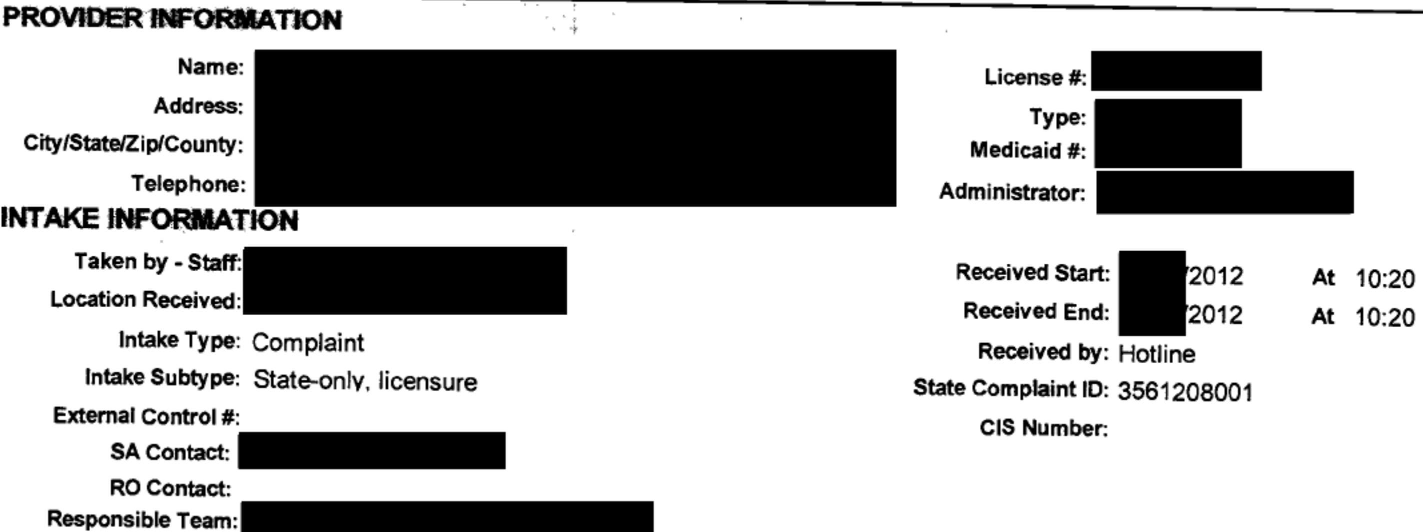
Printed:
Due Date: 12/01/2012
Priority: Non-IJ Medium

Intake ID
Facility I
Provider Number:
Mgmt.Unit:

ACTS Complaint/Incident Investigation Report



PROVIDER INFORMATION

Name:
Address:
City/State/Zip/County:
Telephone:

License #:
Type:
Medicaid #:
Administrator:

INTAKE INFORMATION

Taken by - Staff:
Location Received:
Intake Type: Complaint
Intake Subtype: State-only, licensure
External Control #:
SA Contact:
RO Contact:
Responsible Team:
Source:

Received Start: 2012 At 10:20
Received End: 2012 At 10:20
Received by: Hotline
State Complaint ID: 3561208001
CIS Number:

COMPLAINANTS

RESIDENTS/PATIENTS/CLIENTS - No Data

ALLEGED PERPETRATORS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Case triaged as State Moderate.

Patient was seen at the on 8/ 12 for a pre-abortion exam. Ultrasound performed indicated of weeks, days. by date of last menstrual period of 5/ 12 was weeks days.
Patient seen at the on 8/ 12 for an abortion.
Procedure started at: Procedure end time: After examination of the physician decided to began at and ended at Final examination of revealed an of weeks; Estimated of Physician ordered and was administered by 1st LPN at . It was after the procedure was completed that patient began to Physician ordered and 1st LPN administered at a dose of Physician Physician instructed staff to call 911 for transfer to 2nd LPN called 911 a Medical Resident, with the assistance of 2nd LPN, started 1st LPN monitored patient's would not register with electronic machine. 1st LPN documented that patient was but feeling Pulse was The was Ambulance arrived within of call. 2nd LPN notified Emergency room that patient would be arriving.

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: Other Services
Subcategory: Outpatient Services
Seriousness: Moderate
Findings: Substantiated: State deficiencies related to the alleg are cited
Deficiencies Cited: State-T-2008-ORGANIZATION AND ADMINISTRATION. Operator. (751.2 (b))

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Deficiencies Cited: State-T-2056-ORGANIZATION AND ADMINISTRATION. (751.5 (a))

State-T-2114-ORGANIZATION AND ADMINISTRATION. (751.7 (d))

Details: Inadequate management of the patient during a abortion.

Findings Text:

Based on findings from document review and interviews, the care provided to Patient A in connection with a abortion performed at the did not meet generally accepted standards of professional practice for patient safety. Up to date patient information and necessary equipment / supplies were not immediately available for the procedure and management of any complications that might occur. Also, during the emergency that did occur in this case, staff did not and per the facility's patient emergency procedures.

Findings include:

-- Review of Patient A's MR reveals the following information:

On 08/ /12, Patient A presented to for a abortion. An updated ultrasound (US) report in the MR indicates the patient's last menstrual period (LMP) was weeks and ays prior - it states the was eeks and ays" and " " The report does not include al obtained for determining the and does not provide a clear explanation of why a was necessary. The signature of the staff member who performed th is

Physician progress notes (dated later, 08 /12) specifically describe or state the following information:

- An US performed in the on 08/ 2 indicated the was weeks days. would then be eeks and days."

- "Procedure began in usual fashion ... However, After several decision was made to lso requested a was retrieved + (and) initially no could be found to use with the While that was being sought, examined...clearly wks. wks."

- At the completion of the procedure with and were noted. Examination did not reveal a the uterus was thought to be based on accounted for. e was given and was performed lowed but when ceased, increased again. At this time, emergency medical services (EMS) was called. A dose of as given and continued. A established a and administration was initiated. (The MR lacks details about the i.e., used, and rate of administration, as well as the amount prior to EMS transport of patient to a

Progress notes by licensed practical nurse (LPN) #1, dated 08/ 2, state "Attempted to unable to get with ... pulse monitoring continued until arrival of EMS. Las recorded at mmediately post procedure -

LPN #2 documented 911 was called at (arriving minutes later), and that he/she called the emergency room to alert the staff the patient was on way via ambulance.

