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

CENTERS FOR MEDICARE & MEDICAID SERVICES

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

IMPORTANT NOTICE – PLEASE READ CAREFULLY

October 23, 2015

Charlene Conilogue, Administrator
Idaho Surgicenter North
P.O. Box 1386
3369 A. Merlin Drive
Idaho Falls, ID 83404

CMS Provider Number: 13C0001035

Re: Notice of Enforcement Action: 90-day Termination Notice
Conditions For Coverage Not Met

Dear Ms. Conilogue:

After careful review of the facts, the Centers for Medicare and Medicaid Services (CMS) has determined that the Idaho Surgicenter North no longer meets the requirements for participation as a provider of Ambulatory Surgical Centers (ASC) in the Medicare program established under Title XVIII of the Social Security Act. The center is now placed on a 90-day termination notice based on the completion date of the survey. **This letter serves as notification that effective November 19, 2015 the Secretary of the Department of Health and Human Services intends to terminate its provider agreement with the Idaho Surgicenter North.**

BACKGROUND

To participate as a provider of ASC services in the Medicare and Medicaid Programs, a provider must meet all the Conditions for Coverage (CfC) established by the Secretary of Health and Human Services. When a provider is found to be non-compliant with the Medicare Conditions of Coverage for ASC, the provider no longer meets the requirements for participation in the Medicare program. The Social Security Act Section 1866(b) authorizes the Secretary to terminate a provider's Medicare provider agreement if the provider no longer meets the regulatory requirements for ASC. 42 CFR § 489.53 authorizes the Centers for Medicare and Medicaid Services to enforce this termination action.

On **August 21, 2015**, the Idaho Bureau of Facility Standards (State survey agency) completed a recertification survey at Idaho Surgicenter North. The investigation found deficiencies and CMS agrees with the State survey agency that the following conditions were not met:

42 CFR 416.41 Governing Body and Management

42 CFR 416.51 Infection Control

These deficiencies limit the capacity of Idaho Surgicenter North to provide services of adequate level and quality. The details of the above deficiencies are listed on the enclosed Statement of Deficiencies (Form CMS 2567) which was sent to you.

On **September 17, 2015** you submitted a Plan of Correction which served as your allegation of compliance. On **October 13, 2015** a revisit was conducted at Idaho Surgicenter North by the Idaho Bureau of Facility Standards to determine compliance. The revisit found that Idaho Surgicenter North continues to be out of compliance with the above Conditions for Coverage. Based on the State survey agency's revisit findings, CMS is imposing termination action against Idaho Surgicenter North for continued non-compliance with the requirements of the Medicare ASC program.

This 90-day termination action can be avoided by correcting the deficiencies prior to the effective date of the termination. CMS must receive a **credible allegation of compliance** in a timely manner, immediate implementation of your plan, and verified by the State survey agency that the deficiencies have been corrected. An acceptable plan of correction, which includes acceptable completion dates, must contain the following elements:

- Plan of Correction for each specific deficiency cited;
- Procedure/process for implementing the acceptable plan of correction for each deficiency cited;
- Monitoring and tracking procedures to ensure the plan of correction's effectiveness and continued compliance with regulatory requirements;
- Quality Assessment and Performance Improvement (QAPI) addresses improvement in systems to prevent the likelihood of re-occurrence of the deficient practice.
- A completion date for correction of each deficiency cited;
- Individual responsible for implementing the acceptable plan of correction with signature and title.

Please submit an acceptable Plan of Correction by **October 28, 2015** via post mail, fax or email to:

DHHS Center for Medicare and Medicaid Services
Division of Survey, Certification & Enforcement – Region 10
Attention: Fe Yamada
701 Fifth Avenue, Suite 1600, MSRX-400
Seattle, WA 98104
Fax: 206-615-2088
marie.yamada@cms.hhs.gov

PUBLIC NOTICE OF TERMINATION

In accordance with 42 CFR 489.53(d). CMS will publish legal notice of your pending termination action in a newspaper within your locale at least 15 days prior the termination date or by November 4, 2015.

APPEAL RIGHTS

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

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

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

If you have no internet access and would prefer to file your appeal in writing, please contact the DAB office below:

Chief, Civil Remedies Division **Departmental Appeals Board MS 6132** **Cohen Building, Room 637-D** **330 Independence Avenue, SW** **Washington, D.C. 20201**	**Please also send a copy to:**	**Chief Counsel, DHHS** **Office of General Counsel** **701 Fifth Avenue, Suite 1620** **M/S RX-10** **Seattle, WA 98121-2500**

If you have any questions, please contact Fe Yamada of my staff at (206) 615-2313 or by email at marie.yamada@cms.hhs.gov.

Sincerely,

Patrick Thrift, Manager
Western Division of Survey & Certification
Seattle Regional Office

cc: Idaho Bureau of Facility Standards
DHHS Regional Counsel

IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

TAMARA PRISOCK-ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
DEBBY RANSOM, R.N., R.H.I.T – Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, Idaho 83720-0036
PHONE: (208) 334-6626
FAX: (208) 364-1888
E-mail: fsb@dhw.idaho.gov

CERTIFIED MAIL: 7012 3050 0001 2125 5679

October 23, 2015

Charlene Conilogue, Administrator
Idaho Surgicenter North
3369 A Merlin Drive
Idaho Falls, ID 83404

RE: Idaho Surgicenter North, Provider #13C0001035

Dear Ms. Conilogue:

Based on the revisit at Idaho Surgicenter North on October 13, 2015, by our staff, we have determined that Idaho Surgicenter North continues to be out of compliance with the Medicare Conditions of Participation of **Governing Body and Management (42 CFR 416.41) and Infection Control (42 CFR 416.51**.

The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567). Also enclosed is your copy of a Post-Certification Revisit Report (CMS-2567B), listing deficiencies that have been corrected.

In our letter to you dated September 4, 2015, we stated: "failure to correct the deficiencies and achieve compliance will result in our recommending that the Centers for Medicare and Medicaid Services (CMS) Region X Office, Seattle, Washington, terminate your approval to participate in the Medicare program."

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

Sincerely,

Debby Ransom for
NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

NW/pmt
Enclosures
cc: 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
	13C0001035	A. BUILDING _____ B. WING _____	R 10/13/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO SURGICENTER NORTH	3369 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 follow-up survey of your ASC from 10/8/15 to 10/13/15. Surveyors conducting the survey were: Laura Thompson, RN, HFS, Team Leader Rebecca Lara, RN, HFS Acronyms used in this report include: AAMI - Association for the Advancement of Medical Instrumentation AORN - Association of Peri-Operative Registered Nurses ASC - Ambulatory Surgical Center ED - Emergency Department QAPI - Quality Assurance and Performance Improvement QI - Quality Indicators RN - Registered Nurse	{Q 000}	RECEIVED OCT 27 2015 FACILITY STANDARDS	
{Q 040}	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. This CONDITION is not met as evidenced by:	{Q 040}	Refer to attached POC	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: C. Mulgrew — TITLE: Administrator — (X6) DATE: 10-27-15

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 040}	Continued From page 1 Based on staff interview and ASC policies, it was determined the ASC failed to ensure the Governing Body developed, implemented, and monitored policies and programs necessary to ensure all patient needs were met. This resulted in the inability of the facility to ensure quality health care services were provided in a safe manner. Findings include: 1. During the ASC's 8/21/15 recertification survey, the Condition for Coverage: Governing Body and Management (Q40) was found out of compliance due, in part, to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented and monitored necessary to minimize infections and communicable diseases. The ASC was found out of compliance with the Condition for Coverage: Infection Control (Q240) and associated standard level deficiencies. The ASC submitted a Credible Allegation of Compliance/Plan of Correction, dated 9/17/15, which stated "Governing Body addressed the failure to comply with Idaho SurgiCenter North policies on Infection Control by approving a budget and agreeing to oversee and monitor practices pertaining to staff participation in programs and in-services that will improve Infection Control practices and minimize infections and communicable diseases..." The ASC alleged compliance as of 9/24/15. However, a follow up survey was conducted from 10/08/15 to 10/13/15. At that time, the ASC's Credible Allegation of Compliance/Plan of Correction was not comprehensively monitored necessary to ensure compliance was achieved and sustained. Refer to Q240 Condition for	{Q 040}		

