

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001156	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/02/2012
NAME OF PROVIDER OR SUPPLIER INDIANA SKIN CANCER AMBULATORY SURGICAL CENTER LL			STREET ADDRESS, CITY, STATE, ZIP CODE 701 E COUNTY LINE RD STE 208 GREENWOOD, IN 46143		
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 005648</p> <p>Survey Date: 10/1/2012 through 10/2/2012</p> <p>Surveyors: Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>Albert Daeger Medical Surveyor</p> <p>QA: claughlin 10/30/12</p>	S0000			

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

TITLE

(X6) DATE

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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S0012	<p>410 IAC 15-2.2-1 COMPLIANCE WITH RULES 410 IAC 15-2.2-1 (b)</p> <p>(b) Components required for licensure as a center are the following:</p> <p>(1) Governing body. (2) Quality assessment and improvement. (3) Infection control program. (4) Laboratory services. (5) Medical records, storage, and administration. (6) Medical staff, anesthesia, and surgical services. (7) Patient care services. (8) Pharmaceutical services. (9) Physical plant, equipment maintenance, and environmental services. (10) Radiology services.</p> <p>Based on document review and staff interview, the facility failed to ensure Radiology Services were either provided under arrangements or conducted internally.</p> <p>Findings included:</p> <p>1. Indiana Skin Cancer ASC Radiology Services policy, last reviewed 7/9/2010, states "Radiology Services are not utilized in the Indiana Skin Cancer ASC."</p>	S0012	<p>S012 1. An agreement with the St. Francis radiology department has been drafted for the Indiana Skin Cancer Center. This agreement has been recieved from St. Francis and approved by the board of the Indiana Skin Cancer Center. 2. This deficiency will be prevented by the implementation of the above mentioned agreement. Our radiology agreement will be monitored in the future by inclusion of a section in our quarterly QA minutes looking at radiology services. 3. Dr. Murphy is responsible for the correction of this deficiency.4. This deficiency will be corrected by Nov 28th, 2012</p>	11/28/2012			

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	<p>2. Indiana Skin Cancer ASC Laboratory & Radiology Follow Up policy, last reviewed 7/9/2010, states, "For imaging studies requiring prior authorizations (ie CT, PET scan, MRI), the patient will be given a radiology order to take with them and will be asked to schedule their appointment at the radiology center of their choice."</p> <p>3. At 12:14 PM on 10/1/1012, staff member #1 confirmed Radiology Services was a requirement for a state licensure and the facility does not provide that service.</p> <p>4. The Indiana Skin Cancer ASC list of support Services: Contracted Services did not list Radiology Services being provided by any outside contracted provider.</p>				

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S0176	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on policy review, employee training file review, and interview, the facility failed to provide documentation of training in the proper mixing of the facility's anesthetic solution for 3 of 3 registered nurses (RNs) who performed this function (#6, 7, and 11).</p> <p>Findings included:</p> <p>1. The facility policy "Medication Administration", last reviewed 07/09/10, indicated, "...B. Administration: 1. All medications must be prepared and administered according to established policies."</p> <p>2. The facility policy regarding anesthesia, last reviewed 07/09/10, indicated, "...Administration of Anesthesia, Anesthesia will be administered by a qualified physician or by trained personnel under the direct</p>	S0176	S1761. This deficiency will be corrected by updating the training records for all involved personnel to accurately and completely reflect what training has been performed including competency in mixing the anesthetic solution. 2. This deficiency will be prevented in the future by adding the complete description of training for local anesthesia including mixing to the annual training records and competency assessment. 3. Dr. Murphy is responsible for the correction of this deficiency. 4. This deficiency will be corrected by Nov 15th, 2012	11/15/2012			