-- The policy and procedure (P&P) titled " " dated 2010, indicates that in an emergency situation the patient's must be documented every until the situation has stabilized or the client is transferred. The P&P also indicates that when uterine occurs, will be provided by at minute.

ACTS Complaint/Incident Investigation Report

-- In summary, in this abortion case involving complication of

* The US report was visually difficult to read, did not contain complete information and also lacked the date of the procedure and the complete signature of the

* There is no indication the was rechecked at the abortion visit as directed in the pre-abortion US report.

* Staff did not verify the availability of all necessary equipment prior to the start of the procedure.

* A was not available for back up when the did not work.

* The patient's were not carefully monitored and recorded during the emergency.

* was not to the patient.

Based on findings from document review and interview, staff were not complying with the facility policy and procedure (P&P) regarding the performance of ultrasounds (USs). In reports of US examinations done by , the reports lack evidence oversight was provided during the procedure and that the interpretation the provided was reviewed and finalized by a physician. Also, in ultrasound (US) reports reviewed in medical records (MRs), complete details as well as the signature of an interpreting physician were lacking.

Findings include:

-- Per review of the facility P&P titled " " dated 2011, it indicates an US may only be performed by an affiliate-employed certified sonographer ... or an affiliate physician privileged in the performance of gynecologic US. It also indicates that personnel interpreting and providing final reports for gynecologic USs must be affiliate physicians.

Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director (or designee) for review. It states that a minimum of 20 scans must be completed by the trainee.

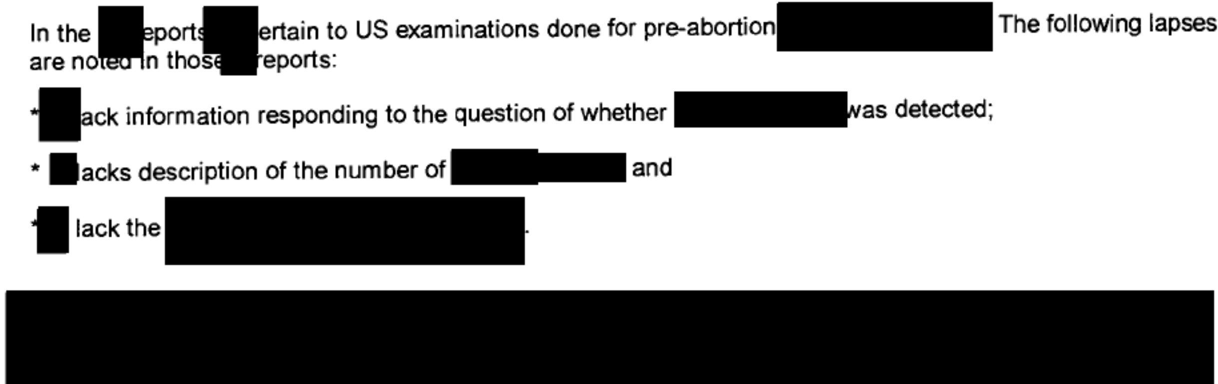
-- Review of Patient F's MR reveals performed and signed the reports with the words after his/her signatures. There is no documentation indicating that another practitioner or physician observed the or reviewed the interpretation the provided on the reports.

-- Review of the MRs for Patients reveals the following lapses in the reports of US examinations performed by

* lack evidence the findings were interpreted by an affiliate physician (i.e., physician signatures are lacking);

* lack the date of the procedure;

* contain sonographer signatures that are



In the eports ertain to US examinations done for pre-abortion The following lapses are noted in those eports:

* ack information responding to the question of whether was detected;
* acks description of the number of and
* lack the .

Based on findings from document review and interview, information recorded in medical records (MRs) was incomplete. The MR for Patient A lacks complete information regarding an hat was during an emergency (see pertinent findings in tag T2031). Also, the US reports in Patient A's and other patients' MRs lack complete information and legible signatures (see the findings in tags T2031 and T2056).

SURVEY INFORMATION

Event ID	Start Date	Exit Date	Team Members	Staff ID
LX5S11	11/05/12	11/05/12		25327
				21517

Intakes Investigated: eceived: 10/17/2012)

SUMMARY OF CITATIONS:

Event ID	Exit Date	Tag
LX5S11	11/05/2012	
		State - Link to This Intake
		T2008-ORGANIZATION AND ADMINISTRATION. Operator.
		T2114-ORGANIZATION AND ADMINISTRATION.
		T2056-ORGANIZATION AND ADMINISTRATION.
		State - Not Related to any Intakes
		T0000-INITIAL COMMENTS

EMTALA INFORMATION - No Data

ACTS Complaint/Incident Investigation Report

ACTIVITIES

Type	Assigned	Due	Completed	Responsible Staff Member
Medical Records Requested	11/05/2012		11/05/2012	
Schedule Onsite Visit	11/05/2012		11/30/2012	
Telephone Contact - Other	11/06/2012		11/06/2012	
Additional Information Requested	11/06/2012		11/06/2012	
Electronic Contact	11/13/2012		11/13/2012	
Telephone Contact - Other	11/19/2012		11/19/2012	
File Review	11/26/2012		11/26/2012	
Additional Information Requested	12/21/2012		12/21/2012	
Telephone Contact - Other	12/26/2012		12/26/2012	
Telephone Contact - Other	02/13/2013		02/13/2013	
Additional Information Requested	03/27/2013		03/27/2013	
Additional Information Requested	04/01/2013		04/01/2013	
Telephone Contact - Other	04/05/2013		04/05/2013	
Telephone Contact - Other	04/08/2013		04/08/2013	
Investigation Report Completion	04/10/2013		04/10/2013	
Telephone Contact - Other	04/29/2013		04/29/2013	
Supervisory Review and Sign Off	04/29/2013		04/29/2013	