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{Q 040}	Continued From page 2 Coverage: Infection Control and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented and monitored necessary to minimize infections and communicable diseases.	{Q 040}		
{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, 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. The ASC was previously cited at Q241 during a recertification survey dated 8/21/15. The ASC failed to ensure sufficient action was taken necessary to achieve and sustain compliance. 2. Refer to Q242 as it relates to the ASC's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained. The ASC was previously cited at Q242 during a recertification survey dated 8/21/15. The ASC failed to ensure	{Q 240}	Refer to attached POC	

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{Q 240}	Continued From page 3 sufficient action was taken necessary to achieve and sustain compliance. 3. Refer to Q243 as it relates to the ASC's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in the principles and methods related to infection control. The ASC was previously cited at Q243 during a recertification survey dated 8/21/15. The ASC failed to ensure sufficient action was taken necessary to achieve and sustain compliance. 4. Refer to Q244 as it relates to the ASC's failure to ensure the infection control program was incorporated into the QAPI program.	{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, staff interview, and policy review, it was determined the facility failed to maintain a sanitary and functional environment. This failure had the potential to impact staff and all patients receiving care at the facility. This resulted in the potential for infections to occur and for improper use of disinfection cleansers and inappropriate laundry practices. Findings include: 1. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q241. The ASC submitted a Credible Allegation of Compliance/Plan of Correction, dated 9/17/15,	{Q 241}	Refer to attached POC	

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{Q 241}	Continued From page 4 which alleged compliance. However, a follow up survey was conducted from 10/08/15 to 10/13/15. At that time, the ASC's Credible Allegation of Compliance/Plan of Correction was not comprehensively monitored necessary to ensure compliance was achieved and sustained, as follows: a. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q241 for the ASC's failure to ensure reprocessing was completed in a manner consistent with nationally recognized standards of practice, which included the following: i. During the facility's 8/21/15 recertification survey the ASC was cited for using a name brand household dishwashing liquid to make a foamy bath for cleaning of the instruments. The ASC's Credible Allegation of Compliance/Plan of Correction for Q241, stated "We have purchased enzymatic cleaner to be used during instrument decontamination..." The ASC alleged compliance as of 9/11/15. The policy, "Sterilization and Processing of Re-usable Devices" dated 2015, stated "All articles to be sterilized are to be cleaned with an enzymatic cleaner, decontaminated, and dried thoroughly before re-packaging." The policy did not include the name of the enzymatic cleaner utilized and if it was approved by the Governing Body. Additionally, the policy did not include the manufacture instructions for use of the enzymatic cleaner to ensure instruments were properly disinfected.	{Q 241}		

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{Q 241}	Continued From page 5 On 10/9/15 beginning at 8:25 AM, the Administrator was asked to review the process for disinfection and sterilization of instruments. She stated she was the primary person responsible for disinfecting and reprocessing the instruments. The Administrator stated another scrub technician, who she trained, would fill in for her in her absence. While going through the process of disinfection the Administrator stated she would fill a plastic basin with warm water and add the enzymatic cleanser to the basin. When asked how the temperature of the water was monitored, the Administrator stated she did not monitor the water temperature. The Administrator stated she then soaked the instruments for 5-7 minutes in the enzymatic cleanser prior to scrubbing with a brush. When asked about manufacture instructions related to time length for soaking instruments, the Administrator stated she was not aware of the manufacture instructions for soak times. The manufacture instructions for the enzymatic cleaner were reviewed in the presence of the Administrator. The manufacturer instructions stated "Water temperature should not exceed 150 degrees F." Additionally, the manufacture instructions stated instruments were to soak for 2 minutes. The Administrator stated she was not aware of the manufacture instructions prior to the review with the surveyors. When asked on 10/13/15 at 11:00 AM, how the Governing Body monitored the ASC to ensure correction of the previously identified deficient practices the Administrator, a member of the Governing Body, stated there was no monitoring	{Q 241}		

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{Q 241}	Continued From page 6 for the implementation of the new processes or policies. The Governing Body failed to provide oversight and monitoring to ensure the enzymatic cleanser was being used per manufacture instructions. ii. During the facility's 8/21/15 recertification survey the ASC was cited due to instruments being decontaminated, stored for 2 weeks, and then sterilized. The ASC could not ensure bacterial growth did not occur during the lapse of time from cleaning of the instruments until they were sterilized. The ASC's Credible Allegation of Compliance/Plan of Correction for Q241, stated "All instruments will be disinfected with enzymatic cleaning solution to ensure that bacterial growth doesn't occur between the time of cleaning and sterilization. Additionally, all instruments will be processed and not left on the shelf for any length of time other than the length of time it takes to wrap them for processing. After instruments are processed and dry, they will be removed from the autoclave and stored in the OR cupboards marked 'STERILE' in bins, per present policy." The ASC alleged compliance as of 9/11/15. A policy, "Sterilization and Processing of Re-usable Devices" dated 2015, stated "Items to be sterilized should be decontaminated in a controlled environment using standard precautions, packaged according to established guidelines, and sterilized using the appropriate methods. Instruments, supplies, and equipment reprocessed by Idaho SurgiCenter North will be prepared in a manner to assure maintenance of sterility and promote delivery to the sterile field in	{Q 241}		

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{Q 241}	Continued From page 7 an aseptic manner." The policy included the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities 2008, and AORN 2015 Recommended Practices for Sterilization in the Perioperative Setting as references. During an interview on 10/08/15 at 2:23 PM, the Director of Operations stated she received training on sterilization of instruments from the Administrator. She stated she did not perform disinfection of instruments. The Director of Operations stated the Administrator disinfected the instruments, dried them, and then wrapped them in preparation for sterilization. She stated after the instruments were wrapped she was responsible for placing them in the autoclave and assuring the sterilization process was completed. The Director of Operations stated there were times when she did not complete the sterilization for all wrapped instruments, and she would leave the wrapped instrument packs in a plastic bucket on a shelf, to be completed on Monday, 72 hours after disinfection and wrapping began. The CDC Guideline for Disinfection and Sterilization in Healthcare Facilities 2008, stated "Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI and other professional organizations. Packaging of instruments for sterilization should be sufficiently strong to resist punctures and tears to provide a barrier to microorganisms and moisture." By leaving the wrapped packages on a shelf, for 72 hours or more, prior to placement in the autoclave and finishing the sterilization process,	{Q 241}		

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{Q 241}	Continued From page 8 the ASC was placing the wrapped packages at risk for contamination or compromise by microorganisms and risking the integrity of the surgical instruments inside the package. When asked if the sterilization was performed and completed immediately after wrapping the instruments, the Administrator stated "No." She stated at times the wrapped instruments were left, in a plastic bin on a shelf in the reprocessing room, until the following Monday. The Administrator confirmed the process of disinfection and sterilization began on Friday, after all scheduled procedures were completed, and not finished until Monday, 72 hours later. When asked on 10/13/15 at 11:00 AM, how the Governing Body monitored the ASC to ensure correction of the previously identified deficient practices the Administrator, a member of the Governing Body, stated there was no monitoring for the implementation of the new processes or policies. The Governing Body failed to ensure the Credible Allegation of Compliance/Plan of Correction was comprehensively monitored necessary to ensure regulatory compliance was achieved. b. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q241 for the ASC's failure to ensure laundry was handled in a manner consistent with nationally recognized standards of practice. The ASC's laundry, including scrubs, linens, patient gowns, mop heads, utility towels, and nurse's caps were laundered by an employee at the employee's home.	{Q 241}		