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	<p>supervision of a physician. Drawing Up of Syringes, R.N. or Surgical Assistant: Multiple syringes are drawn up from multiple dose vials. 5ml (milliliters) of 8.4% sodium bicarbonate and 0.15 ml of clindamycin (300mg [milligrams]/ml) is injected into the 50 ml multidose vial of 1% epi. lidocaine hydrochloride. Syringes are filled from the vials through an 18-gauge needle that is left in place to prevent re-entry. Each syringe is labeled by means of the date and staff member's signature. No syringe is kept for more than one week to maintain optimal epinephrine effect, as per pharmaceutical advice. ...Administration/Monitoring Local Anesthesia Patients, In preparation for surgery the following trained personnel may give local anesthesia per standing order by [physician #1]: other credentialed physicians, RNs and MAs (Medical Assistants) trained in the administration of local anesthesia."</p> <p>3. Review of the training file for staff member #6, a registered nurse, indicated annual competency from 08/20/12, which documented, "...IX. Local Anesthetic, Demonstrates knowledge in proper administration and dosing of local anesthetic." The record lacked any documentation of competency in mixing the anesthetic solution.</p>			

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	<p>4. Review of the training file for staff member #7, a registered nurse, indicated annual competency from 09/04/12, which documented, "...IX. Local Anesthetic, Demonstrates knowledge in proper administration and dosing of local anesthetic." The record lacked any documentation of competency in mixing the anesthetic solution.</p> <p>5. Review of the training file for staff member #11, a registered nurse, indicated annual competency from 08/31/12, which documented, "...IX. Local Anesthetic, Demonstrates knowledge in proper administration and dosing of local anesthetic." The record lacked any documentation of competency in mixing the anesthetic solution.</p> <p>6. Review of the training file for staff member #2, the Clinical Practice Manager, indicated annual competency from 08/31/12 for the same knowledge of administration of the anesthetic, but also, "Demonstrates knowledge in proper mixing of local anesthetic." This staff member's file was the only one that contained documentation of competency in mixing the anesthetic solution.</p> <p>7. At 2:25 PM on 10/02/12, staff member #1 indicated the registered nurses were all trained to mix the solution, prepare the</p>						

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	syringes, and administer the anesthetic, but the MAs could draw up the syringes and administer the anesthetic, but could not mix the solution. Both staff members #1 and #2 confirmed the discrepancies with the training records.			

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S0446	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(x)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(x) A program of linen management.</p> <p>Based on observation, document review, and staff interview, the facility failed to ensure impermeable gowns are worn over the employees scrubs during a surgical procedure as stated per policy and failed to ensure surgical attire and scrubs were being monitored for proper washing and drying per CDC guidelines.</p> <p>Findings included:</p> <p>1. At 11:05 AM on 10/1/2012, a surgical procedure was observed in the Procedure Room (Operating Room). Patient N26 was having a surgical procedure performed on his/her left ankle area. The</p>	S0446	<p>S 446 1. This deficiency will be corrected by having all scrubs professionally laundered in compliance with CDC guidelines for Laundry in Health Care Facilities by a laundry service. Employees will change into laundered scrubs in the facility and leave them there for laundering at the end of the work day. 2. This deficiency will be prevented in the future by ongoing use of a professional laundry service for all employees wearing scrubs. This will be monitored in the future by inclusion in our QA minutes a section on the proper use and laundering of scrubs in our facility. 3. Dr. Murphy is responsible for the correction of this deficiency 4. This deficiency will be correctly by Nov 28th, 2012.</p>	11/28/2012			

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	<p>procedure was being performed by staff member #1 and assisted by staff member #2. The staff members were wearing gloves and masks when performing the procedure; however, the two staff members wore their scrubs that they were wearing all day and did not use cover gowns over the scrubs.</p> <p>2. The Indiana Skin Cancer ASC Procedure Room Attire, last reviewed 7/9/2010, states, "Procedure room attire is to provide effective barriers that prevent transmission of microorganisms to the patient, to protect personnel from infected patients, and prohibit contamination. Procedure room attire consists of impermeable gown, gloves (non sterile), protective eye wear, face shield and/or mask."</p> <p>3. At 12:30 PM on 10/1/2012, staff member #2 confirmed cover gowns were not worn over their scrubs during the ankle procedure on</p>			

