel safety, by following the AORN recommendations on Hand Hygiene, the ASC medical staff will be performing hand washing upon arrival at the health care facility, before and after every patient contact, before putting gloves on and after removing gloves or other personal protective equipment, any time there is a possibility that there has been contact with blood or other potentially infectious materials or surfaces, before and after eating, before and after using the restroom, before leaving the health care facility, and when hands are visibly soiled.

The ASC medical staff will be performing the four general types of hand hygiene, AORN recommended, in the perioperative environment: washing hands that are visibly soiled, hand hygiene using alcohol-based products, surgical hand scrubs, and surgical hand scrubs using an alcohol-based surgical hand rub product.

Wall mounted hand sanitizers dispensers have been ordered for the OR suites to make hand cleaning easier with greater accessibility for staff and will be installed upon receipt.

These actions will improve patient safety receiving services at the ASC and also staff safety, ensuring risk of infections and communicable diseases are minimized.

Completion date for correction of deficiency: **July 8, 2016**

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 Infection Control Manager will ensure proper training of staff and evaluate perioperative personnel in their understanding of hand hygiene in accordance with AORN guidelines. The training and competency validation will be noted on the new Infection Control Staff Training and Competency Verification log. This tracking of adherence of staff to ASC policy and procedure on proper hand washing may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction:
Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.

Q240 Infection Control and Sanitary Environment Q241

Plan of Correction for failure of personnel working in the decontamination area to wear PPE.

Action that will be taken to correct this specific deficiency:

Following AORN Guidelines, "Cleaning and Care of Surgical Instruments Recommendation VI" All personnel working in the decontamination area and handling contaminated instruments must wear PPE, including a fluid-resistant gown with sleeves, gloves, mask, eye protection and shoe covers. Hand hygiene must be performed after PPE is removed.

Personal protective equipment will be placed where it is readily available to personnel entering the area in which there is a risk of exposure.

Education, training and evaluation regarding these practices will be conducted.

Description of how the actions will improve the processes that led to the deficiency:

Splashes, splatters, and skin contact can be reasonably anticipated by personnel handling contaminated instruments which are a potential source of transmissible pathogens and put staff at risk for exposure to blood, body fluids, and other potentially infectious materials. Personal protective equipment helps to protect the individual from exposure in the decontamination area.

These actions are now part of the ASC's comprehensive infection control program and are also in compliance with the OSHA Blood Borne Pathogen Precautions.

Completion date for correction of deficiency: **July 8, 2016**

The ASC Medical Staff, after receiving education and training (which was annotated and will be ongoing) regarding these PPE requirements in the decontamination area, is currently practicing these AORN recommendations.

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 Infection Control Manager will ensure proper training of staff and evaluate perioperative personnel in their understanding of PPE requirements in accordance with AORN guidelines and OSHA Blood Borne Pathogen Precautions. Staff training and competency verification will be noted on the new Infection Control Staff Training and Competency Verification log. This tracking of adherence of staff to ASC policy and procedure on proper use of PPE may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction: Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.

Q240 Infection Control and Sanitary Environment Q241

Plan of Correction for failure of reprocessing of instruments including instrument cleaning / decontamination and the processing of instruments to be sterilized in a manner consistent with nationally recognized standards of practice.

Action that will be taken to correct this specific deficiency:

The Coeur d'Alene Foot & Ankle Surgery Center selected AORN as its nationally recognized guidelines for complying with generally accepted infection control standards of practice.

Therefore, the AORN Guideline for Cleaning and Care of Surgical Instruments will be followed. Education, training and competency validation of staff regarding these practices will be conducted.

All instruments and devices used in Coeur d'Alene Foot & Ankle Surgery Center surgeries will be cleared by the US Food and Drug Administration (FDA) for use in surgery and have written, manufacturer-validated cleaning and decontamination instructions for use (IFU).

Instruments will be cleaned and decontaminated as soon as possible after use and contaminated instruments will be contained during transport to a decontamination area. Personnel working in the decontamination area and handling contaminated instruments must wear PPE as described previously. AORN guidelines for hand washing will be observed as described previously.

The decontamination and sterile processing area, including the sinks and ultrasonic cleaner, will be cleaned in accordance with the AORN recommended Cleaning practices as noted on the Cleaning Checklist and Terminal Cleaning practices as noted on the Terminal Cleaning Checklist with the ASC approved germicidal cleaner and in accordance with manufacturer instructions for proper preparation, handling, use, storage and disposal.

Surgical instruments will be inspected and evaluated for cleanliness and correct working order after decontamination and if soiled or defective, will be removed from service until they are cleaned or repaired.