Printed: [redacted]

Due Date: 12/01/2012

Priority: Non-IJ Medium

Intake ID [redacted]

Facility ID [redacted]

Provider Number:

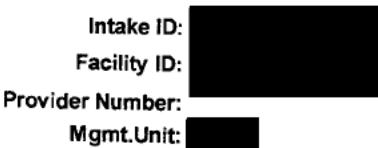
Mgmt.Unit: [redacted]

ACTS Complaint/Incident Investigation Report

INVESTIGATIVE NOTES

CONTACTS - No Data

Printed:
Due Date: 12/01/2012
Priority: Non-IJ Medium



Intake ID:
Facility ID:
Provider Number:
Mgmt.Unit:

ACTS Complaint/Incident Investigation Report

AGENCY REFERRAL

Agency	Contact Name	Date Referred	Due Date	Agency Visit	Report Received	RO/SA
Island Peer Review Orgranization (IPRO)		12/19/2012			01/30/2013	S

LINKED COMPLAINTS - No Data

DEATH ASSOCIATED WITH THE USE OF RESTRAINTS/SECLUSION - No Data

Reason for Restraint:
Cause of Death:

NOTICES

Notification:

Date	Type	Party	Method
10/17/2012	Acknowledgement to Complainant	Central Office	E-Mail

PROPOSED ACTIONS

Proposed Action	Proposed Date	Imposed Date	Type
State Only Actions	04/29/2013	04/29/2013	Federal
POC (No Sanction)	04/29/2013	04/29/2013	State

Closed: 01/13/2014 **Reason:** Paperwork Complete

END OF COMPLAINT INVESTIGATION INFORMATION

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

May 6, 2013

RE: Complaint #
Corrected Statement of Deficiencies

Dear

In connection with the complaint referenced above, on April 29, 2013, this office issued a Statement of Deficiencies (SOD) to your facility. The purpose of this letter is to provide a corrected copy of the SOD. You will note that the reference to two tag numbers on page 7 of the SOD has been corrected. Previously, the SOD contained two references to Tag T2031. Tag T2031 has been changed to T2008 in both references. Please accept my apologies for any inconvenience this may have caused.

The time frame for submission of a Plan of Correction remains the same, no later than 10 business days from receipt of the April 29, 2013 letter.

If you have any questions, please feel free to contact

Sincerely,

Attachment

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING: ______ B. WING ______	C 11/05/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

(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) COMPLETE DATE
T 000	INITIAL COMMENTS PF OPERATING CERTIFICAT NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT # THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.	T 000		
T2008	751.2 (b) ORGANIZATION AND ADMINISTRATION. Operator. The responsibilities of the operator shall include but not be limited to: (b) ensuring that all patients receive quality health care and services provided in accordance with generally accepted standards of professional practice. This Regulation is not met as evidenced by: Based on findings from document review and interviews, the care provided to Patient A in connection with a abortion performed at the did not meet generally accepted standards of professional practice for patient safety. Up to date patient information and necessary equipment / supplies were not immediately available for the procedure and management of any complications that might occur. Also, during the emergency that did occur in this case, staff did not and per the facility's patient	T2008		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 11/05/2012
NAME OF PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE	

(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) COMPLETE DATE
T2008	Continued From page 1 emergency procedures. Findings include: -- Review of Patient A's MR reveals the following information: On 08/ /12, Patient A presented to for a abortion. An undated ultrasound (US) report in the MR indicates the patient's last menstrual period (LMP) was weeks and days prior - it states the was weeks and days" and The report does not include all obtained for determining the and does not provide a clear explanation of why a repeat was necessary. The signature of the staff member who performed th is Physician progress notes (dated later, 08/ /12) specifically describe or state the following information: - An US performed in the on 08/ 12 indicated the was weeks days. would then be weeks and days." - "Procedure began in usual fashion ... However, After several decision was made t lso requested a + (and) initially no could be found to use with th While that was being sought, examined...clearly Est wks."	T2008		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HP0930D	A. BUILDING: ____ B. WING ____	C 11/05/2012

NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE

(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) COMPLETE DATE
T2008	Continued From page 2 - At the completion of the procedure with and were noted. Examination did not reveal a the uterus was based on ccounted for. was given and was performed. but when . At this time, emergency medical services (EMS) was called. A dose of as given and continued. A medical resident established a and was initiated. (The MR lacks details about the i.e., who , used, the as well as the prior to EMS transport of patient to a Progress notes by licensed practical nurse (LPN) #1, dated 08 12, state "Attempted to unable to get with ... continued until arrival of EMS. Last at immediately post procedure - LPN #2 documented 911 was called at (arriving minutes later), and that he/she called the emergency room to alert the staff the patient was on her way via ambulance. -- The olicy and procedure (P&P) titled dated 2010, indicates that in an	T2008		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HP0930D	A. BUILDING: ____ B. WING ____	C 11/05/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

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T2008	Continued From page 3 emergency situation the patient's must be documented every minutes until the situation has stabilized or the client is transferred. The P&P also indicates that when occurs will be provided by at -- In summary, in this abortion case involving complication of * The US report was visually difficult to read, did not contain complete information and also lacked the date of the procedure and the complete signature of the proceduralist. * There is no indication the was rechecked at the abortion visit as directed in the pre-abortion US report. * Staff did not verify the availability of all necessary equipment prior to the start of the procedure.	T2008		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HP0930D	A. BUILDING: ______ B. WING ______	C 11/05/2012

NAME OF PROVIDER OR SUPPLIER [redacted] CODE

(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) COMPLETE DATE
T2008	Continued From page 4 * A [redacted] was not available for back up when the [redacted] did not work. * The patient's [redacted] were not carefully [redacted] and [redacted] ever [redacted] minutes during the emergency. * [redacted] was not [redacted] to the patient.	T2008		
T2056	751.5 (a) ORGANIZATION AND ADMINISTRATION. Operating Policies and Procedures. The operator shall ensure: (a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice. This Regulation is not met as evidenced by: Based on findings from document review and interview, [redacted] staff were not complying with the facility policy and procedure (P&P) regarding the performance of ultrasounds (USs). In reports of [redacted] US examinations done by a [redacted] the reports lack evidence oversight was provided during the procedure and that the interpretation the [redacted] provided was reviewed and finalized by a physician. Also, in [redacted] ultrasound (US) reports reviewed in [redacted] medical records (MRs), complete details as well as the signature of an interpreting physician were lacking. Findings include: -- Per review of the facility P&P titled [redacted] dated [redacted] 2011, it indicates an US may	T2056		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HP0930D	A. BUILDING: ______ B. WING ______	C 11/05/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