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	<p>patient N26.</p> <p>4. CDC 2003 Guidelines for Environmental Infection Control in Health Care Facilities states, " Laundry in a health-care facility may include bed sheets and blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes for surgical procedures. Use of current control measures should be continued to minimize the contribution of contaminated laundry to the incidence of health-care-associated infections. The control measures described in this section of the guideline are based on principles of hygiene, common sense, and consensus guidance; they pertain to laundry services utilized by health-care facilities, either in-house or contract, rather than to laundry done in the home. The purpose of the laundry portion of the standard is to protect the worker from exposure to potentially infectious materials during collection,</p>			

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	<p>handling, and sorting of contaminated textiles through the use of personal protective equipment, proper work practices, containment, labeling, hazard communication, and ergonomics. Home laundering would be expected to remove this level of soil adequately. However, if health-care facilities require the use of uniforms, they should either make provisions to launder them or provide information to the employee regarding infection control and cleaning guidelines for the item based on the tasks being performed at the facility. "</p> <p>5. CDC 2003 Guidelines for Laundry in Health Care Facilities states, "Hot water provides an effective means of destroying microorganisms, and a temperature of at least 71 C (160 F) for a minimum of 25 minutes is commonly recommended for hot-water washing. Chlorine bleach provides an extra margin of safety. A total available chlorine residual</p>			

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	<p>of 50-150 ppm is usually achieved during the bleach cycle. The last action performed during the washing process is the addition of a mild acid to neutralize any alkalinity in the water supply, soap, or detergent. The rapid shift in Ph from approximately 12 to 5 also may tend to inactivate some microorganisms. Recent studies have shown that a satisfactory reduction of microbial contamination can be achieved at lower water temperatures of 22-50 C when the cycling of the washer, the wash formula, and the amount of chlorine bleach are carefully monitored and controlled."</p> <p>6. At 2:15 PM on 10/1/2012, staff member #2 indicated there were a few extra scrubs in the locker room on a shelf, but most of them were in the employee's lockers. The staff member indicated the scrubs were issued to the staff by the facility, but the individual employees laundered them at home. The staff member indicated the employees</p>				

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	<p>can wear their scrubs in from home and return home in them, they do not have to change at the facility. The staff member indicated the facility has a laundry service but they only launders the patient's gowns.</p> <p>7. At 1:00 PM on 10/2/2012, staff member #2 indicated he/she could not assure the employee's scrubs that are being washed at their homes are meeting the CDC guidelines for Laundry in Health Care Facilities. The staff member confirms he/she does not monitor the washing and drying of the scrubs that he/she does.</p>			

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S0908	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)(3)</p> <p>(a) Patient care services must require the following:</p> <p>(3) That a registered nurse serves as head nurse supervising patient care services personnel.</p> <p>Based on job description review and interview, the facility failed to designate a registered nurse to supervise patient care services personnel.</p> <p>Findings included:</p> <p>1. Review of the facility's job description for the registered nurse indicated, "Organizational Relationship: Employee is directly responsible to the Practice Manager for all medical policies and procedures in this practice."</p> <p>2. At 3:15 PM on 10/02/12, the Clinical Practice Manager, staff member #2, indicated he/she was responsible for the nursing staff and other direct care givers. He/she indicated he/she was a board certified physician, but was employed as the manager and not credentialed as a physician. He/she confirmed a registered nurse did not supervise the patient care services personnel.</p>	S0908	S9081. This deficiency will be corrected by appointing Kim Taylor RN as our supervisor of nursing services.2. This deficiency will be prevented in the future by continuing to have an RN in a supervisory position in our ASC. 3. Dr. Murphy is repsonsible for the correction of this deficiency4. This deficiency will be corrected by 11.28.2012	11/28/2012			

