

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150175	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/04/2013
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NAME OF PROVIDER OR SUPPLIER THE HEART HOSPITAL AT DEACONESS GATEWAY LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 4007 GATEWAY BLVD NEWBURGH, IN 47630
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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
S000000	<p>This visit was for a State hospital licensure survey.</p> <p>Dates: 06/03-04/13</p> <p>Facility Number: 011772</p> <p>Surveyors: Carol Laughlin, RN Public Health Nurse Surveyor</p> <p>Jennifer Hembree, RN Public Health Nurse Surveyor</p> <p>Ken Ziegler, MT Medical Surveyor</p> <p>QA: cloughlin 06/11/13</p>	S000000		

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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S000592	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(i)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following:</p> <p>(D) 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>(i) Sanitation. Based on observation, interview and document review, the infection control committee failed to ensure adherence to facility policy for cleaning the Operating Rooms (ORs) and procedure rooms for 2 of 3 rooms observed and failed to ensure cleaning supplies were stored according to policy for 1 soiled utility room toured.</p> <p>Findings include:</p> <p>1. During tour of the surgery and cath lab department beginning at 11:20 a.m. on 6/4/13 and accompanied by staff members #1, 2 and 16, it could not be determined that the rooms had been appropriately cleaned by the following observations: (A) Cath lab room #4 was cleaned, had clean linens applied and was ready for</p>	S000592	<p>Correction Plan: P&P CVL-8 Cleaning Guidelines for the Cardiovascular Lab (CVL) has been revised to add the following to section II.A.1 "All trash and used supplies from the previous case will be removed from the room." In addition, Section II.A.5 was added and states "The exterior surface of the anesthesia machine and monitoring equipment is wiped down at the end of each case." Recurrence Prevention: Staff is responsible for ensuring the rooms are cleaned and ready for the next case. Should this recur, an incident will be documented in the Midas incident reporting system and the employee(s) counseled. Responsible Person(s): Nursing Manager and CVL Team Lead. All reports to be submitted to</p>	06/28/2013			

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	<p>use. A crumpled surgical mask was observed on top of the anesthesia machine work surface.</p> <p>(B) OR #2 was cleaned, had clean linens applied and was ready for use. Two (2) opened and partially used vials of medication were observed on top of the anesthesia cart.</p> <p>2. The following items were observed stored in the soiled utility room:</p> <p>(A) A mop with a dry mop head leaning against the counter adjacent to the sink.</p> <p>(B) A large barrel of clean mop heads with no lid sitting beside the sink area.</p> <p>(C) Liners used for linens and trash within the surgery and cath lab rooms were stored on top of the counter.</p> <p>(D) Containers of cleaning solutions used for environmental cleaning of the surgery and cath lab rooms was observed in the room as well.</p> <p>3. Staff member #2 indicated the following during tour:</p> <p>(A) Staff member #2 indicated during tour that OR #2 had not been used on 6/4/13.</p> <p>(B) The cleaning supplies were being stored in the soiled utility room at this time due to construction in the area.</p> <p>4. Facility policy titled "ENVIRONMENTAL SANITATION"</p>		<p>Executive Director/CNO Completion Date: P&P revision completed June 19, 2013. Employee training on the P&P CVL – 8 to be completed by June 28, 2013 Correction Plan: Per the Surgery P&P Manual F-13 Environmental Sanitation, section A. Cleaning prior to the first procedure of the day, the room was re-cleaned on June 4, 2013. This policy also states that "Prior to any procedure, the operating room should be visually inspected for total cleanliness by the scrub and circulating person before the case cart, supplies and equipment are brought into the room. " Surgery personnel had inspected OR#2 first thing in the morning and were unaware the anesthesiologist had been in the room. Staff would have seen this prior to the start of a case. Removed the meds left on the anesthesiologist cart, placed an incident in Midas and re-cleaned the room. The issue was discussed with the Director of Anesthesiology and the responsible physician. Recurrence Prevention: Should the incident recur the incident reporting process will be followed. Responsible Person(s): DHS Surgery Managers, Team Leads and Staff. All reports to be submitted to Executive Director/CNO Completion Date: June 4, 2013 Correction Plan: The mop, clean mop heads,</p>		