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T2056	Continued From page 5 only be performed by an affiliate-employed certified sonographer ... or an affiliate physician privileged in the performance of gynecologic US. It also indicates that personnel interpreting and providing final reports for gynecologic USs must be affiliate physicians. Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director (or designee) for review. It states that a minimum of 20 scans must be completed by the trainee. -- Review of Patient F's MR reveals performed USs and signed the reports with the words after his/her signatures. There is no documentation indicating that another practitioner or physician observed the or reviewed the interpretation the provided on the reports. -- Review of the MRs for Patients reveals the following lapses in the reports of US examinations performed by who were -certifed US sonographers: * lack evidence the findings were interpreted by an affiliate physician (i.e., physician signatures are lacking); * lack the date of the procedure; * contain sonographer signatures that are either illegible or are covered In the reports, pertain to US examinations done for pre-abortion gestational dating. The following lapses are noted in those reports:	T2056		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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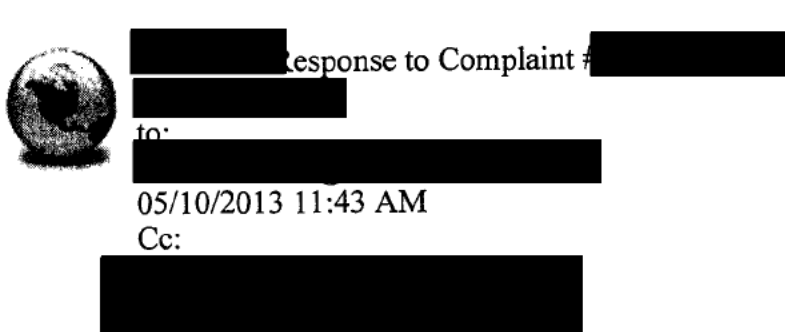
T2056	Continued From page 6 * lack information responding to the question of whether , was detected; * lacks description of present; and ack th	T2056		
T2114	751.7 (d) ORGANIZATION AND ADMINISTRATION. Medical record system. The operator shall: (d) ensure that the medical record for each patient contains and centralizes all pertinent information which identifies the patient, justifies the treatment and documents the results of such treatment. This Regulation is not met as evidenced by: Based on findings from document review and interview, information recorded in medical records (MRs) was incomplete. The MR for Patient A lacks complete information regarding an during an emergency (see pertinent findings in tag T2008). Also, the US reports in Patient A's and other patients' MRs lack complete information and legible signatures (see the findings in tags T2008 and T2056).	T2114		



Response to Complaint #

to:

05/10/2013 11:43 AM

Cc:

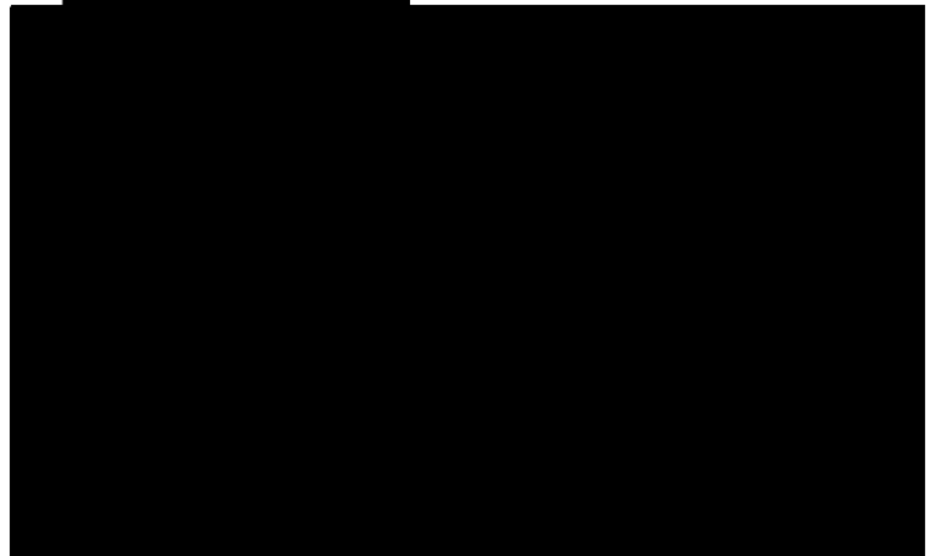
POC # 1

2 Attachments

image001.png DoH 5-10-13.zip

Annette, this note is transmit the sponse including a cover letter, the plan of correction and back-up documents for complaint # appreciate electronic confirmation of receipt. Please let me know if for any reason you have difficulty opening this zip file. We will also deliver to the DOH on Monday a memory stick with the same documents if that proves easier to open. You can reach me at the phone number below or over the weekend on my cell phone numbe

Many thanks.



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T 000	INITIAL COMMENTS PFI OPERATING CERTIFICATE NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.	T 000		
T2008	751.2 (b) ORGANIZATION AND ADMINISTRATION. Operator. The responsibilities of the operator shall include but not be limited to: (b) ensuring that all patients receive quality health care and services provided in accordance with generally accepted standards of professional practice. This Regulation is not met as evidenced by: Based on findings from document review and interviews, the care provided to Patient A in connection with a abortion performed at the did not meet generally accepted standards of professional practice for patient safety. Up to date patient information and necessary equipment / supplies were not immediately available for the procedure and management of any complications that might occur. Also, during the emergency that did occur in this case taff did not and per the facility's patient	T2008		

May 10, 2013

Re: ***Complaint***

Dear

I am writing in response to your April 29, 2013 letter regarding the Summary Statement of Deficiencies with respect to the above-referenced complaint.

also has proactively hired additional medical and clinical professionals. We have hired a (please see the attached *cv*) who recently and a (please see the attached *cv*), both of whom o reinforce lessons learned. We have strengthened our emergency procedures for the entire provider team including physicians, LPNs, RNs, and NPs,PAs, and we have directed our medical director to carry out continuous in-service training for clinicians. We have attached a Plan of Correction which indicates the steps we have taken and the steps which we will put in place

We do, however, wish to correct two specific findings in the Statement of Deficiencies which allege tha[redacted] ailed to comply with its own internal policies and procedures related to ultrasound training, interpretation and privileging.