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S1010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on observation, policy review, and interview, the facility failed to ensure policies were consistent and addressed labeling and storage of syringes of anesthetic solution and failed to ensure the syringes were labeled appropriately.</p> <p>Findings included:</p> <p>1. During the tour of the facility, beginning at 2:00 PM on 10/01/12 and accompanied by staff member #2, the following observations were made:</p> <p>A. Eight syringes containing a clear solution, labeled "LEC 9/28/12 KT", in a drawer of the cart in exam room #1.</p> <p>B. Approximately 80 syringes containing a clear solution, labeled "LEC 9/28/12 KT", in the locked medication cabinet in the nurses' station.</p> <p>C. Four syringes containing a clear solution, labeled "LEC 9/28/12 KT", in a</p>	S1010	<p>S1010 1. This deficiency was addressed in several ways. First, the manufacturer of the lidocaine, clindamycin and sodium bicarbonate was contacted to recheck on the safety and efficacy of said medications once drawn up into a sterile syringe. The manufacturer of these drugs is Hospira in Lake Forest IL. This was discussed with Hospira's medical staff and we were given the following information: For lidocaine, this medication can be safely stored in sterile syringes with no loss of efficacy for 90 days. The reference for this information was given from the Hospira medical staff as Lawrence Trissel's "Handbook of Injectable Drugs" page 949. We also contacted Hospira about the injectable clindamycin which we use. The only information available from their references was that injectable clindamycin retains</p>	11/01/2012	

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	<p>drawer of the cart in the procedure room.</p> <p>2. The facility policy regarding anesthesia, last reviewed 07/09/10, indicated, "...Administration of Anesthesia, Anesthesia will be administered by a qualified physician or by trained personnel under the direct supervision of a physician. Drawing Up of Syringes, R.N. or Surgical Assistant: Multiple syringes are drawn up from multiple dose vials. 5ml (milliliters) of 8.4% sodium bicarbonate and 0.15 ml of clindamycin (300mg [milligrams]/ml) is injected into the 50 ml multidose vial of 1% epi. lidocaine hydrochloride. Syringes are filled from the vials through an 18-gauge needle that is left in place to prevent re-entry. Each syringe is labeled by means of the date and staff member's signature. No syringe is kept for more than one week to maintain optimal epinephrine effect, as per pharmaceutical advice."</p> <p>The policy lacked documentation of how to store the prepared syringes according to any manufacturer's directions.</p> <p>3. The facility policy "Injection Safety Policies", last reviewed 07/09/10, indicated, "...Medications that are pre-drawn are labeled with the time of draw, medication name and strength, and</p>		<p>95% efficacy after 48hours of being drawn into a syringe. Once again the source for this information was Trissel's "Handbook of Injectable Drugs" page 396. Clindamycin is added to our local anesthesia as an extra precautionary measure to keep our infection rate as low as possible. <i>It is not necessary to use it but is done for the extra safety of our patients.</i> A very complete article on the use of intra-incisional clindamycin was provided to the survey team at the time of inspection. (Griego, Zitelli et all as authors). This article showed definitively that intra-incisional clindamycin lowers the rate of post operative infection after Mohs surgery and can be stored in syringes for 7 days. We feel it is one of the many reasons the infection rate at our facility is considerably and consistently below traditional infection rates in similar surgical practices. Finally, the manufacturer of sodium bicarbonate (also Hospira) was once again contacted for information on the safety and efficacy of storage of this medication. According to the "Handbook of Injectable Drugs" page 1389 this medication can be safely stored in a syringe for 7 to 30 days at room temperature.</p> <p>Having contacted and reviewed the information from the direct source of these medications, our current practice of discarding our local anesthetic</p>				

