The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA00312640 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 22386, HPES

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.

Health and Safety Code Section 1280 1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

Health and Safety Code Section 1279 1(c): "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."

The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.

Health and Safety Code 1279 1
(b) For purposes of this section, "adverse event" includes any of the following:
(1) Surgical events, including the following:
(2) Surgery performed on the wrong patient

Corrective actions accomplished for the patient affected: CA 00312640

Corrective actions accomplished for the patient(s) identified to have been affected by the deficient practice:

Patient A who underwent the IVC filter placement was informed of the fact that results from another patient were read into her record resulting in placement of the IVC filter. Medical options were reviewed with the patient at that time with plan to remove the filter at a later date as appropriate.

Patient B's case was reviewed to determine the need for additional follow-up. It was determined that the results for Patient B were correct and that the patient was on the appropriate medical regimen.

How other patients having the potential to be affected by the same deficient practice will be identified, and what corrective actions will be taken:

Upon recognition of the event, a thorough review was conducted to determine contributing factors and to affirm that no additional patients were
Implied. No additional patients were impacted. The process from physician order to staff exam processing and reading/resulting by physicians was examined in detail to identify current practices and to develop an appropriate action plan.

What immediate measures and systematic changes will be put into place to ensure that the deficient practice does not recur?

The following actions were taken immediately:

- Staff exam processes were modified to require staff to do no more than two (2) exams prior to placing exams in the physician reading cubicle.
- Patient control sheet and technologist worksheet must have pre-printed patient demographic stickers on each document.
- The patient control sheet and technologist worksheet must be stapled together.
- A mandatory staff meeting was held for all staff (except those on leave of absence) to review the process changes.

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**Event ID**: 123456789
**Date**: 11/7/2012
**Time**: 3:34:37 PM

**Laboratory Director's Signature**: Daryn J. Kumar, Chief Executive Officer
**Date**: 11/13/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting provided it is determined that other safeguards provide sufficient protection to the patient. Except for nursing homes, the findings above are disclosable 60 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 required to continued program participation.
<table>
<thead>
<tr>
<th>ID</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (Each deficiency must be preceded by full regulatory or LSC identifying information)</th>
<th>ID</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (Each corrective action should be cross-referenced to the appropriate deficiency)</th>
<th>COMPLETE DATE</th>
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<tbody>
<tr>
<td>2</td>
<td></td>
<td>Continued from page 2 placement) secondary to test results placed in the patient's chart in error.</td>
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<td>- The Department of Cardiology notified all cardiologists by letter reminding them to correlate the Powerscribe (dictation system) and PACS (imaging system) to confirm the proper patient is being accessed on both systems/computers.</td>
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<td>On 6/14/12 at 11:30 a.m., the clinical records for Patient 1 and Patient 2 were reviewed:</td>
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<td>- A follow up item was placed on the next Department of Cardiology agenda to remind the cardiologist of the necessity to correlate Powerscribe and PACS.</td>
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<td>Patient 1 was seen in the Emergency Department (ED) on 6/12 with symptoms of chest pain and right lower leg pain and swelling. The ED physician discharged Patient 1 from the ED for continued treatment in the Observation Unit of the hospital. Prior to discharge home on 6/12 at 12:00 p.m., an ultrasound of the right lower leg was ordered and performed.</td>
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<td>- Contact was made with Nuance (Powerscribe dictation system parent company) and GE (PACS imaging system parent company) to request an interface between the two systems that would allow the Cardiology PACS system to function in the same manner as the Radiology PACS system.</td>
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<td>The clinical record for Patient 2 indicated the patient was seen in the ED on 6/12 for the chief complaint of leg swelling and possible blood clot to the right leg. An ultrasound was ordered and performed at 11:30 a.m. on 6/12. The results of this ultrasound indicated a blood clot to the saphenous vein of the right leg. Patient 2 was appropriately treated and discharged home.</td>
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<td>In addition to the immediate change in staff processes, a systematic change was made to connect the Powerscribe dictation system to the PACS imaging system so that the physician can call up the patient in the PACS system and the F2 key to populate that patient's demographics will automatically</td>
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<td>The clinical record for Patient 1 indicated that the result of Patient 2's ultrasound was dictated into Patient 1's medical record. The result of the ultrasound meant for Patient 2 was dictated by the cardiologist (MD 2) on 6/12 which stated &quot;... Findings: Examination of the right deep vein system and proximal (upper) portion of the greater saphenous vein (large vein of the leg) shows deep venous thrombus (deep blood clot) at the osium of greater saphenous vein.&quot; The ultrasound result for Patient 1 which showed a blood clot was reviewed</td>
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by Patient 1’s Primary Medical Doctor (PMD). The PMD sent Patient 1 to the hospital for admission on 06/14/12 for the treatment of a blood clot.