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	<p>last reviewed/ revised 2/12 states ON PAGE 2: "CLEANING BETWEEN CASES" and page 3: "12. Horizontal surfaces of furniture and equipment that have been involved in the procedure are cleaned with a hospital-grade disinfectant.....17. Ready operating room for next case by: a. Place clean linen on OR table and armboards."</p> <p>5. Facility policy titled "High Risk Area Cleaning" last reviewed/ revised 5/11 states on page 2 under Cardiovascular Laboratory: "2. After each case:Dispose of trash...." Page 2 states under Operating Rooms...."3. All needed equipment, materials, and supplies are located in the two custodial closets."</p>		<p>liners and cleaning solutions were moved to the Cath Lab custodial closet. P&P CVL-8 Cleaning Guidelines for the Cardiovascular Lab was revised. Section II. F was added and states, "Cleaning supplies will be kept in the clean custodial closet." Recurrence Prevention: If the policy is not followed an incident will be noted in the Midas system and the employee counseled.</p> <p>Responsible Person(s): Nursing Manager and Team Lead Any violations will be reported to the Executive Director/CNO Completion Date: June 5, 2013 Correction Plan: Staff member #2 confirmed that OR#2 had not been used on 6/4/2013 from the surgery staff. The surgery staff was unaware the anesthesiologist had left 2 vials of medication on his cart. Per F-13 Environmental Sanitation of the Surgery P&P Manual, section C.12 and C. 17, the horizontal surface and equipment were re-cleaned with a hospital-grade disinfectant to ready the room for the next scheduled case. Recurrence Prevention: Should this recur an incident will be noted in Midas, staff re-educated and the room re-cleaned prior to use.</p> <p>Responsible Person(s): Surgery Manager and Team Lead - All reports will be submitted to Executive Director/CNO Completion Date: June 4, 2013 Correction Plan:</p>	

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			<p>The mop, clean mop heads, liners and cleaning solutions were moved to the Cath Lab custodial closet. P&P CVL-8 Cleaning Guidelines for the Cardiovascular Lab was revised. Section II. F was added and states, "Cleaning supplies will be kept in the custodial closet." Recurrence Prevention: If the policy is not followed an incident will be noted in the Midas system and the employee counseled.</p> <p>Responsible Person(s): Nursing Manager and Team Lead</p> <p>Completion Date: June 5, 2013 Correction Plan: Staff member #2 confirmed that OR#2 had not been used on 6/4/2013 from the surgery staff. The surgery staff was unaware the anesthesiologist had left 2 vials of medication on his cart. Per F-13 Environmental Sanitation of the Surgery P&P Manual, section C.12 and C. 17, the horizontal surface and equipment were re-cleaned with a hospital-grade disinfectant prior to ready the room for the next scheduled case. Recurrence Prevention: Should this recur an incident will be noted in Midas, the physician will be counseled, staff re-educated and the room re-cleaned prior to use. Surgery Manager and Team Lead will audit the area monthly and submit a report to the MEC for ongoing review. Responsible Person(s): Surgery Manager and Team Lead All reports to be submitted to</p>	

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			<p>Executive Director/CNO Completion Date: June 4, 2013 The correction plan is twofold. Correction Plan: The Environmental Services Manager has developed a clean room log to be posted on the doors of the cath labs, EP lab and 2 OR rooms that require the person cleaning the room to document the date, time and their initials. Staff preparing to use the room will immediately know the last time the room was terminally cleaned and if 24 hours has past necessitating the room to be cleaned prior to use. Recurrence Prevention: Staff will be educated on the posted clean room log. Logs will be turned in to the Environmental Services Manager at the end of the month. Surgery Manager and Team Lead will audit the area monthly and submit a report to the MEC for ongoing review. Responsible Person(s): Environmental Services Manager and CVL Nursing Manager & Team Lead - Any reports will be reported to the Executive Director/CNO Completion Date: June 24, 2013 B. Correction Plan: The mop, clean mop heads, liners and cleaning solutions were moved to the Cath Lab custodial closet. The P&P CVL-8 Cleaning Guidelines for the Cardiovascular Lab was revised. Section II. F was added and states, "Cleaning supplies will be kept in the clean custodial</p>		

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			closet." Recurrence Prevention: Staff will be educated on the revised policy to prevent recurrence. Responsible Person(s): Nursing Manager and Team Lead - All reports to be submitted to Executive Director/CNO Completion Date: Supplies were moved to the custodial closet and education completed on June 5, 2013.		