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	<p>the expiration date (one week after draw for lidocaine)."</p> <p>4. The facility policy "Medication Control & Accountability", last reviewed 07/09/10, indicated, "...C. Labeling: 1. Drugs and biologicals are labeled with name, strength, quantity, expiration date, and appropriate accessory or cautionary information. ...3. Medication drawn into a syringe must be labeled and dated and shall be destroyed at the end of each working day."</p> <p>5. During the tour of the facility, beginning at 2:00 PM on 10/01/12, staff member #2 indicated the labeling on the predrawn syringes indicated they contained lidocaine with epinephrine plus clindamycin and were drawn up on 9/28/12 by the nurse whose initials were on the syringe. He/she indicated the syringes were used for 7 days after that date, then discarded if not used. He/she also indicated the syringes were stored protected from light.</p> <p>6. At 2:00 PM on 10/02/12, staff members #1 and #2 acknowledged the inconsistencies with the medication policies and lack of manufacturer storage information regarding the anesthesia mixture.</p>		<p>syringes after 7 days of being drawn is consistent with manufacturers directions. Second, at the inspectors request the labeling of the syringes have been changed. A clear label in now affixed to every syringe drawn including the time and date of draw, the medication name and strength, the initials of the individual who prepared the anesthetic, and the expiration date. 2. This deficiency will be prevented in the future by clarification of our medication policies. Our policies have been changed to match the practices we have adopted. We have revised our medication practices to be in accordance with manufacturer's guidelines. This will be monitored in an ongoing and daily fashion by all nursing staff to make sure that our medication practice policies are followed. 3. Dr. Michael Murphy is responsible for this change. 4. This deficiency has been corrected as of Nov 1st 2012</p>				

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S1164	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(i)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review, the facility failed to weekly sharpen and conduct monthly preventive maintenance on the Leica SP9000 Histology equipment.</p> <p>Findings included:</p> <p>1. The Cryostat/Shandon Linstain Stainer/Leica SP9000 Sharpener form specifies the knives are to be</p>	S1164	<p>S1164</p> <p>1. This deficiency will be addressed by correctly updating our preventative maintenance logs. The SP9000 sharpener and the cryostat knives were both maintained during the period in question but some of the logs were incomplete. These have been correctly updated.</p> <p>2. This deficiency will be prevented in the future by adding the review of the lab maintenance logs to the quarterly ASC meeting agenda.</p> <p>3. Dr. Michael Murphy is responsible for this change</p>	11/15/2012

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	<p>sharpen weekly and knife sharpener maintenance should be conducted monthly.</p> <p>2. The Cryostat/Shandon Linistain Stainer/Leica SP9000 Sharpener forms for the month of January 2012 through September 2012 were reviewed. January 2012 log revealed the knife sharpener maintenance was not performed during the month. The June 2012 log revealed the knife sharpener maintenance was not performed during the month. The July 2012 log revealed the knives were not sharpened for the 4 weeks of the month and the knife sharpener maintenance was not performed during the month.</p>		4. This deficiency as been corrected as of Nov 1st, 2012.	

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S1198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based on document review, the facility failed to coordinate their annual Disaster Preparedness Drill with appropriate community, state, and federal agencies.</p> <p>Findings included:</p> <p>The 6/24/2011 ISCC ASC Disaster Preparedness Drill was reviewed. The simulated situation was a Bomb/Explosion. The five questions identified on the form were: What action was taken?; Were all staff of ISCC notified? ; Where patients properly triaged by a trained medical professional?; Were all staff prepared for their roles in an emergency?; and What problems/issues arose?. The</p>	S1198	<p>S11981. This deficiency will be addressed by adding to the Disaster Preparedness Drill Form a line about how appropriate community, state or federal agencies were notified. 2. This deficiency will be prevented in the future by updating the form in question and using the updated form going forward.3. Dr. Michael Murphy is responsible for this change4. This deficiency will be corrected by Nov 15h, 2012.</p>	11/15/2012			

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	criteria listed on the forms did not identify how appropriate community, state, and/or federal agencies were notified. The 6/28/2012 Disaster Preparedness Drill documentation was reviewed for a natural incident (tornado). This form also did not identify how the appropriate community, state, and/or federal agencies were notified.				