MD 3 (Intervention Radiologist) performed the IVC filter placement on 06/12 at 7:50 a.m. on Patient 1 and indicated in the medical record: "Impression: Successful retrievable inferior vena cava filter placement." The procedure was performed under conscious sedation (a technique of providing anestheletic medication in such a way that patient remains awake). Patient 1 was discharged home in stable condition on 06/12 on medications to follow-up with PMD.

The clinical record for Patient 1 indicated a return visit to the ED on 06/12 for continued right leg pain and swelling. During this visit, the ED physician (MD 4) ordered a repeat ultrasound of the right lower extremity. This ultrasound was interpreted as being normal (no blood clot seen). Because of questions related to this interpretation, the MD 4 asked for the original ultrasound image to be pulled and re-looked at. The image of the first ultrasound for Patient 1 was reported as normal.

On 06/14/12 at 12 p.m., during an interview, the Quality Manager (QM) stated Patient 1 underwent an unnecessary surgical procedure when an IVC filter placement was done on 06/12. This surgery was based on an ultrasound performed on another patient (Patient 2). The QM stated the hospital did not have a policy and procedure for the processing of ultrasounds at the time of the ultrasound for Patient 1. The QM stated the reason for not having a policy and procedure was because the ultrasound report was incomplete.

Title/Position of person responsible for implementing the correction:
Director of Imaging Services
Chair, Department of Cardiology

Date the immediate correction of the deficiency was accomplished:
Process changes were made and staff meeting held on May 30, 2012
Letter to Cardiologist was sent on July 7, 2012
Department of Cardiology meeting was held on July 27, 2012
Enhancement to Nuance was requested on June 14, 2012
Enhancement/systematic correction to Nuance was completed and implemented on August 2, 2012

A description of the monitoring process and positions of person responsible for monitoring. How the facility plans to monitor its performance to ensure corrective actions are achieved for its effectiveness, and how it will be integrated into the quality assurance system:

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the error in dictating Patient 2's ultrasound results onto Patient 1's medical record was due to an ultrasound processing error.

On 6/14/12 at 2 p.m., the Director of Imaging Services (DIS) stated the hospital internal investigation found that the likely reason why Patient 2's results were dictated onto Patient 1's medical record was that the Control Sheet and Worksheet for Patients 1 and 2 were intermingled by the US Tech. The US Tech is responsible to ensure the Control Sheet and Worksheet were for the same patient.

The DIS explained the physician would take out the two sheets of paper (Control Sheet and Worksheet) and input the patient name in one system (EHR) and bring up the patient in the other system in order to view the ultrasound on the computer monitor. The DIS explained that the intermingling of the Control Sheet of Patient 1 with the Worksheet of Patient 2 was the most likely scenario in how the results for Patient 2 were dictated onto Patient 1's medical record.

The DIS stated on and prior to 2 physicians did not routinely check to make sure the digital ultrasound that was being read on one computer monitor matched the patient for which the EHR was being dictated on the other computer monitor. The DIS stated that the two computer systems - the EHR or medical record for patients and the digital storage of the ultrasound - did not directly communicate. The DIS stated that the hospital had no policy and procedure on the processing and

- Effective May 30, 2012, clerical staff will run an "End Exam List" daily to ensure all exams are dictated within 24 hours of exam completions.
- An audit tool was developed to assess the matching of the control sheet and technologist's worksheet have no handwritten patient demographics and that only preprinted stickers have been used on both sheets.
  - 30 records per month will be audited
  - An audit tool was developed and used by staff to evaluate the cardiologist reading area checking each physician's reading cubicle three (3) times per day to ensure that technologist's worksheets and patient control sheets are for the same patient, have been stapled, and the appropriate exam has been done.
  - The Director of Imaging will summarize the audits statistically on a monthly basis using the hospital performance improvement methodology (FADE) and submitted to the Risk Management Coordinator by the third (3rd) Monday of the month for the previous month for a minimum of (4) months.
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### Dictation of Ultrasound