1. [redacted] **Compliance with that Policy**: We have attached [redacted] policy which was revised in [redacted] 2011, and was implemented in [redacted] 2011 (the "2011 Policy"). A revised [redacted] policy was drafted in [redacted] 2012. However, that policy did not actually go into effect until [redacted] 2012 (the "[redacted] 2012 Policy"). Although both of these policies were provided to the lead inspector from your office, the 2011 Policy – and not the [redacted] 2012 Policy -- was the one which was in effect at the time Patient A underwent the [redacted] abortion procedure on August [redacted] 2012. Of note, [redacted] only performs ultrasound procedures in the [redacted] pregnancy. The 2011 Policy outlines the specific duties of the ultrasound provider in providing these services, and specifically permits [redacted] to interpret the ultrasound findings. Therefore, we believe that [redacted] followed the procedures set forth in the applicable 2011 Policy at the time the ultrasound was performed on Patient A. The more complex formulary specified in [redacted] of the [redacted] 2012 Policy was mistakenly relied upon by the Department in its Statement of Deficiencies with respect to this complaint (see TAG T2056, pp. 5-6). [redacted] the [redacted] 2012 Policy covers all forms of ultrasound services, including ultrasound services [redacted] pregnancy. These provisions are not applicable [redacted] since we do not perform ultrasound services [redacted] Accordingly, we respectfully request that the Department correct the statement in the second paragraph of TAG T2056 on page 5 of the Statement of Deficiencies which states that [redacted] staff was not complying with the facility policy and procedure regarding the performance of ultrasounds."

2. **Training and Privileging for Sonography (TAG T2056, page 6)**: [redacted] at [redacted] who perform ultrasounds are trained by [redacted] Medical Director, who is the director of ultrasonography fo[redacted] Following this training, the [redacted] must perform ultrasound procedures under peer review according to a specific evaluation sheet. Once all these steps are complete, the individual is recommended by the Medical Director to [redacted]s Board for ultrasound privileges. We respectfully request that this portion of the findings be revised before the final report is issued on this case.

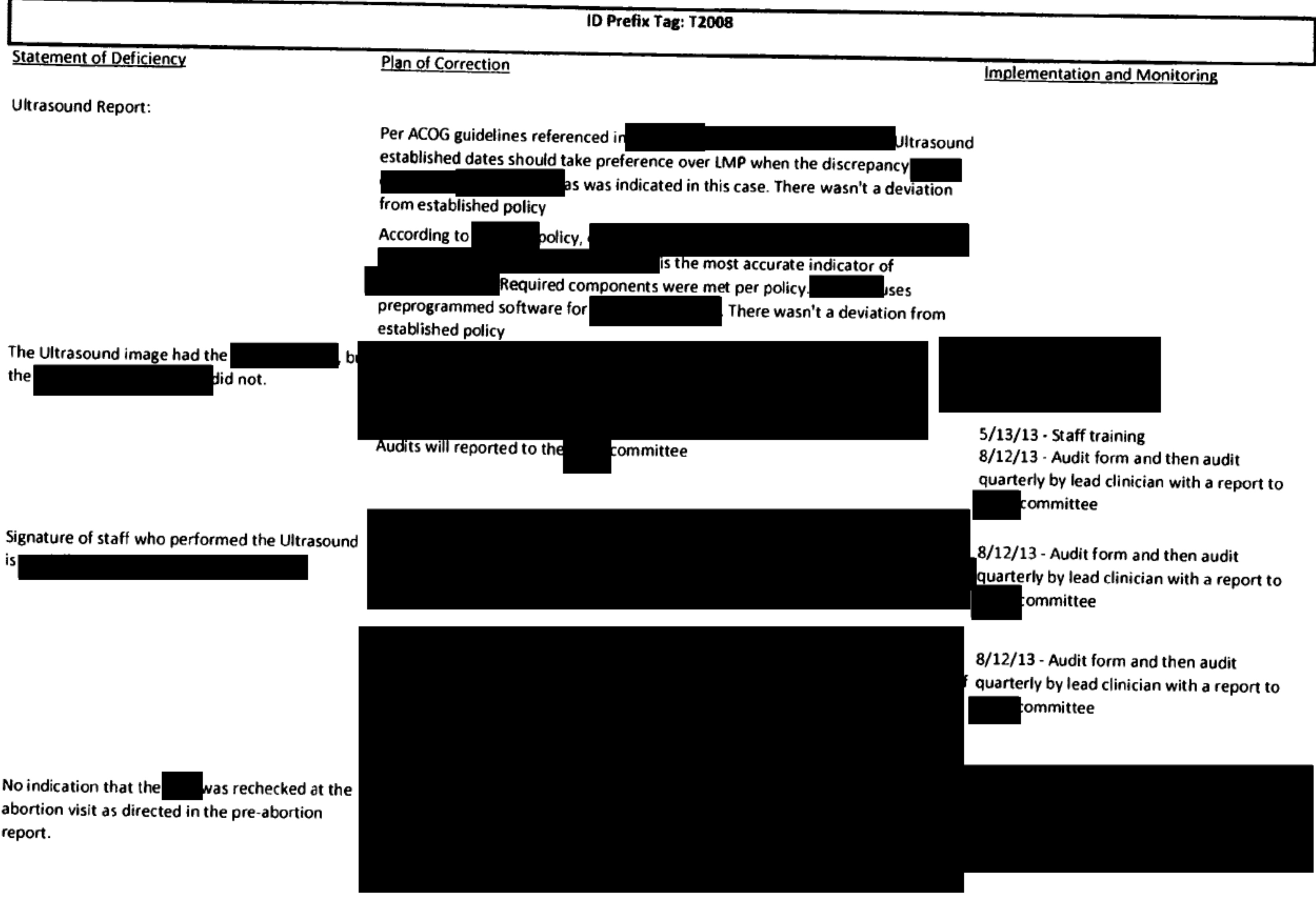
Sincerely,

[redacted]