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{Q 241}	Continued From page 9 The ASC's Credible Allegation of Compliance/Plan of Correction for Q241, stated "On 8-22-15 at the Special Governing Body meeting, it was decided that going forward we will contract with a healthcare accredited laundry service for laundering of patient linens and staff scrub wear in accordance with the 2015 AORN Guidelines for Perioperative Practice. [Administrator's name] took bids from two different places and secured a contract with [laundry service's name and location] on 9-15-15. All ASC staff will be required to wear this scrub wear...The agreement is in place, but due to the nature of the inventory we require, the first delivery will not take place until 10-12-15. Thereafter, the pickup and delivery day will be every other Monday to keep soiled laundry from sitting for long periods of time. The laundry to be picked up will not be stored at the ASC, but on the clinic side in an area designated for storage of Biohazardous waste. These changes were made to our Infection Control Manual..." A policy, "Laundry" dated 2015, stated "Laundering of scrubs, linens, and patient gowns is done by a healthcare accredited laundry service. Recommended practices for surgical attire worn within the semi-restricted and restricted areas of the surgical environment will be followed. All surgical scrubs, linens, and patient gowns will be laundered using approved laundry guidelines by an approved laundry service." A tour of the ASC was conducted on 10/08/15 beginning at 2:20 PM, with the Director of Operations. When asked about laundry services, she stated a contract was signed with a laundry service but did not start until 10/16/15. The	{Q 241}		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(Q 241)	Continued From page 10 Director of Operations was then asked how laundry was stored until the contract service started, and she stated she was continuing to take the soiled laundry to her residence and washing it there. When asked about contacting the laundry service regarding interim services she stated she did not contact them and the Administrator was responsible for all contracts with the ASC. The Director of Operations stated she kept a log of the laundry she had washed in her residence. A request was made to review the log. The laundry log documented 20 loads of ASC laundry were done at the Director of Operations residence between 8/21/15 and 10/03/15. The log included documentation of the date, contents of laundry, detergent/bleach, start time, finish time, and initials. Laundry, which was washed at the Director of Operations residence, included blankets, patient gowns, sheets, pillowcases, scrub tops and pants, cleaning cloths, and mop pads. When asked about the laundry services, on 10/09/15 at 8:25 AM, the Administrator stated the Director of Operations was responsible for securing a contract with a laundry service. She stated "I know it's supposed to start around the 16th of October." When the Administrator was informed the Director of Operations continued to take soiled laundry to her home for washing, she stated she was not aware of this situation. A copy of the contract for laundry service was requested. The contract agreement included the date for the first installment of linens, 10/12/15. The contract listed the Administrator of the ASC as the contact person. Additionally, the contract	(Q 241)		

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{Q 241}	Continued From page 11 agreement was signed by the Administrator on 9/14/15. When asked on 10/13/15 at 11:00 AM, how the Governing Body monitored the ASC to ensure correction of the previously identified deficient practices the Administrator, a member of the Governing Body, stated there was no monitoring for the implementation of the new processes or policies. The Governing Body failed to ensure the Credible Allegation of Compliance/Plan of Correction was comprehensively monitored necessary to ensure regulatory compliance was achieved. 2. A policy, "Pest Control" dated 2015, stated "A pest-control specialist with appropriate credentials will be contracted to provide regular pest control services that meets the needs of Idaho SurgiCenter North and uses approved chemicals and/or physical methods of pest control." On 10/09/15 beginning at 8:25 AM, the ASC's reprocessing area, located in a room connected to the procedure area, was observed. A bottle of bug spray was observed in an open cabinet in the room. The Administrator, who was present during the observation, was asked about the bug spray. She stated the bottle was not supposed to be stored in the ASC. The Administrator removed the bottle of bug spray from the reprocessing room immediately. The Governing Body failed to ensure their policy was followed by staff for pest control and Infection Control in the ASC.	{Q 241}		

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{Q 242}	Continued From page 12	{Q 242}	Refer to attached POC	
{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 staff interview, policy review and review of infection control documentation and employee inservice/education documents, it was determined the ASC failed to ensure that an ongoing infection control program was sufficiently implemented and monitored to ensure the health and safety of all patients receiving care in the ASC. The ASC's infection control program did not provide evidence that it thoroughly prevented, controlled or investigated possible infections and communicable diseases. These failed practices had the potential to negatively impact patient health and safety, resulting in patient infection due to poor infection control practices. Findings include: 1. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q242. The ASC submitted a Credible Allegation of Compliance/Plan of Correction, dated 9/17/15, which alleged compliance. However, a follow up survey was conducted from 10/08/15 to 10/13/15. At that time, the ASC's Credible Allegation of Compliance/Plan of Correction was not comprehensively monitored to	{Q 242}		

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{Q 242}	Continued From page 13 ensure compliance was achieved and sustained, as follows: a. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q242 for the ASC's failure to ensure surveillance activities include ongoing monitoring of patients, visitors, and staff, as well as the analysis of data to detect changes or infection trends. During an interview, with the Infection Control Officer on 8/21/15 at 12:00 PM, she stated surveillance activities included hand washing monitoring. However, she stated the last monitoring occurred in October, 2014. The ASC's Credible Allegation of Compliance/Plan of Correction for Q242, stated "On 9-11-15 a Special Governing Body Meeting was held and [staff's name], RN, our Infection Control Officer was present. The Governing Body stated that responsibility for Infection Control takes more time than [name] was currently dedicating to it. She agreed and committed to more effort which will require more time than 15%. She will dedicate 25% of her time at the ASC to monitoring activities that will include surveillance of staff and patients in regard to current trends in Infection Control. The job description in the Personnel Manual for Infection Control Officer lists the things that she will make part of her accounting in performance of her responsibility. They are: Conducts staff training to ensure constant implementation of Infection Control practices; Conducts surveillance for detecting the infection source for the purpose of prevention; Follows and investigates the incidents of	{Q 242}		

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{Q 242}	Continued From page 14 nosocomial infections, generating reports and presenting them to the medical director; Monitors the execution of preventive measures and provides guidance to staff; Prepares quarterly statistical information for presentations in QAPI meetings as requested; Monitors and manages staff exposure incidents and infectious illnesses; and Implement necessary policies and procedures for infection control consistent with national standards and guidelines." The ASC's Credible Allegation of Compliance/Plan of Correction for Q242 also stated the Infection Control Officer would be "...accountable to the Governing Body going forward and will take a more active role in this aspect of operations of Idaho SurgiCenter North." A policy, "Education" dated 2015, stated "The educational programs at Idaho SurgiCenter North will include, but not be limited to the following annually..." Additionally, the policy stated, "Employees will receive new hire training within 30 days of hire...Refresher training will be provided at least annually." The policy did not include the changes outlined in the Credible Allegation of Compliance/Plan of Correction, which included quarterly and ongoing training of staff for Infection Control issues. The Infection Control Officer was interviewed on 10/09/15 at 11:00 AM. When asked about the development of the ASC's infection control policies and procedures, to ensure they were consistent with national standards and guidelines, the Infection Control Officer was uncertain which specific national guidelines the ASC followed. She stated she thought the ASC utilized	{Q 242}		

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{Q 242}	Continued From page 15 standards from more than one national infection control organization, such as AORN and/or the CDC, but she was unable to provide clarification. When asked about staff training and monitoring to ensure the ASC's infection control policies and procedures were being implemented, the Infection Control Officer stated she had not provided infection control training for ASC staff since the ASC's 8/21/15 recertification survey. She stated the only infection control related training provided to the ASC staff, since the recertification survey of 8/21/15 was instrument sterilization training, by the Administrator. However, the Infection Control Officer confirmed that only 2-3 staff members were actively involved with the instrument sterilization process. This training did not pertain to all ASC staff. The Administrator was interviewed on 10/09/15, beginning at 8:30 AM, and on 10/13/15, beginning at 11:00 AM. She stated she had provided an employee inservice related to instrument sterilization on 9/11/15, but confirmed there are only 2-3 individuals who are responsible for sterilizing instruments at the ASC. She agreed the training provided did not pertain to all employees. The Administrator also confirmed the Infection Control Officer had not provided any infection control training to employees or patients of the ASC since the recertification survey on 8/21/15. The ASC's staff inservice manual was reviewed on 10/08/15. The manual included a section for each employee which documented evidence of inservices/education employees received. Although there was evidence each employee received training about instrument sterilization on	{Q 242}		