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S000608	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(ix)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (D) 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>(ix) Requirements for personal hygiene and attire appropriate for work settings.</p> <p>Based on observation, interview and document review, the facility failed to ensure staff members adhered to appropriate dress code per policy and standard of practice for the surgery area as well as the cath lab area and failed to include recognized standards of practice within the policy for the dress code in the cath lab area.</p> <p>Findings include:</p> <p>1. During tour of the surgery and cath lab area beginning at 11:20 a.m. on 6/4/13 and accompanied by staff members #1, 2, and 16 the following observations were made: (A) Anesthesia provider #1 was observed</p>	S000608	<p>Anesthesiology, Surgery and CVL Departmental Correction Plans for Appropriate Dress Code 1. Correction Plan: Anesthesiology Re-education will take place at the July Anesthesia Department meeting on the appropriate dress code for attire per the AORN Guidelines, Recommendations II and IV as well as Surgery Policy F-11 Operating Room Attire and Surgery Policy F-12 Universal Precautions. Recurrence Prevention: Should the incident recur after the July education an incident will be noted in Midas. The Director of the Anesthesiology Department and the President of The Heart Hospital MEC will be notified of any physician that violates the</p>	07/31/2013			

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	<p>in OR #1 during a Carotid surgery case with a very small cloth skullcap with Disney characters sitting on top of his/her head. The cap did not cover the front, both sides, or the back of his/her hair.</p> <p>(B) RN #1 was observed in the cath lab area with a t-shirt under his/her scrub attire. The t-shirt sleeves were exposed below the scrub top.</p> <p>(C) Additionally, several staff members were observed in the cath lab standing inside the room and not directly participating in the procedure without surgical masks on.</p> <p>2. Staff member #1 indicated in interview at 1:00 p.m. on 6/4/13 that the facility follows AORN standards for dress code adherence.</p> <p>3. Facility policy titled "OPERATING ROOM ATTIRE" last reviewed/ revised 12/12 states on page 2 of 4: (A) All possible head and facial hair, including sideburns and neckline, should be covered when in the semirestricted and restricted zones of the surgical suite.....Surgeon caps (skullcaps) may be worn, but hair must be covered." The policy listed AORN as a reference.</p> <p>4. Facility policy titled "OSHA STANDARDS FOR THE CVL" (CVL= Cardiovascular lab) last reviewed/ revised</p>		<p>policy who will then be counseled. Responsible Person(s): Director of the Anesthesiology Department and Surgery Manager - All reports to be submitted to Executive Director/CNO Completion Date: July 31, 2013 2. Correction Plan: Cardiovascular Lab Staff Policy and Procedure CVL-52 Recommended Practices for Cath Lab Attire was written on June 19, 2013 to reflect the AORN standards and recommendations for dress code. Proper attire has been reviewed with the staff. Education on the new policy will be completed and documented by July 3, 2013. Recurrence Prevention: Any violation of the dress code will be documented in the Midas reporting system and any violations will be followed with disciplinary action. The CVL Nursing Manager and Team Lead will audit the staff for compliance and submit a monthly report for the MEC to review. Responsible Person(s): Nursing Manager and Team Lead - All reports to be submitted to Executive Director/CNO Completion Date: July 3, 2013</p>				