Policies and procedures for cleaning and care of instruments used in surgery will be developed according to manufacturer IFU, which will be reviewed periodically, revised as necessary, and readily available in the practice setting in which they are used.

Functional workflow patterns will be established in the following order, from potentially high contamination areas to clean areas: decontamination area, preparation and packaging, sterilization processing, sterile storage, and clean distribution.

Hand hygiene is to be performed prior to handling surgical instruments after they are cleaned and appropriate attire / PPE according to AORN guidelines will be worn when preparing clean items for sterilization, including gloves and surgical hats.

Items to be sterilized will be inspected for cleanliness and proper function in accordance with AORN's Guideline for Cleaning and Care of Surgical Instruments.

Description of how the actions will improve the processes that led to the deficiency:

Cleaning instruments as soon as possible after use can help prevent formation of biofilm and dried blood which can become more difficult to remove with time. Moistening and removing gross soil at the point of use, if possible, or as soon as possible, can help prevent organic material and debris from drying on instruments. Instruments will be kept moist until they are cleaned with either a towel moistened with water placed over the instruments or with a specific enzymatic foam / detergent. Containment of contaminated instruments decreases the potential for injury to personnel or their exposure to blood, body fluids, or other potentially infectious materials and helps prevent damage to the instruments during transport. Following the manufacturers written IFU decreases the possibility of selecting and using cleaning products and equipment that may damage instruments and cleaning processes that may do the same.

Following the AORN Guideline for Cleaning and Care of Surgical Instruments protects the instruments from damage, and provides the patients receiving services at the ASC and the staff a decreased risk of infection.

Performing proper hand hygiene and wearing the appropriate PPE by the staff protects not only the staff, but the patients as well from potential exposure to infectious material.

Completion date for correction of deficiency: **July 8, 2016**

A transport container is in use for cleaning instruments as soon as possible in the OR and for transport to the decontamination area. Manufacturer Derron and Miltex IFU for the ASC instruments have been obtained are readily available and staff has been trained in following these recommendations so the IFU statements are currently being observed as are the AORN guidelines for the Cleaning and Care of Surgical Instruments.

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 Infection Control Manager will ensure proper training of staff and evaluate perioperative personnel in their understanding of reprocessing of instruments, including instrument cleaning / decontamination and the processing of instruments to be sterilized in a manner consistent with AORN standards of practice. Validation of personnel competency has been documented on the new Infection Control Staff Training and Competency Verification log. This tracking of adherence of staff to ASC policy and procedure regarding the aforementioned procedures, may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction:
Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.

Q240 Infection Control and Sanitary Environment Q241

Plan of Correction for failure to follow nationally recognized guidelines for terminal cleaning.

Action that will be taken to correct this specific deficiency:

The Coeur d'Alene Foot & Ankle Surgery Center selected AORN as its' nationally recognized guidelines for complying with generally accepted infection control standards of practice. Therefore, the medical staff at the ASC will be using the AORN recommendations on Environmental Cleaning. Education, training and competency verification regarding these practices will be conducted.

Per AORN Recommendation I, The ASC will establish cleaning procedures and frequencies in the perioperative practice setting in order that the patient will be provided with a clean, safe environment. A clean environment will be reestablished after the patient is transferred from the area. Perioperative areas will be terminally cleaned. The AORN adapted Cleaning and Terminal Cleaning schedules will be used to verify that the cleaning is being performed at the times designated.

All personnel will take precautionary measures to limit transmission of microorganisms when performing environmental cleaning and handling waste materials.

The ASC medical staff will follow AORN recommended cleaning procedures including damp dusting and pre-procedure cleaning, clean environment practices, post-procedure cleaning, terminal cleaning, sterile processing areas, scheduled cleaning of items not terminally cleaned, and enhanced cleaning as applicable.

Personnel responsible for the cleaning will be designated and AORN Cleaning Checklists and Terminal Checklists will be completed by the personnel responsible.

Per AORN recommendation, The Coeur d'Alene Foot & Ankle Surgery Center will select cleaning chemicals and tools for use in the perioperative setting by evaluating several factors as detailed previously and staff will be trained to use these items in accordance with manufacturer instructions for proper preparation, handling, use, storage and disposal.

Description of how the actions will improve the processes that led to the deficiency:

By following AORN nationally recognized standards for Environmental Cleaning and disinfection in the perioperative practice standards, the risk of pathogen transmission in the perioperative setting will be reduced, providing the patient with a clean and safe environment. Established cleaning and terminal cleaning schedules will ensure consistency in providing that clean and safe environment. Establishing various cleaning schedules, such as cleaning before work begins, reestablishing a clean setting after the patient leaves the area to prevent cross-contamination and terminal cleaning to reduce the number of pathogens and the amount of dust and debris all contribute to a functional and sanitary environment.