Attachments:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

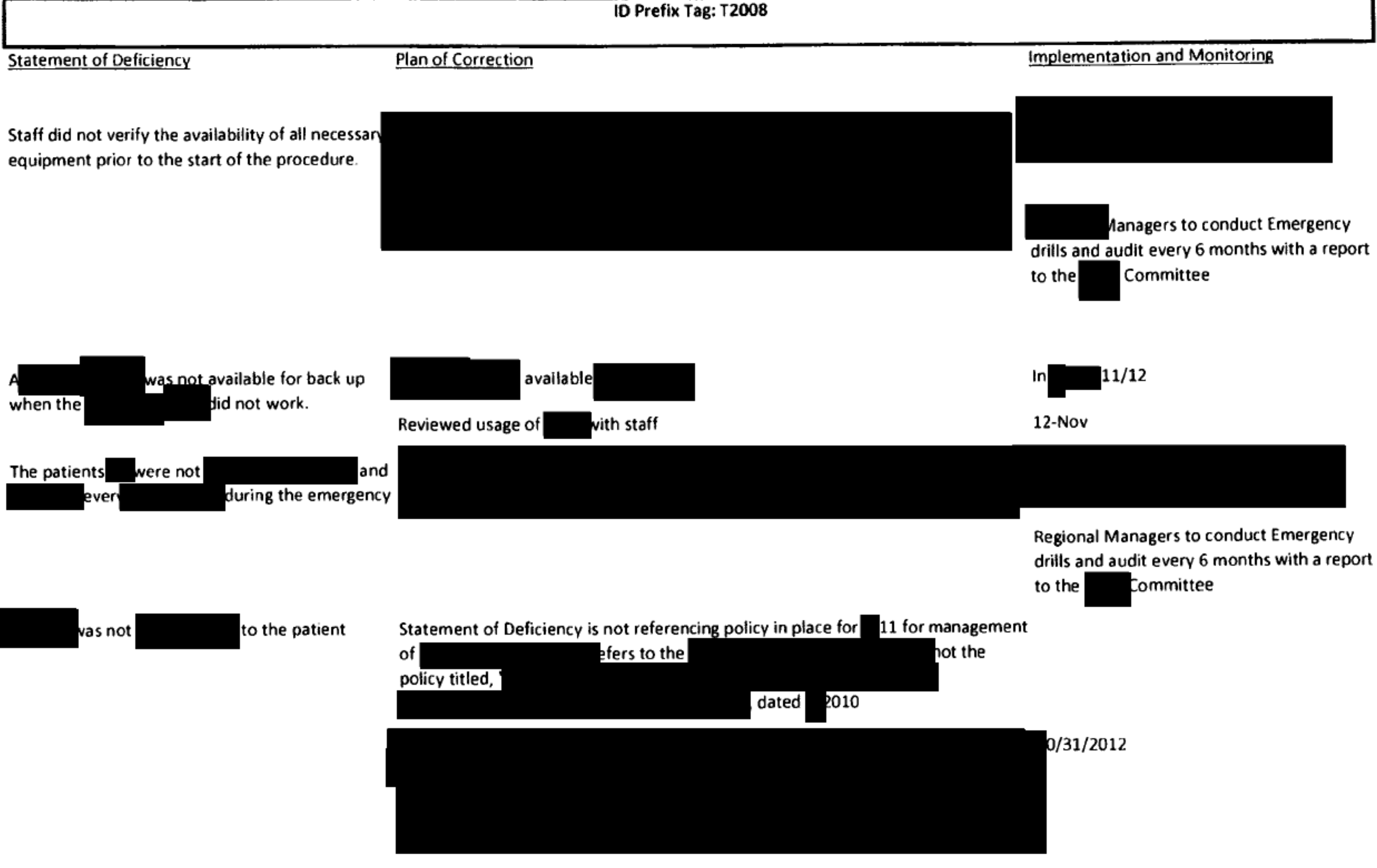
Plan of Correction to Complaint



ID Prefix Tag: T2008

Statement of Deficiency	Plan of Correction	Implementation and Monitoring
Ultrasound Report:		
	Per ACOG guidelines referenced in Ultrasound established dates should take preference over LMP when the discrepancy as was indicated in this case. There wasn't a deviation from established policy	
	According to policy, is the most accurate indicator of Required components were met per policy. uses preprogrammed software for There wasn't a deviation from established policy	
The Ultrasound image had the , b the did not.	Audits will reported to the committee	5/13/13 - Staff training 8/12/13 - Audit form and then audit quarterly by lead clinician with a report to committee
Signature of staff who performed the Ultrasound is		8/12/13 - Audit form and then audit quarterly by lead clinician with a report to committee
		8/12/13 - Audit form and then audit quarterly by lead clinician with a report to committee
No indication that the was rechecked at the abortion visit as directed in the pre-abortion report.		