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(Q 242)	Continued From page 16 9/11/15, there was no documentation the Infection Control Officer provided infection control education since the 8/21/15 recertification survey. When asked on 10/13/15 at 11:00 AM, how the Governing Body monitored the ASC to ensure correction of the previously identified deficient practices the Administrator, a member of the Governing Body, stated there was no monitoring for the implementation of the new processes or policies. The Governing Body failed to ensure the Credible Allegation of Compliance/Plan of Correction was comprehensively monitored necessary to ensure regulatory compliance was achieved. b. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q242 for the ASC's failure to ensure 48 hour post surgical assessment occurred in accordance with the ASC's policy. The ASC's Credible Allegation of Compliance/Plan of Correction for Q242, stated "When the Governing Body met on 09-11-15, they changed the policy that states that patients would be seen within 48 hours after surgery for assessment to match our practice of calling the patient within 24 hours of their surgical procedure. Patients have the after-hours phone number at their disposal to call if any problems should arise; it rings directly to [physician's name's] phone. The next time patients are evaluated is in the office the week after surgery on either a Wednesday or a Thursday for dressing changes, and they are seen by [physician's name]. The 2nd post op visit is 12-13 days after surgery at the time that sutures are	(Q 242)		

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{Q 242}	Continued From page 17 removed. This schedule of visits is working and is a good way for us to monitor the progress and potential for problems with surgery patients. It is the best way that our staff has of providing care for patients and ensuring that their recovery is on track. This was changed in the Nursing Manual by [Administrator's name] on 9-15-15." On 10/09/15 at 11:00 AM, the Infection Control Officer was asked about processes and practices related to the detection and prevention of infection. The Infection Control Officer stated the ASC had not had a post-operative infection in the last 6 years. However, she confirmed the only methods of infection identification and detection the ASC utilized were through staff making 24 hour, post-operative calls to patients, patient follow-up visits and patient surveys. She confirmed there was no process for monitoring patients for possible post-operative infections who may have chosen to follow up with another healthcare provider, or who may have presented to the ED of the local hospital with complications. The Infection Control Officer stated any complications were discussed during staff meetings. However, she confirmed there was no formal process in place to ensure all information related to infection control monitoring was effectively communicated to her. When asked if the ASC tracked the use of post-operative antibiotics and investigated to determine the reason the antibiotics were prescribed, the Infection Control Officer stated they did not track the use of post-operative antibiotics. The ASC's Administrator was interviewed on 10/09/15 beginning at 8:30 AM and on 10/13/15, beginning at 11:00 AM. When asked how patients are followed post-operatively for possible	{Q 242}		

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{Q 242}	Continued From page 18 infection, she stated patients are monitored through phone calls, follow-up visits and the patient survey. The "Post-Operative Patient Questionnaire," the document referred to as the patient survey, was reviewed. The document included questions which the patients could respond with a "yes or no." Examples included, but were not limited to, "Was your surgery scheduled at a time convenient for you?...Was the waiting time within acceptable limits?...Were the nurses pleasant, helpful and efficient?" Additionally, the document included an area for patients to make comments or suggestions. The form did not include signs or symptoms of infection, or questions regarding possible infection. The ASC's Administrator was interviewed on 10/09/15 beginning at 8:30 AM, and on 10/13/15 beginning at 11:00 AM. the Administrator was unable to verify whether patients were educated regarding the signs and symptoms of infection, and she did not believe the patient survey included the signs and symptoms of infection. She stated in lieu of contacting the physician or the ASC, many patients often phoned or presented to the local ED if they experienced post-operative complications. The Administrator confirmed the ASC had not implemented a process to track possible post-operative infections if/when patients followed up with an ED or another medical provider. She was unable to provide any evidence of a formal process to ensure post-surgical infection information/data was effectively communicated to the Infection Control Officer. The Governing Body was not providing oversight and monitoring to ensure post-operative infection information was provided	{Q 242}		

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{Q 242}	Continued From page 19 to the Infection Control Officer. The ASC Physician was interviewed by telephone on 10/09/15 beginning at 8:30 AM. He stated post-operative infections were infrequent and occurred "maybe once a year." He verified the methods for detecting possible post-operative infections were as the Infection Control Officer stated: post-operative phone calls, follow up visits and patient surveys. When asked about the use of post-operative antibiotics, he said he frequently prescribed antibiotics for comorbid conditions (a condition that occurs simultaneously in a patient) such as a productive cough or other medical complications requiring the use of antibiotics. The use of antibiotics was not monitored or tracked in the ASC. On 10/09/15 at 11:00 AM, when asked about other surveillance activities related to the detection and prevention of infection, the Infection Control Officer was unable to provide evidence of surveillance activities which were conducted since the recertification survey on 8/21/15. When asked on 10/13/15 at 11:00 AM, how the Governing Body monitored the ASC to ensure correction of the previously identified deficient practices the Administrator, a member of the Governing Body, stated there was no monitoring. The Governing Body failed to ensure the Credible Allegation of Compliance/Plan of Correction was comprehensively monitored necessary to ensure regulatory compliance was achieved. c. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q242 for the ASC's failure to ensure an annual review and revision of	{Q 242}		

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{Q 242}	Continued From page 20 infection control policies and procedures occurred in accordance with the ASC's policy. The ASC's Credible Allegation of Compliance/Plan of Correction for Q242, stated "The Governing Body granted the Infection Control Officer, [Infection Control Officer's name] RN, the opportunity for more education for this responsibility. As a QAPI committee member, she will be given time at each quarterly meeting to address concerns and inform staff of trends and will be expected to contribute to study and benchmarking activities by providing data collection for evaluation. She will be accountable to the Governing Body going forward, assessing the program under her direction and will take a more active role in this aspect of operations at Idaho Surgicenter North. To this point, and since the survey conducted on 08-21-15, she has taken an active role in Infection Control Policy updates and changes demonstrating that she is capable of managing Infection Control at the facility. She was interviewed as part of a performance evaluation by the [Administrator's name], Administrator, as a member of the Governing Body and committed to more concentrated efforts on 09-11-15. This performance review is found in [Infection Control Officer's name] personnel file. Follow up to this evaluation will take place within 3 months by way of a performance review conducted by [Administrator's name], Administrator, no later than December 11, 2015. This evaluation will be presented to the Governing Body for review after completion." The ASC's Administrator was interviewed on 10/09/15 beginning at 8:30 AM, and on 10/13/15 beginning at 11:00 AM. The Governing Body and the Governing Body's oversight of the ASC's	{Q 242}		

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{Q 242}	Continued From page 21 infection control program was discussed. She stated the ASC's Governing Body was comprised of herself, the Physician Owner/Operator and the Director of Operations. She was unable to provide any evidence of formal monitoring or oversight of the infection control program, or the activities of the Infection Control Officer. The Governing Body was not effectively monitoring the Infection Control Officer to ensure sufficient information was garnered on which to base her 12/11/15 evaluation. The Governing Body failed to ensure the Credible Allegation of Compliance/Plan of Correction was comprehensively monitored necessary to ensure regulatory compliance was achieved.	{Q 242}		
{Q 243}	416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION The program is - Under the direction of a designated and qualified professional who has training in infection control. This STANDARD is not met as evidenced by: Based on personnel record review and staff interview, it was determined the ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in the principles and methods related to infection control. This prevented the ASC from utilizing the knowledge base of a trained professional to develop, implement and monitor an effective infection control program. This failed practice had the potential to negatively impact facility staff and all patients who received care at	{Q 243}	Refer to Attached POC	