Using the AORN Cleaning and Terminal Cleaning schedules and checklists will verify that the types of cleaning are being performed at the proper times and that the cleaning procedures of items are consistent.

Completion date for correction of deficiency: **July 15, 2016**

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 Infection Control Manager will ensure proper training of staff. AORN Key Environmental Cleaning Takeaways Tools, Guidelines at a Glance and the AORN Environmental Cleaning of Perioperative spaces Policy and Procedure Information Guides, will be used for training of personnel performing environmental cleaning in the ASC perioperative space. The expected outcome is that the patient is free from signs and symptoms of infection.

The Infection Control Manager will evaluate perioperative personnel in their understanding of Environmental Cleaning, including Terminal Cleaning, in accordance with AORN guidelines. AORN Environmental Cleaning Guideline Audit Tools and Gap Analysis Tools will be used to help the ASC access compliance of the staff to the Coeur d'Alene Foot & Ankle Surgery Center policy and procedures for environmental cleaning.

The training and competency validation will be noted on the new Infection Control Staff Training and Competency Verification log. This evaluation will help determine areas where additional training may be needed and may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction: Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.

Q240 Infection Control and Sanitary Environment Q241

Plan of Correction for failure to establish work flow patterns in a manner consistent with nationally recognized guidelines.

Action that will be taken to correct this specific deficiency:

Functional workflow patterns will be established in the following order, from potentially high contamination areas to clean areas: decontamination area, preparation and packaging, sterilization processing, sterile storage, and clean distribution as covered previously in the Cleaning and Care of Surgical Instruments section. The Coeur d'Alene Foot & Ankle Surgery Center remodel of the ASC as previously described, will establish a separate room for the decontamination area which will be separate from where clean items are handled.

In accordance with AORN Guidelines for Perioperative Practice, the Coeur d'Alene Foot & Ankle Surgery Center OR doors will be kept closed except during the entry and exit of patients and personnel. The personnel will minimize the number of operating room door openings and the doors will be closed during the surgical procedure except when opening is required for a procedure-related reason.

The ASC will accomplish this minimization of the number of door openings of the OR through preplanning so that turbulence from opening the door is minimized. Preplanning will include the storage of instruments, supplies, lab equipment, etc. for the case within the operating room so the staff will not have to exit the OR to obtain or retrieve these supplies. To help ensure that operating room doors remain closed during the surgical procedure, confirmation will be established that all instruments and supplies are present before the incision is made.

Description of how the actions will improve the processes that led to the deficiency:

The remodel of the ASC as described previously that will create a physical separation of decontamination areas from areas where clean items are handled will minimize the risk of cross-contamination and establish a work flow conducive to a sanitary environment in accordance with acceptable standards of practice and nationally recognized guidelines, ensuring patient risk of infections and communicable diseases are minimized.

According to AORN, the opening of the operating room door disrupts its filtered atmosphere, with the possibility of increasing contamination above the surgical wound. The studies all support keeping the doors closed during the surgical procedure except when opening is required for a procedure-related reason. By reducing traffic flow in the OR and reducing the necessity of the personnel needing to go in and out of the OR, the potential for negative air quality in that area is reduced which likewise decreases the risk of surgical site infections for surgical patients.

Completion date for correction of OR workflow deficiency: **July 8, 2016**
The Coeur d'Alene Foot & Ankle Surgery Center remodel is in process as previously described, with completion date is expected by July 26, 2016.

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 Infection Control Manager will ensure proper training of staff and evaluate perioperative personnel in their understanding of limiting Operating Room Traffic. Validation of personnel competency has been documented on the new Infection Control Staff Training and Competency Verification log. This tracking of adherence of staff to ASC policy and procedure regarding the work flow may include direct observation, and / or the use of tools to evaluate the competency. Tracking compliance may also be part of a future QAPI Project as determined by the Quality Management Program.

Title of the Person responsible for implementing the acceptable plan of correction:
Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.

Q 240 416.51 INFECTION CONTROL Q242

Plan of Correction for failure to evaluate and identify breeches in the Infection control Program

Action that will be taken to correct these specific deficiencies:

Infection Control Manager: The Coeur d'Alene Foot & Ankle Surgery Center will have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program. Due to staff changes, the infection control manager assignment was shared by two of the registered nurses, one of which is part time and whose on site hours are reducing due to impending retirement. To achieve compliance and to ensure that plan is comprehensive, that there is ongoing monitoring and evaluation of the Infection Control Program to verify that there is adherence to the ASC infection control policies and guidelines, the Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center has decided that the infection control manager will be a full time registered nurse who is able to spend sufficient time on-site directing and monitoring the infection control program.