Plan of Correction to Complaint



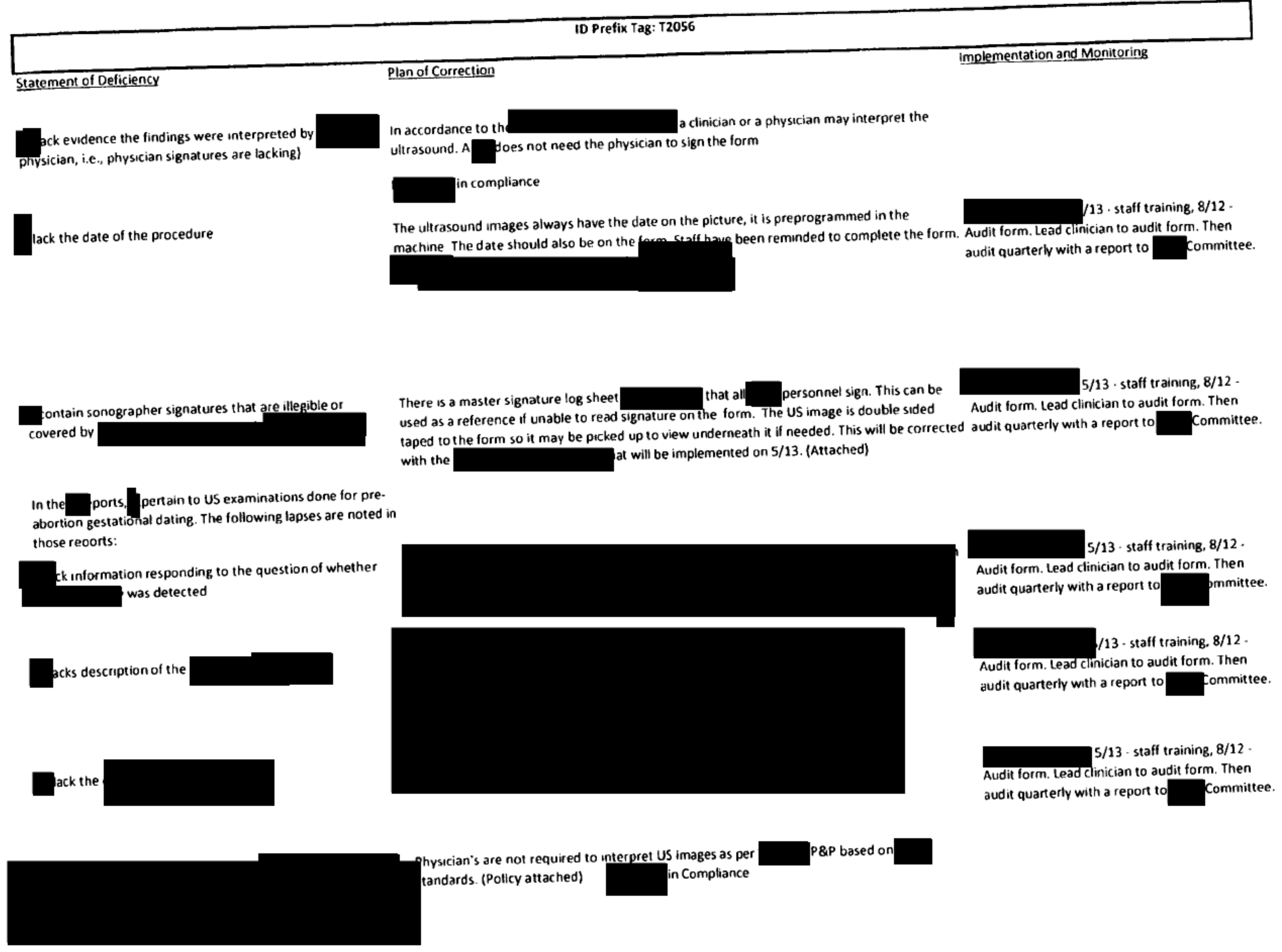
ID Prefix Tag: T2008		
Statement of Deficiency	Plan of Correction	Implementation and Monitoring
Staff did not verify the availability of all necessar equipment prior to the start of the procedure.		anagers to conduct Emergency drills and audit every 6 months with a report to the Committee
A was not available for back up when the did not work.	available Reviewed usage of with staff	In 11/12 12-Nov
The patients were not and ever during the emergency		Regional Managers to conduct Emergency drills and audit every 6 months with a report to the ommittee
vas not to the patient	Statement of Deficiency is not referencing policy in place for 11 for management of efers to the ot the policy titled, dated 2010	
		0/31/2012

Plan of Correction to Complaint

ID Prefix Tag: T2056

Statement of Deficiency	Plan of Correction	Implementation and Monitoring
Per review of the facility P&P titled dated 011, it indicates an US may only be performed by an employed certified sonographer...or physician privileged in the performance of gynecologic US. It also indicates that personnel interpreting and providing final reports for gynecologic US's must be physicians.	In accordance wit policy, the personnel that y perform Ultrasound in Abortion Care are, non-licensed personnel, licensed nurses, clinicians, certified sonographers and physicians. Personnel a who perform are, licensed nurses, clinicians and physicians. Staff who may interpret re, clinicians and physicians. Only clinicians and physicians interpret ultrasounds at s in compliance	
Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director, (or designee) for review. It states that a minimum of 20 scans must be completed by the trainee.		
Review of Patient F's MR reveals performed Us and signed the reports with the words fter his/her signature. There is no documentation indicating that another practioner or physician observed the trainee or reviewed the interpretation the rovided on the reports.	In accordance to policy, dated 2011 Personnel, Staff who provide ultrasound services, #2, Training and Proctoring monstrates adherence to the policy in that, trainees complete the accredited training, he trainees participate in hands-on training with appropriately trained and skilled personnel and are proctored by direct observation in the performance AND/OR interpretation of ultrasound until competence is reached and is determined by staff who are privileged to interpret. This is demonstrated after 20 scans have been successfully completed and reviewed by Ultrasound Director. All scans that a trainee completes are reviewed internally. also scans images to our other clinics so a NP, PA or MD may review a scan at a and provide input. s in compliance	
Review of the MRs for Patient eveals the following lapses in the reports of US examinations performed by who were certified US sonographers		