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(Q 243)	Continued From page 22 the ASC. Findings include: 1. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q243. The ASC submitted a Credible Allegation of Compliance/Plan of Correction, dated 9/17/15, which alleged compliance. However, a follow up survey was conducted from 10/09/15 to 10/13/15. At that time, the ASC's Credible Allegation of Compliance/Plan of Correction was not comprehensively monitored to ensure compliance was achieved and sustained, as follows: a. During the ASC's 8/21/15 recertification survey, the ASC was cited at Q243 for the ASC's failure to ensure the ASC functioned under a qualified professional, who had training in the principles and methodology related to infection control. The ASC's Credible Allegation of Compliance/Plan of Correction for Q243, stated "On 9-11-15 a Special Governing Body Meeting was held and [staff's name], RN, our Infection Control Officer was present. The Governing Body stated that responsibility for Infection Control takes more time than [name] was currently dedicating to it. She agreed and committed to more effort which will require more time than 15%. She will dedicate 25% of her time at the ASC to monitoring activities that will include surveillance of staff and patients in regard to current trends in Infection Control. The Governing Body also granted the Infection Control Officer the opportunity for more education, with compensation for travel, etc. Ms. [Name] is currently researching educational	(Q 243)		

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{Q 243}	Continued From page 23 opportunities that will make her the expert on Infection Control at Idaho SurgiCenter North...." The job description in the Personnel Manual for Infection Control Officer listed the responsibilities which were included in accounting for performance accountability. They were as follows: "Conducts staff training to ensure constant implementation of Infection Control practices; Conducts surveillance for detecting the infection source for the purpose of prevention; Follows and investigates the incidents of nosocomial infections, generating reports and presenting them to the medical director; Monitors the execution of preventive measures and provides guidance to staff; Prepares quarterly statistical information for presentations in QAPI meetings as requested; Monitors and manages staff exposure incidents and infectious illnesses; and Implement necessary policies and procedures for infection control consistent with national standards and guidelines." The Infection Control Officer was interviewed on 10/09/15 at 11:00 AM. When asked about the development, of the ASCs infection control policies and procedures to ensure they were consistent with national standards and guidelines, the Infection Control Officer was uncertain which specific national guidelines the ASC followed regarding the development of infection control policies and procedures. She stated she thought the ASC utilized standards from more than one national infection control organization, such as AORN and/or the CDC, but she was unable to provide clarification.	{Q 243}		

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IDAHO SURGICENTER NORTH	3369 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 243)	Continued From page 24 When asked about staff training and monitoring to ensure the ASC's infection control policies and procedures were being implemented, the Infection Control Officer stated she had not provided infection control training for ASC staff since the ASC's 8/21/15 recertification survey. She stated the only infection control related training provided to the ASC staff, since the recertification survey of 8/21/15, was instrument sterilization training, provided by the ASC's Administrator. However, the Infection Control Officer confirmed only 2-3 staff members were actively involved with the instrument sterilization process. This training did not pertain to all ASC staff or patients receiving care in the ASC. The Infection Control Officer was asked about processes and practices related to the detection and prevention of infection. She stated the ASC had not had a post-operative infection in the last 5 years she was employed. However, she confirmed the only methods of infection identification and detection the ASC utilized were through staff making 24 hour, post-operative calls to patients, patient follow-up visits and patient surveys. She stated there was not a process for monitoring patients for possible post-operative infections who may have chosen to follow up with another healthcare provider, or who may have presented to the ED of the local hospital with complications. When asked if the ASC tracked the use of post-operative antibiotics and investigated to determine the reason the antibiotics were prescribed, the Infection Control Officer stated they did not track the use of post-operative antibiotics.	(Q 243)		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001035	A. BUILDING _____ B. WING _____	R 10/13/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO SURGICENTER NORTH	3309 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 243}	Continued From page 25 Additionally, when the Infection Control Officer was asked about other surveillance activities related to the detection and prevention of infection, she was unable to provide evidence of any surveillance activities which were conducted since the recertification survey on 8/21/15. Evidence of education, specific to infection control and oversight of an infection control program, was requested from the Infection Control Officer during the survey. She provided the following documents that indicated completion of a course, from the website, "MEDLINEUNIVERSITY." The courses the Infection Control Officer completed included the following: -Back to Basics: A Fresh Look at Asepsis, completed 9/20/2015 -Back to Basics: Appropriate Surgical Scrub Attire, completed September 20, 2015 -Blood Borne Pathogens, completed 9/21/2015 -Breaking Through Hand Hygiene & Skin Care Barriers, completed 9/22/2015 The ASC failed to ensure the Infection Control Officer was adequately educated/trained in infection control principles and methodology and adequately prepared to direct the ASC's Infection Control Program.	{Q 243}		
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -]	Q 244	Refer to attached POC	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001035	A. BUILDING _____ B. WING _____	R 10/13/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO SURGICENTER NORTH	3369 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 244	Continued From page 26 An integral part of the ASC's quality assessment and performance improvement program This STANDARD is not met as evidenced by: Based on interview, review of infection control documentation, QAPI documents, and ASC policies, it was determined the facility failed to incorporate infection control into the QAPI program. This failed practice had the potential to negatively impact all patients receiving care at the facility and interfered with the ASC's ability to identify infections and improve infection control practices. Findings include: The National Center for Biotechnology Information website, accessed 10/14/15, defined quality indicators as follows: "...The QIs are evidence based and can be used to identify variations in the quality of care provided on both an inpatient and outpatient basis. These measures are currently organized into four modules: the Prevention Quality Indicators (PQIs), the Inpatient Quality Indicators (IQIs), the Patient Safety Indicators (PSIs), and the Pediatric Quality Indicators (PDIs)..." The Oxford University Press website, accessed 10/14/15, stated "Clinical indicators assess particular health structures, processes, and outcomes. They can be rate- or mean-based, providing a quantitative basis for quality improvement, or sentinel, identifying incidents of care that trigger further investigation. They can assess aspects of the structure, process, or outcome of health care. Furthermore, indicators can be generic measures that are relevant for most patients or disease-specific, expressing the	Q 244		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO SURGICENTER NORTH	3369 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 244	Continued From page 27 quality of care for patients with specific diagnoses." The "QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM," dated 9/09/15, was reviewed, as it related to infection control in the ASC. "QAPI INDICATORS" were listed on page 20 of the document, which included 28 indicators. "Infection" was the only documented quality indicator, related to infection control. There was no documentation concerning the specific indicators that were developed related to infection control in the ASC. The program did not include documentation related to measurable infection control data, or how the data was tracked and utilized to improve patient care. There was no mention of infection control quality/performance indicators that addressed potential high risk or problem prone areas. The "QI Meeting Minutes," dated 8/21/15, were reviewed during the survey. According to the meeting minutes, the Administrator and Infection Control Officer were in attendance. Infection control was mentioned in the meeting minutes once, and stated "...The Infection Control Manual was re-evaluated this week by [Name], our Infection Control Officer." The ASC's Administrator was interviewed on 10/09/15, beginning at 8:30 AM, and on 10/13/15, beginning at 11:00 AM. The Administrator stated she was the individual overseeing the ASC's QAPI program. When asked how the ASC's Infection Control Program was monitored through the QAPI program, she stated there were quality indicators related to infection control included in the Quality Program. She stated the quality	Q 244		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001035	A. BUILDING _____ B. WING _____	R 10/13/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO SURGICENTER NORTH	3360 A MERLIN DRIVE IDAHO FALLS, ID 83404

(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 244	Continued From page 28 indicators were discussed in the quarterly quality meetings. The Administrator was unable to relay specific information included in the Quality Program, about the infection control quality indicator(s.) She was unable to discuss infection control data, including how the data was tracked and analyzed, through the Quality Program. Additionally, the Administrator was unable to explain how the infection control data was used to improve the quality of patient care in the ASC. The Administrator confirmed that while the infection control program had been mentioned in the QAPI Program, measurement of data and quality indicators related to infection control were not included. The infection control program was not incorporated into the ASC's QAPI program.	Q 244		

ISCNORTH 2567 RESPONSE

Q 040 GOVERNANCE

- **Plan of Correction for deficiency:** Governing Body (GB) hired an individual whose primary function would be to serve as Infection Control Officer (ICO) and maintain an acceptable Infection Control Program (ICP). ISCN will pay for training for the ICO; she will receive specific and adequate training for her responsibility of direction of the ICP. Surveillance and monitoring of the ICP will be conducted by the GB by performing Infection Risk Assessment annually. GB has approved changes to Infection and QAPI Policy Manual. GB will perform monitoring activities in regard to the performance of the ICO, in annual performance reviews. Results of these performance evaluations will be found in her personnel file.