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	<p>2/1/11 states under procedure: "The CVL personnel will adhere to specific OSHA standards as recommended in the following policy....." page 2 states: "10. Physician and Scrub Assistant will wear sterile gown, sterile gloves, face mask and hats during procedure....."</p> <p>5. The facility failed to have a policy for the CVL area complying with AORN standards and recommendations for dress code.</p> <p>6. AORN recommended practices for Surgical attire states on page 1 of 20: "These practice settings include traditional operating rooms (ORs), cardiac catheterization laboratories....." Page 7 states: "III.b.1. All personal clothing should be completely covered by the surgical attire.....personal clothing that extends above the scrub top neckline or below the sleeve of the surgical attire should not be worn." Under Recommendation IV on page 7, the policy states: "All personnel should cover head and facial hair, including sideburns and the nape of the neck, when in the semirestricted and restricted areas." Under Recommendation VI on page 12, the policy states: "All individuals entering the restricted areas should wear a surgical mask when open sterile supplies and equipment are present." Under</p>			

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	Glossary on page 15, the policy states: "Restricted area Includes the OR and procedure room....."			

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S000762	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(f)(13)</p> <p>(f) All inpatient records, except those in subsections (g), shall document and contain, but not be limited to, the following:</p> <p>(13) A discharge summary authenticated by the physician. A final progress note may be substituted for the discharge summary in the case of a normal newborn infant and uncomplicated obstetric delivery. The final progress note should include any instruction given to the patient and family.</p> <p>Based on document review and staff interview, the facility failed to ensure discharge summaries were completed according to facility Medical Staff By Laws for 4 of 11 medical records (patients #N1, N2, N6, and N9).</p> <p>Findings include:</p> <p>1. Facility Medical Staff By Laws last approved on 4/26/12 states on page 8 under section 7: "The discharge summary or final progress note must contain the reason for hospitalization, the significant findings, the procedures performed and treatment rendered, the patient's condition on discharge and any specific instructions given to the patient and/or family....."</p>	S000762	<p>Correction Plan: Physicians will be reeducated regarding EMR discharge summary completion. Random chart audits will be conducted to ensure the required content is included and completed within 30 days of discharge. Recurrence Prevention: Patterns and trends will be reported to the MEC bi-monthly. Responsible Persons: Quality/Compliance Officer will conduct the chart audits and reports will be submitted to the Executive Director/CNO and President of the Heart Hospital Medical Staff Completion Date: July 26, 2013</p>	07/26/2013

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	<p>2. Review of patient #N1 medical record indicated the following:</p> <p>(A) The patient was admitted to the facility on 12/29/12 and expired on 12/31/12.</p> <p>(B) The discharge summary lacked documentation of all finding and treatments rendered. Under hospital course, the document stated "Cause of death was anoxic encephalopathy due to cardiac arrest with complete hrt block and shock."</p> <p>3. Review of patient #N2 medical record indicated the following:</p> <p>(A) The patient was admitted to the facility 3/17/13 and expired on 3/17/13.</p> <p>(B) The discharge summary failed to document the procedures performed and treatment rendered. Under hospital course, the document stated "the patient remained critical w grave prognosis and comatose. Family withdrew support. Pt expired of natural causes."</p> <p>4. Review of patient #N6 medical record indicated the following:</p> <p>(A) He/she was admitted on 2/7/13 and was discharged on 2/9/13.</p> <p>(B) The progress note failed to include the reason for hospitalization, significant findings, procedures performed, treatments rendered, and the patients condition on discharge. The final</p>						

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	<p>progress note stated "Home. Everything discussed with family and patient."</p> <p>5. Review of patient #N9 medical record indicated the following: (A) The patient was admitted on 3/12/13 and discharged on 3/15/13. (B) The medical record lacked a discharge summary.</p> <p>6. Staff member #16 verified the medical record information at 2:00 p.m. on 6/4/13.</p>			