The infection control manager will ensure a functional, sanitary environment for surgical patients to minimize sources and transmission of infections and communicable disease based on AORN nationally recognized infection control guidelines. The infection control manager will define ASC actions to prevent, identify, and manage infections and communicable diseases, including mechanisms to immediately implement corrective actions and preventive measures to improve SSI in the ASC. The Coeur d'Alene Foot & Ankle Surgery Center currently has a policy and procedure in place to track SSI infections, which, to date have been very low, and also has procedures in place to manage such infections. The full time IC Manager will modify these procedures and any other infection control policy and procedures as necessary for adaptation with AORN guidelines and such changes will be will be noted in the Quarterly Reports of the Governing Body and evaluated by the Quality Management Program.

The infection control manager will be directed by a health care professional with training in infection control. Michelle Kopriva, RN, BSN is now the full time Infection Control Manager of the Coeur d'Alene Foot & Ankle Surgery Center. In her new position, she has completed the AORN Infection Prevention _Package CE:6.8 hours June 27, 2016, and completed on July 5, 2015 received Certificates of Completion in Cleaning and Disinfection, Part 1; the Back to Basics: Environmental Cleaning; and Implementing Recommended Practice for Environmental Cleaning. She will be continuing her infection control education and obtain her certification within this year. Having a full time on site infection control manager will correct the deficiency of the ASC being unable to achieve compliance and ensure that there is ongoing monitoring and evaluation of the Infection Control Program and adherence to the ASC infection control policies and guidelines, now based on standards of a nationally recognized organization, AORN.

Policy Review: Policies and procedures assist in the development of patient and workplace safety, quality assessment, and performance improvement activities, establish authority, responsibility, and accountability within the facility and also serve as operational guidelines that are used to minimize patient and health care worker risks, standardize practice, and direct perioperative personnel. The Coeur d'Alene Foot & Ankle Surgery Center currently conducts a policy review at least annually, of all of the ASC policy and procedure, including infection control. With new policy implementation, however, and in an effort to better *monitor and evaluate the infection control program, especially the policies and procedures wherein deficiencies existed, for the cleaning and care of instruments used in surgery, surgical hand hygiene, environmental cleaning, and workflow practices,* the Infection Control policies and procedures will be reviewed on an ongoing basis this next year and the AORN guidelines and recommendations will continue to be incorporated and will be noted in the Quarterly Reports of the Governing Body.

Education: The Coeur d'Alene Foot & Ankle Surgery Center staff members currently receive infection control training and participation as noted on the ASC In-service Log and was viewed by the surveyors. Individual continuing education is documented and placed in the employee's file. With the implementation of new policy based on the AORN Guidelines, the Coeur d'Alene Foot & Ankle Surgery Center staff members will receive in depth training, both through in-

services and also computer based. The ASC purchased the AORN's Guidelines for Perioperative Practice via eSubscription, so the staff will be able to access the guidelines that were printed, and also on the computer and AORN offers an abundance of continuing education materials and courses which the ASC will encourage and provide time for medical staff participation. In-services for the practice of the new policies are also being conducted and have been documented as well as the competency verification of the practices. This is noted on the new Infection Control Staff Training and Competency Verification log.

Description of how the actions will improve the processes that led to the deficiency:

Having an infection control manager who is a full time registered nurse and who is able to spend a majority of her time on-site directing the infection control program will enable more thorough compliance to the ASC infection control policy and guidelines and will also ensure that there is ongoing monitoring and evaluation of the Infection Control Program to identify any breeches.

Current and ongoing documented education for the Coeur d'Alene Foot & Ankle Surgery Center medical staff members as described above will promote a better understanding of the practices and ensure compliance with the ASC / AORN policies and recommended practices to help prevent and control infections and communicable diseases.

Ongoing review this next year of the ASC Infection Control Policy, especially the policies and procedures where deficiencies were noted, such as in the cleaning and care of instruments used in surgery and proper use of PPE for that purpose, in surgical hand hygiene, in environmental cleaning and using approved germicidal solutions for that purpose, and in work flow patterns, in addition to revising other policy in accordance with the AORN guidelines and recommendations, all will contribute to the ASC having an explicit infection control program as defined in the standards. A composite of this review will be noted in the Quarterly Governing Body reports.