- **Procedure for implementing an acceptable PoC for deficiency:** ISCN hired an ICO, Erica Klein, RN. She will be directed by GB in her performance of monitoring activities at the facility. She will serve on GB and QAPI Committee in order to make IC and its activities an integral part of QAPI, with reporting and accountability made quarterly to the GB. At the Special GB Meeting to be held on 10-29-15, GB will conduct Infection Risk Assessment; this assessment of the ICP will be performed annually by the GB. The ICO will be evaluated annually by the GB in performance evaluations. The entire ICP will be evaluated quarterly by GB and changes will be made to the program and its activities as required. QAPI manual was updated by the GB on 10-25-15 to include responsibilities for Infection Control Officer and new Organizational Chart; Infection Manual was updated on 10-25-15 to include changes to sanitary environment and sterilization processes. The GB has considered a goal to pay for Board Certification for the ICO. This goal is to be discussed at upcoming GB meetings and will be decided based on cost and regulatory requirements.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** GB will query (by phone or in writing) the ICO prior to the quarterly meeting in regard to current progress activities. At the quarterly meeting, she will be required to show progress reports containing evidence of data collection and be able to explain the reasons and conclusions for tracking of specific sets of data; the GB will assess the reports and presentation of this data collection, and make recommendations for improvement of processes that will improve patient outcomes and prevent infection. QAPI coordinator will support the ICP and its officer by completing records and preparing the data for reporting; aid in setting goals for outcomes and processes; and attaining thresholds for optimal performance by comparing outcomes with national comparative data. Summaries and reports will be reviewed and decisions regarding further study and analysis will be made by the GB. These reports and supporting data collection will be filed in the QAPI binder for future reference. All proof of evidence and submission of information are filed with the GB minutes.

- **QAPI addresses systems improvement to prevent deficiency recurrence:** GB and QAPI will function collaboratively with the ICP and officer as she monitors dimensions of performance relating to infection control. Some of those are incidence, prevalence, and severity of problem-prone areas; safety to patients who receive care at ISCN; compliance by staff as it relates to their performance in sanitary environment and safe sterilization practices. IC activities and program will be an ongoing part of the QAPI program. QAPI coordinator and the ICO will meet monthly for purposes of accountability and to ensure the effectiveness of the program activities in place. GB will review these recommendations and make changes that will make the ICP more effective in prevention of patient infection. GB will consider changes and add indicators to the Infection Prevention Indicator list as necessary. QAPI committee will ensure that appropriate actions are taken in response to negative analyses when working toward performance improvement as it relates to infection prevention. Upon completion of data collection and analysis, the data will be compiled and reported to the GB. Evidence of these activities will be found in and filed with the GB minutes.

- **Completion dates for correction of deficiency:**
    - 10-24-15: Erica Klein was hired as Infection Control Officer
    - 10-24-15: AORN Ambulatory Infection Course was completed by Dr. Quinton
    - 10-26-15: AORN Ambulatory Infection Course was completed by Erica Klein, RN-ICO
    - 10-25-15: QAPI and Infection manuals were updated
    - 10-29-15: ICO will present data collection for review; future goals for the program; and her plan for monitoring and surveillance activities; first monthly meeting for ICO and QAPI coordinator; Infection Risk Assessment will be performed by GB for ICP

- **Individual responsible for implementing the acceptable PoC with signature and title:**

Charlene Conilogue, Admin.

Q 240

- **Plan of Correction for deficiency:** Governing Body (GB) made a decision to hire an individual whose primary function would be to serve as Infection Control Officer (ICO) and maintain an acceptable Infection Control Program (ICP). She will receive specific and adequate training for her responsibility; Dr. Quinton also desired to secure training in Infection Control (IC). These 2 individuals have been trained in IC. The newly hired officer has dedicated her efforts to maintaining and structuring the ICP to meet the requirements for surveillance and monitoring as is necessary to be an integral part of Quality Assessment and Performance Improvement (QAPI). GB has approved policies that will ensure efficacy of the ICP in relation to processing of instruments, laundry practices, monitoring of wash water temperature, length of instrument soaking in enzymatic solution, and the policy for not maintaining pesticide at Idaho SurgiCenter North (ISCN).

- **Procedure for implementing an acceptable PoC for deficiency:** ISCN hired an ICO, Erica Klein, RN. She will dedicate 80% of her time at the facility to the direction of the ICP, including surveillance of staff and patients, analysis of infection trends, and monitoring activities that will be integral to the QAPI Program. She will serve on GB and QAPI Committee in order to make IC and its activities an integral part of QAPI, with reporting and accountability made quarterly to the GB. At the Special GB Meeting to be held on 10-29-15, **she will present data collection for patient infection surveillance for the year 2014-present** for review; and will present for approval, **the surveillance plan for hand hygiene, safe injection practices, and monitoring methods for instrument processing** that she has put in place for the upcoming quarter. **She will create forms for surveillance that include Implant Follow Up; Post-Operative Surveillance by Surgeon; and 30-Day Phone Call Follow Up for Pt Complications (to be completed by ICO). We will not be mailing surveys for purposes of collecting patient information as it is the least effective way to gather this data.** She will provide infection control training for the facility staff on 10-30-15 on **environmental cleaning.** This training will serve as our quarterly staff training and is relevant for all staff. She will also provide refresher training for the staff annually; and maintain at least quarterly education for her own responsibility. She will use data collection tools to monitor sanitary environment to ensure a functional and sanitary environment for patients and staff as she participates on QAPI, as well as conduct surveillance and monitoring for staff and patients relating to preventing and controlling infections and communicable disease. She has obtained infection prevention training in the principles and methods necessary to direct the ICP (see dates below). QAPI manual was updated on 10-25-15 to include responsibilities for Infection Control Officer. She and Dr. Quinton are registered for the APIC Infection Prevention Academy to be held April 17-24, 2016 in San Diego. The GB has considered a future goal to secure Board Certification for the ICO. This goal is to be discussed at upcoming GB meetings and will be decided based on cost and regulatory requirements.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** The ICO will be given time at each quarterly GB meeting to address concerns and receive direction. GB will query (by phone or in writing) the ICO prior to the quarterly meeting in regard to current activities. At the quarterly meeting, she will be required to show progress reports containing evidence of data collection and be able to explain the reasons and conclusions for tracking of specific sets of data. QAPI coordinator will support the ICP and its officer by recording and preparing the data for reporting, aid in setting goals and thresholds for attainment, and making recommendations for improvement. Summaries and reports will be reviewed and decisions regarding further study and analysis will be made by the GB. These reports and supporting data collection will be filed in the QAPI binder for future reference. All proof of evidence and submission of information will be found in and filed with the GB minutes.

- **QAPI addresses systems improvement to prevent deficiency recurrence:** QAPI will function collaboratively with the ICP and officer as she monitors dimensions of performance relating to infection control. Some of those are incidence, prevalence, and severity of problem-prone areas;

safety to patients who receive care at ISCN; compliance by staff as it relates to their performance in sanitary environment and safe sterilization practices. IC activities and program will be an ongoing part of the QAPI program. QAPI committee will ensure that appropriate actions are taken in response to analyses when working toward performance improvement as it relates to infection prevention. Upon completion of data collection and analysis, the data will be compiled for reporting to the GB and presented. Evidence of these activities will be found in and filed with the GB minutes.

- **Completion dates for correction of deficiency:**
  - 10-24-15: Erica Klein was hired as Infection Control Officer on;
  - 10-24-15: AORN Ambulatory Infection Course was completed by Dr. Quinton
  - 10-26-15: AORN Ambulatory Infection Course was completed by Erica Klein, RN-ICO
  - 10-25-15: QAPI manual was updated to include ICO responsibilities and new Organizational Structure diagram
  - 10-29-15: ICO will present data collection for review; future goals for the program; and her plan for monitoring and surveillance activities
  - 10-30-15: Quarterly staff training by ICO

- **Individual responsible for implementing the acceptable PoC with signature and title:** Charlene Conilogue, Admin.