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NAME OF PROVIDER OR SUPPLIER THE HEART HOSPITAL AT DEACONESS GATEWAY LLC				STREET ADDRESS, CITY, STATE, ZIP CODE 4007 GATEWAY BLVD NEWBURGH, IN 47630			
(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			
S001014	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7(c)</p> <p>(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.</p> <p>Based on observation, staff interview, and document review, the facility failed to ensure the medication administration policy was followed in 1 of 2 operating rooms (ORs) observed:</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. During tour of the surgery and cath lab department beginning at 11:20 a.m. on 6/4/13 and accompanied by staff members #1, 2 and 16, it was observed OR #2 was cleaned, had clean linens applied and was ready for use. Two (2) opened and partially used vials of medication were observed on top of the anesthesia cart. The vials were not marked as to when they were opened and lacked date of expiration according to policy. 2. Staff member #2 indicated during tour that OR #2 had not been used on 6/4/13. 3. Facility policy titled "MEDICATION 	S001014	<p>S1014 Pharmaceutical Services Correction Plan: OR#2 was ready for use on the morning of 6/4/2013. A case was scheduled for OR#1. The surgery manager and team lead spoke with the anesthesiologist on the case. He started to set up for the case in OR#2 instead of OR#1. Per Deaconess Health Systems' (DHS) Medical Staff Rules and Regulations, Section VI.2. Medical Quality Review and Section VI.3 Incident/Occurrence Reporting the incident is to be reviewed by the Medical Director and Drug Control Officer. The Director of Anesthesiology will meet with the individual anesthesiologist. Recurrence Prevention: The Surgery Manager and Team Lead will continue to monitor the OR1 and 2. Should the incident recur the current process will be followed, plus reported to the Executive Director/CNO, Director of Anesthesiology and President of the Medical Executive Committee. Responsible</p>	07/31/2013			

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	ADMINISTRATION" last reviewed/revised 10/22/12 states on page 2: "5. Medications should be removed from a secure area (ie. staffed nursing units....operating rooms....) upon administration time and given immediately. If medications are not administered to the patient they should be returned promptly back to the designated secure area or wasted....." Page 6 of policy states "Multidose vials that are utilized will be given an expiration date once punctured according to USP 797 guideline dating of 28 days....."		Person(s): DHS Director of Anesthesiology, THH Medical Director, DHS Drug Control Officer and the Executive Director/CNO. Completion Date: July 31, 2013		

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S001028	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(E)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent. Based on document review and observation, the facility failed to ensure security of medications in 1 of 2 rooms in the non-invasive unit.</p> <p>Findings include:</p> <p>1. Facility policy titled "MEDICATION ADMINISTRATION" last reviewed/revised 10/22/12 states on page 2: "3. Non-controlled Substances a. Must be stored within an ADC, locked cabinet, locked cart, or locked drawer. b. Medications cannot be left at the bedside unsecured."</p> <p>2. During tour of the non-invasive unit beginning at 9:45 a.m. on 6/4/13 and accompanied by staff members #1 and #14, the following unsecured medications</p>	S001028	<p>Correction Plan: The staff in the Non-Invasive Department have been re-educated on P&P40-31 Medication Administration section V.B.3.a and b which requires all Non-controlled Substances to a. Be stored within an ADC, locked cabinet, locked cart, or locked drawer, and b. Medications cannot be left at the bedside unsecured." Recurrence</p> <p>Prevention Plan: A faulty lock was repaired in treatment room 1. The Non- Invasive Manager will randomly audit the two treatment rooms monthly for the next 90 days to ensure cabinets remain locked. Reports will be submitted to the Quality/Compliance Officer. Action shall follow the incident reporting process should another incident occur.</p> <p>Personnel Responsible: Non-invasive Department Manager and Quality Compliance</p>	08/30/2013

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	<p>were observed in procedure/treatment room #1 which was not occupied by staff:</p> <p>(A) An unlocked cabinet containing a small plastic tote with medications including, but not limited to, Atropine, Flumazenil, Aminophylline, and Adenosine.</p> <p>(B) An unlocked cabinet under the counter contained pre-filled syringes of Normal Saline.</p> <p>(C) An unlocked cabinet beside the bed contained bags of .9% Sodium Chloride I.V. solution.</p>		<p>Officer. All results will be reported to the Executive Director/CNO. Completion Date: Locked fixed June 5, 2013. Audits completed by August 30, 2013.</p>	