The Quality Management Program described below will assist in evaluating staff compliance and in formulating plans for corrective actions, as well as provide data that may be used to determine whether the ASC is within their goals and, if not, identify areas that may require corrective actions of any breeches in infection control. The data will also provide ongoing feedback regarding whether problems are improving, stabilizing, or worsening and indicate the need for the design of Quality Assurance Performance Improvement Projects.

Since Coeur d'Alene Foot & Ankle Surgery Center selected AORN as its nationally recognized guidelines for complying with generally accepted infection control standards of practice and paid to become a member of AORN and also purchased AORN's Guidelines for Perioperative Practice through eSubscription, ASC perioperative personnel are currently receiving documented training on line and also engaged in practices of the new policies which have been documented and will continue to be documented. A separate Infection Control in-service / Training form has been developed and is currently in use for this documentation.

The validation of the competency and of the ASC staff's adherence to the new infection control policies and procedures in place regarding the cleaning and care of instruments used in surgery and proper use of PPE for that purpose, in surgical hand hygiene, in environmental cleaning and using approved germicidal solutions for that purpose, in work flow patterns and in staff adherence to Manufacturer instructions (IFU) in an effort to correct deficiencies, is currently under surveillance as the in-service training and actual practices are conducted. Competency

validation of the new infection control procedures are documented on a new, separate Infection Control in-service / training form that has been developed and is currently in use for this competency validation documentation.

Completion date for correction of deficiency: **July 15, 2016**

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:

Quality Management Program: As part of the Quality Management Program of the Coeur d' d'Alene Foot & Ankle Surgery Center, which includes monitoring compliance with all policies, procedures, protocols, and other infection control program requirements, the ASC will:

Evaluate the cleaning, decontamination, and care of instruments and the staff use of personal protective equipment using such tools as the ANSI/AAMI Observation Audit Handling, Collection and Transport of Contaminated Items: Cleaning and Other Decontamination Processes as well as direct observation of staff practices by the Infection Control Manager.

Evaluate surgical hand hygiene procedures and to identify and respond to opportunities for improvement. Barriers that may exist for surgical hand hygiene will be recognized and addressed. Removing barriers to hand hygiene will help health care personnel improve adherence to these procedures. Some of the identified barriers are hand hygiene products causing irritation, sinks not conveniently located, lack of supplies, understaffing, and patient needs that take priority. According to AORN guidelines, direct observation is considered the most effective measurement. Observational surveillance of surgical hand hygiene practices provides direct information on compliance by health care personnel. Direct observation also can determine the areas of strengths and weaknesses in hand hygiene practices and allows for improvement in the process. Tools, such as the Patient Safety Tool: Hand Hygiene Observation Form from Johns Hopkins Medicine or the Institute for Healthcare Improvement Hand Hygiene Use Monitoring Form will be used by the ASC to evaluate and monitor hand hygiene compliance, as well as direct observation of staff practices by the Infection Control Manager.

Evaluate perioperative personnel by observing their participation in quality assurance and performance improvement activities that are consistent with the ASC's plan to improve understanding of and compliance with the principles and processes of environmental cleaning using facility approved germicidal solutions. AORN has a variety of audit tools that the ASC will use in determining the degree of compliance with the principles and processes of environmental cleaning, such as AORN Environmental Cleaning Guideline Audit Tools, Gap Analysis Tools and AORN Competency Verification Tools, as well as direct observation of staff practices by the Infection Control Manager.

Evaluate rates of and reasons for OR door openings that occur while sterile supplies are open. The ASC will use direct observation by Infection Control Manager of staff practices regarding OR traffic patterns and will conduct a study of traffic in the operating room as a risk for infections.

The Coeur d'Alene Foot & Ankle Surgery Center Governing Body including the owners, is meeting monthly in addition to the regular quarterly meeting during this transition period of remodel and correction of deficiencies for general oversight and direction of the process. This includes surveillance or evaluation in monitoring compliance for the correction of deficiencies of the facility policies and procedures described above and in accordance with AORN Infection Control guidelines. Future QAPI projects will be discussed and designed for areas where additional data is needed on problems identified with infection control, thereby making the **infection control program integrated into the ASC's QAPI program**.

Title of the Person responsible for implementing the acceptable plan of correction: Michelle Kopriva, RN, Infection Control Manager. Also the Quality Assurance Review Committee and Governing Body of the Coeur d'Alene Foot & Ankle Surgery Center (consisting of the RN Administrator, Rita Kinney, Medical staff of the Surgery Center in addition to the Owners) will be monitoring the compliance as detailed later under the Quality Management Section.