Q 241 SANITARY ENVIRONMENT

- **Plan of Correction for deficiency:** ISCN hired Erica Klein as ICO to direct the ICP and its activities. She will provide quarterly staff training that is relevant to staff responsibility as it pertains to infection control and sanitary environment. Infection Policy Manual (IPM) has been updated to include the missing specific information relating to enzymatic cleaner and water temperature. Logs have been created and added to recordkeeping books that contain tracking and accountability of staff for this information. Instrument reprocessing training will be provided to staff by the ICO. Laundry policy was updated to reflect changes pertaining to acceptable storage, pickup and delivery services. GB approved these policy changes on 10-23-15 and this will be noted in the 10-30-15 GB minutes.

- **Procedure for implementing an acceptable PoC for deficiency:** Ms. Klein will create and use data collection tools such as logs and surveillance forms to monitor dimensions of performance relating to sanitary environment to ensure a functional and sanitary environment for patients and staff over the next quarter. She will also conduct surveillance and monitoring for staff and patients relating to preventing and controlling infections and communicable disease. IPM was

updated to include the name of the enzymatic cleaner, maximum temp of wash water, length of instrument soaking time in enzymatic solution per the manufacturer instructions. A log page has been added to our Instrument Processing and Sterilization Log Book for recording of this information. The product information is included in our policy manual under "Addendums". IPM has been updated to include instruction that all packaged materials are to be processed immediately after packaging and a log located in the Instrument Processing and Sterilization Log Book is to be completed by the operator performing this task. Laundry Policy will be changed to state that laundry will remain in a bag in a covered receptacle and will remain at the ASC until it is picked up by the service. IPM has also been updated to include specific information prohibiting use and storage of insecticides at ISCN. These policy changes were reviewed and approved by GB on 10-16-15. Staff will be notified of these changes at the next staff training meeting on 10-30-15. Charlene Conilogue received 1 credit hour (3 hours) of training "2015 Best Practices for Instrument Reprocessing" on 10-22-15. The sources for this training material are: AAAHC; AAMI; AORN; CMS; The Joint Commission; and the CDC. She also successfully completed the AORN Infection Prevention Course training on 10-25-15. All personnel who have responsibility for instrument processing and sterilization will receive training from Charlene Conilogue as directed by the ICO.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** Proof of the monthly mandatory staff training for infection control will be maintained in personnel files. Logs and records pertaining to sanitary environment and reprocessing practices will serve as tracking and monitoring devices that can be audited and reviewed for accuracy and correct practices. These audits and reviews will be part of the QAPI and ICP as it pertains to safety, responsibility, and infection control and the surveillance reporting results will presented to GB quarterly. Ms. Klein will present a plan to the GB on 10-30-15 that will **demonstrate tracking methods created for monitoring staff compliance in regard to safe hand hygiene; safe injection practices; and logging information regarding correct practices for instrument processing.**

- **QAPI addresses systems improvement to prevent deficiency recurrence:** QAPI will function collaboratively with the ICP monitoring dimensions of performance relating to IC as it relates to education and compliance by staff and their performance in sanitary environment and safe sterilization practices. All staff will receive training and be required to follow policy for safe practices and infection prevention. Surveillance and monitoring performed by the ICO will be the methods by which compliance and efficacy of training are evaluated. This information will be analyzed and presented to GB at the next regularly scheduled GB Meeting.

- **Completion dates for correction of deficiency:**
    - 10-09-15: Correction of instrument processing practice was made to match our policy. All items packaged for sterilization will be processed the same day.

- 10-10-15: Logs were created to collect the information for water temp and enzymatic parameters mentioned above.
- 10-11-15: An Infra-red thermometer was purchased for monitoring the wash water temperature.
- 10-15-15: A timer was purchased for monitoring the length of the enzymatic soak for instruments.
- 10-16-15: Governing Body approved Manual changes
- 10-22-15: Policy Manuals were updated to show changes
- 10-22-15: Charlene Conilogue was trained on Instrument Reprocessing (SPS Medical)
- 10-25-15: Charlene Conilogue took AORN Program for Infection Prevention training
- 10-29-15: Governing Body Meeting
- 10-30-15: Staff Training by ICO

- **Individual responsible for implementing the acceptable PoC with signature and title:** Charlene Conilogue, Admin.

Q 242 INFECTION CONTROL PROGRAM

- **Plan of Correction for deficiency:** ISCN hired an individual whose main duty and function will be to successfully direct our ICP as its officer. Her goal is to structure the program to include ongoing investigative and monitoring activities for tracking infection prevention indicators and trends, and providing data analysis for the purpose of preventing patient infection and improving facility performance in regard to IC. The program will be an integral part of QAPI and she will be responsible to report findings and outcomes of surveillance activity and analyses to the GB.

- **Procedure for implementing an acceptable PoC for deficiency:** The ICO will direct the ICP as a member of both GB and QAPI to include ongoing investigative and monitoring activities for infection trends and communicable diseases, and analysis of appropriate and relevant data. These activities will include monitoring of staff, patients, and visitors of ISCN. The program will be an integral part of QAPI and findings and outcomes of surveillances will be reported to the GB. She will understand and agree to perform the responsibilities listed in her job description and be evaluated for competency periodically (upon hire, at 30 days, and annually thereafter) by Dr. Quinton based on her sustained efforts for direction of this program. He will also be the person to complete employee performance evaluations after evaluating her effort and management of the Infection Control Program. She will be responsible to initiate training for new hires within 30 days of hire, quarterly training for facility staff, and annual refresher

training. The training will be comprised of material taken from the pool of sources we use for IPM and documentation will be found in employee personnel files and the Inservice Binder. QAPI indicators were found to be lacking IC indicators. Ms Klein has requested that we add the following list of infection prevention indicators to the IPM: Hand Hygiene in the Pt Setting, use of PPE in the Pt Setting; Aseptic Technique; Cleaning and Disinfection of the Environment; Isolation Precautions; Instrument Processing and Sterilization; Laundry Management; Blood Glucose Monitor Surveillance; Post op Follow up for Positive Findings; Safe Injection Practices; and Immunization and Exposure Management. These changes were approved by Governing Body and added to the QAPI Manual on 10-25-15. Evidence of this action is found in the 10-30-15 GB minutes.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** Charlene Conilogue and Erica Klein audited the surveillance portion of the IPM using the assessment tool found in the NHSN manual. Missing pieces will be presented to the GB on 10-29-15 and added. Evidence of this approval is found in the GB minutes dated 10-30-15. Charlene Conilogue and Erica Klein will use this tool annually to update surveillance policy as necessary. Credential Officer (Charlene Conilogue) will maintain personnel files that contain documentation of quarterly and annual staff training on IC conducted by the ICO as well as training for her own education. Training activities for staff and the ICO will be reported to the GB quarterly. The ICO will work together to investigate, gather, analyze, and compile data pertaining to infection prevention indicators for review by the GB quarterly. She will create forms for surveillance that include Implant Follow Up; IC Report by Surgeon of Post Op Patient; and 30-Day Phone Call Follow Up for Pt Complications done by the ICO. That information will be added to future data collection to facilitate effective tracking of infection trends. The Medical Director, who has received Infection Prevention Training, will provide competency training and evaluation for the ICO based on her sustained efforts to maintain an effective program for the ICP upon hire, at 30 days, and annually thereafter. These competencies and performance evaluations will be documented in the ICO's personnel file. GB and Dr. Quinton will maintain responsibility for the implementation and success of the ICP by addressing IC quarterly and supporting the ICO in her ongoing responsibility. ISCN will provide funds for the ICO to secure adequate annual training pertaining to her job.