During an interview on 6/14/12 at 3:45 p.m., MD 3 (Intervention Radiologist) stated he performed the IVC filter placement procedure on Patient 1 on 6/14/12 at 7:50 a.m. MD 3 stated, in retrospect, that the IVC filter placement was not indicated in Patient 1 because of the normal ultrasound.

On 6/14/12 at 4:30 p.m., during an interview, US Tech 2 stated he was the technician assigned to perform the ultrasound for Patient 1. US Tech 2 could not offer an explanation as to how the Control Sheet and Worksheet for Patient 1 got intermixed with that of Patient 2.

On 6/14/12 at 5:00 p.m., MD 2 stated he was the cardiologist assigned to read and dictate the ultrasound results for Patient 1. MD 2 confirmed he dictated, in error, the ultrasound results for Patient 2 onto the EHR for Patient 1.

On 7/17/12 at 4:45 p.m., during a telephone interview MD 4 stated he treated Patient 1 on her return visit to the ED on 7/12. MD 4 stated the reason Patient 1 returned to the ED was continued right lower leg pain. MD 4 stated he reviewed Patient 1's clinical history and the placement of the IVC filter on 06/12. MD 4 stated that he questioned the original reading of the ultrasound for Patient 1 because of the continued right lower leg pain. MD 4 requested a review of the ultrasound performed on Patient 1 and noted the ultrasound was normal and did not show a blood clot. MD 4 ordered a repeat ultrasound of the right lower leg.

### Summary Statement of Deficiencies

- A summary will be provided to the Quality Assessment & Improvement Committee following the four (4) months as part of the QAPI process.
- Compliance goal for both audits = 100%.

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**Event ID**: 832211  
**11/7/2012 3:34:37 PM**

**Laboratory Director or Provider/Supplier Representative’s Signature**:  
Daryn J. Kumar, Chief Executive Officer  
11/19/12

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Any deficiency statement and any action taken with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing the institution is determined that other safeguards provide sufficient protection to the patients. (Except for nursing homes, the findings above are non-discoverable 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 non-discoverable 14 days following the date these documents are made available to the facility if deficiencies are cited, an approved plan of correction is required to be made available to the facility.)
which verified that no blood clot was present in Patient 1. MD 4 then stated he notified the HM, MD 2 and MD 3 of the erroneous reading of the ultrasound performed on 12 and the unnecessary placement of the IVC filter on 12.

The results dated 12 for the ultrasound procedures performed on Patient 1 were reviewed by MD 2. MD 2 amended the results to read: "Venous Doppler (ultrasound) on the right lower extremity done on 12, read by me has been reported in error to be positive for thrombus (blood clot) in the greater saphenous vein (large vein of the leg). This error has happened secondary to wrong Control sheet/bar code given to me Control sheet/bar code belonged to a different patient. Current study is negative for deep venous thrombus in the right lower extremity. The ultrasound results for the procedure performed on Patient 1 on 12 was read as normal (without blood clot) by MD 5.

The hospital failed to prevent a surgery on the wrong patient by not having a policy and procedure for the processing of ultrasounds, Patient 1's ultrasound result was not dictated correctly. This failure resulted in Patient 2's ultrasound result being dictated onto Patient 1's EHR. The wrong dictation resulted in an unnecessary surgical procedure performed on Patient 1 and an unnecessary medical device (IVC filter) implanted into her body.

The failure to develop and implement a policy and procedure for the processing of ultrasounds led to surgery on a wrong patient (Patient 1) and led to:

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<th>LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE</th>
<th>TITLE</th>
<th>(X3) DATE</th>
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<tbody>
<tr>
<td>J. Daryn J. Kumar, Chief Executive Officer</td>
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<td>11/19/12</td>
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the licensee's noncompliance with one or more requirements of licensure and caused, or is likely to cause, serious injury or death to the patient. The above facility failures may result in an Administrative Penalty.

This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(e)