- **QAPI addresses systems improvement to prevent deficiency recurrence:** The ICO is a member of the QAPI committee and as such will work with the QAPI coordinator to investigate, gather, analyze, and compile data pertaining to infection prevention indicators for review by the GB quarterly. This information will be analyzed and plotted in adopted report format by the QAPI coordinator in order to establish effective tracking of infection prevention indicators and the need for ongoing monitoring of these indicators. That information will be added to future data collection to facilitate effective tracking of infection prevention indicators. QAPI coordinator and the ICO will meet at least monthly to exchange information, evaluate goals of the ICP, and evaluate implemented practices for tracking and surveillance. This information will be presented

at GB at the regularly scheduled meeting each quarter. Minutes for these monthly meetings will be filed in the minute's binder.

- **Completion dates for correction of deficiency:**
  - 10-16-15: ISCN hired an individual for the primary purpose of maintaining an Infection Control Program
  - 10-25-15: at the ICO's request, infection prevention indicators were added to the IPM
  - 10-26-15: audit of surveillance portion of ICP was conducted by Charlene Conilogue
  - 10-28-15: ICO and QAPI coordinator will build forms appropriate for data collection
  - 10-29-15: ICO will present data collection for study review; set future goals for the program; present plan for monitoring and surveillance activities; receive direction from GB
  - 10-30-15: Quarterly staff training by Infection Control Officer

- **Individual responsible for implementing the acceptable PoC with signature and title: Charlene Conilogue; Admin**

Q 243 INFECTION CONTROL PROGRAM DIRECTION

- **Plan of Correction for deficiency:** ISCN hired an ICO whose main objective will be to successfully direct our ICP. She will dedicate 80% of her time at ISCN to the direction the ICP. Her goal is to structure the program to include ongoing investigative and monitoring activities for tracking infection trends and communicable diseases, and analysis of the data. The program will be an integral part of QAPI and is accountable to report findings and outcomes of surveillances to the GB as a member of the QAPI Committee. She will actively direct the ICP, being present in the facility to conduct monitoring activities and a visible member of the GB.

- **Procedure for implementing an acceptable PoC for deficiency:**
  She has obtained training in the principles and methods necessary to direct the ICP; understands the methodology for IC. She completed the AORN Infection Prevention Course on 10-26-15 and is registered for the APIC Infection Prevention Academy courses to be held April 17-24, 2016 in San Diego. Both she and Dr. Quinton will attend these courses. ISCN will continue to provide opportunities and funding for education for the ICO. The Medical Director who has received the same training will provide competency evaluation for the ICO based on her sustained efforts to maintain an effective program for the ICP upon hire, at 30 days, and annually thereafter. These competencies and performance evaluations will be found in the ICO's personnel file. Laminated reminders that explain IC surveillance and explain the role of the ICO and have been posted at the facility to increase staff awareness and emphasize the priority of the ICP. Staff training on Environmental Cleaning will take place this week and other staff IC education will take place quarterly.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** Charlene Conilogue and Erica Klein will use the NHSN assessment tool annually to update surveillance policy as necessary and make changes that will enhance the efficacy of the ICP. Credentials Officer (Charlene Conilogue) will maintain personnel files that contain evidence of quarterly and annual staff training on IC conducted by the ICO. Training activities for staff and the ICO will be reported to the GB quarterly. The Medical Director, who has received Infection Prevention Training, will provide the competency evaluation for the ICO based on her sustained efforts to maintain an effective program for IC upon hire, at 30 days, and annually thereafter. These competencies and performance evaluations will be documented in the ICO's personnel file. ISCN will provide compensation for the ICO to secure adequate annual training pertaining to her job.

- **QAPI addresses systems improvement to prevent deficiency recurrence:** Charlene Conilogue and Erica Klein will use the NHSN assessment tool annually to update surveillance policy as necessary and make changes that will enhance the efficacy of the ICP. The ICO will work to investigate, gather, analyze, and compile data pertaining to infection prevention indicators for review by the GB quarterly. This information will be reported to the QAPI coordinator, be analyzed and plotted in adopted study format in order to establish effective tracking of infection prevention indicators. That information will be added to future data collection to facilitate effective tracking of infection trends discovery of problem areas that require ongoing evaluation. GB will maintain responsibility for the implementation and success of the ICP by addressing IC quarterly and supporting the ICO in her responsibility.

- **Completion dates for correction of deficiency:**
  - 10-23-15: Erica Klein was hired to fill the role of Infection Control Officer
  - 10-26-15: ICO completed the AORN Infection Prevention Course
  - 10-27, 29-15: ICO and QAPI coordinator set goals for the Infection Control Program; these will be presented at GB on 10-30-15
  - 10-29-15: ICO and QAPI coordinator met to compose logs and tracking tools and for the surveillance to be conducted during the upcoming quarter
  - 10-29-15: Governing Body Meeting; the ICO presented goals and surveillance plans for tracking infection prevention indicators to the GB
  - 10-30-15: Staff training on Infection Control (Environmental Cleaning)

- **Individual responsible for implementing the acceptable PoC with signature and title: Charlene Conilogue; Admin.**

Q 244 INFECTION CONTROL PROGRAM – QAPI

- **Plan of Correction for deficiency:** ISCN hired an ICO direct our ICP. She will dedicate 80% of her time at ISCN to the direction the ICP. Her goal is to structure the program to include ongoing investigative and monitoring activities for tracking infection trends and communicable diseases, and analysis of the data. She will be on the QAPI committee and as such, the ICP will be an integral part of QAPI. She will actively direct the ICP, being present in the facility to conduct monitoring activities and a visible member of the GB. The QAPI coordinator and the ICO will work closely together to accomplish the goal of surveillance and monitoring in order to ensure a safe environment for patients and staff.

- **Procedure for implementing an acceptable PoC for deficiency:** The ICO will be on the QAPI committee, thus making the ICP an integral part of QAPI. She will direct the ICP, conduct facility monitoring activities, and be a visible member of the GB. The QAPI coordinator and the ICO will work closely together to accomplish the goal of surveillance and monitoring to establish and sustain a safe environment for patients and staff. She will receive appropriate training annually for her responsibility as ICO. She will conduct staff IC training quarterly and participate in all GB activities. She will prepare statistical reports and bring her findings to the quarterly GB meeting for review of ongoing monitoring and tracking of activities that trends that would prevent patient infection and increase safe practices for staff.

- **Monitoring and Tracking procedures to ensure plan's effectiveness and continued compliance:** QAPI coordinator will perform quality monitoring of the efficacy of the restructured ICP. This will be accomplished by evaluating the quality and quantity of data presented by the ICO at quarterly GB. Results of this monitoring activity will be presented to GB at a regularly scheduled meeting and plotted by phases for review to determine the need of ongoing surveillance. These findings will be found in the study binder at the facility. GB will hold the ICO accountable through compensation and discipline, for success of the ICP.

- **QAPI addresses systems improvement to prevent deficiency recurrence:** Charlene Conilogue and Erica Klein will use the NHSN assessment tool annually to update surveillance policy as necessary and make changes that will enhance the efficacy of the ICP. The ICO will work to investigate, gather, analyze, and compile data pertaining to infection prevention indicators for review by the GB quarterly. This information will be reported to the QAPI coordinator, be analyzed and plotted in adopted study format in order to establish effective tracking of infection prevention indicators. That information will be added to future data collection to ensure effective tracking of infection trends and discovery of problem-prone areas that require ongoing evaluation. QAPI coordinator will perform quality monitor the efficacy of the restructured ICP. Results of this monitoring will be presented to GB at a regularly scheduled meeting and plotted by phases for review to determine the need for ongoing surveillance.

- **Completion dates for correction of deficiency:**
    - 10-23-15: Erica Klein was hired to fill the role of Infection Control Officer
    - 10-26-15: ICO completed the AORN Infection Prevention Course
    - 10-27, 29-15: ICO and QAPI coordinator set goals for the Infection Control Program; these will be presented at GB on 10-30-15
    - 10-29-15: ICO and QAPI coordinator met to compose logs and tracking tools and for the surveillance to be conducted during the upcoming quarter
    - 10-29-15: Governing Body Meeting; the ICO presented goals and surveillance plans for tracking infection prevention indicators to the GB

- **Individual responsible for implementing the acceptable PoC with signature and title:** Charlene Conilogue; Admin