Plan of Correction to Complain



ID Prefix Tag: T2056

Statement of Deficiency	Plan of Correction	Implementation and Monitoring
ack evidence the findings were interpreted by physician, i.e., physician signatures are lacking)	In accordance to th a clinician or a physician may interpret the ultrasound. A does not need the physician to sign the form in compliance	
lack the date of the procedure	The ultrasound images always have the date on the picture, it is preprogrammed in the machine The date should also be on the form. Staff have been reminded to complete the form.	/13 - staff training, 8/12 - Audit form. Lead clinician to audit form. Then audit quarterly with a report to Committee.
contain sonographer signatures that are illegible or covered by	There is a master signature log sheet that all personnel sign. This can be used as a reference if unable to read signature on the form. The US image is double sided taped to the form so it may be picked up to view underneath it if needed. This will be corrected with the at will be implemented on 5/13. (Attached)	5/13 - staff training, 8/12 - Audit form. Lead clinician to audit form. Then audit quarterly with a report to Committee.
In the ports, pertain to US examinations done for pre-abortion gestational dating. The following lapses are noted in those reoorts:		
ck information responding to the question of whether was detected		5/13 - staff training, 8/12 - Audit form. Lead clinician to audit form. Then audit quarterly with a report to ommittee.
acks description of the		/13 - staff training, 8/12 - Audit form. Lead clinician to audit form. Then audit quarterly with a report to Committee.
ack the		5/13 - staff training, 8/12 - Audit form. Lead clinician to audit form. Then audit quarterly with a report to Committee.
	hysician's are not required to interpret US images as per P&P based on tandards. (Policy attached) in Compliance	

Ultrasound may be provided as part of the following services:

1. Medical and Surgical Abortion
2. Evaluation of Early Pregnancy / Management of Early Pregnancy Complications
3. Pregnancy Diagnosis
4. Prenatal Care
5. IUC insertion and/or localization
6. Other Gynecological Conditions

Approval — Approval for a clinical service includes approval to provide ultrasound as part of that service. Separate approval is not required.

Performance vs. interpretation of ultrasound

1. Performance of the ultrasound is the act of doing the examination — taking the measurements, creating a printed image, and reporting the findings for interpretation.
2. Interpretation of the ultrasound is reviewing the findings, providing an impression or conclusion, and approving and signing the final written report.

Client viewing of ultrasound images — Any client who undergoes an ultrasound at the affiliate **must** be offered the opportunity to view the ultrasound image.

1. Clients who request a copy of the ultrasound image should be accommodated whenever possible.
2. See [redacted] ocumentation, below.

First Trimester — examination of pelvis in first trimester of pregnancy includes evaluation:

1. for presence and location of gestational sac
2. for presence or absence of yolk sac or embryo, and crown-rump length whenever possible
3. for presence or absence of cardiac activity
4. for fetal number
5. of uterus, adnexal structures and cul de sac, if clinically indicated

Second or Third Trimester — examination of pregnancy beyond the first trimester includes:

1. all components of first trimester ultrasound, plus
2. placental localization [redacted]
3. gestational dating, using at least one, and preferably two fetal biometric parameters
4. in third trimester, prenatal clients
   - estimated fetal weight
   - amniotic fluid evaluation
   - fetal position

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- placental grade

Gynecologic diagnostic ultrasound — ultrasound of the non-pregnant female pelvis includes evaluation of the:

1. uterus and myometrium
2. cervix
3. cul-de-sac
4. ovaries
5. fallopian tubes (including absence of visualization)
6. endometrium and endometrial thickness
7. variations from normal size should be accompanied by measurements

Limited Ultrasound — performed when a specific question requires investigation (see below for specific indications for limited ultrasound for specific services)

Real-time Scanners — Real-time scanners should be utilized with an abdominal and/or vaginal approach. A transducer of appropriate frequency (3.5 MHz or higher for abdominal; 5 MHz or higher vaginally) should be used.

Vaginal Probes — must be disinfected between use and **must** always be covered with a condom or other disposable protective sheath when inserted into the vagina.

Ultrasound Capacity — Affiliates providing ultrasound **must** have the capacity to perform abdominal as well as vaginal ultrasound.

Program director — each affiliate providing ultrasound services **must** have a program director who **must** be a physician or advance practice clinician. The program director **must**

1. Complete the ultrasound training in abortion care (either by completing the whole course or completing the
2. Complete the
3. Supervise the affiliate program and assure compliance with
4. Supervise and assure compliance with the quality improvement standards. (See
5. Grant clinical privileges. The program director may designate a clinician(s) who may grant clinical privileges. Any clinician involved in granting privileges **must** pass the proficiency test listed above.

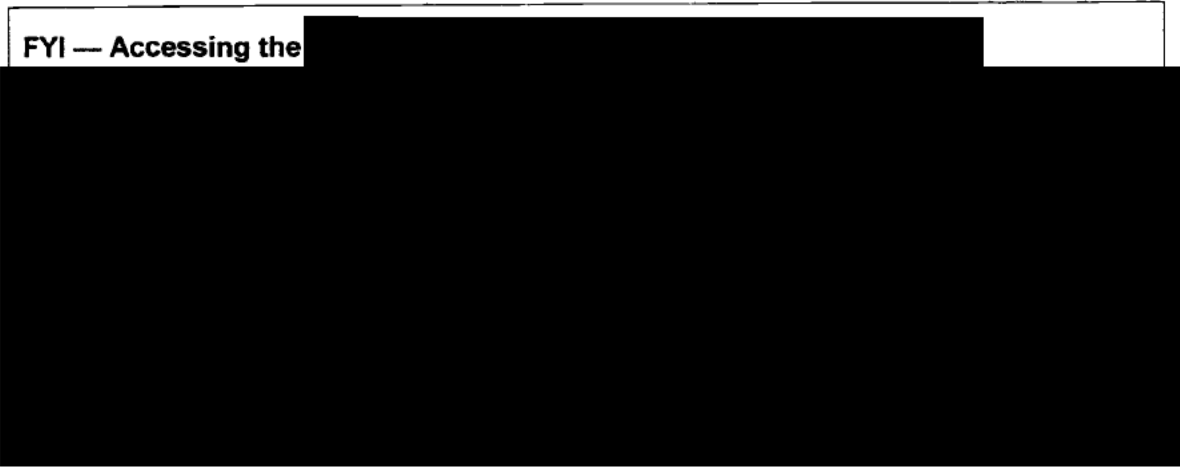
Staff who provide ultrasound services

1. Both licensed and non-licensed personnel may be trained in the provision of ultrasound where allowed by state and local law.
   - Non-licensed staff
     - May perform ultrasound for certain services. See below for details.

Non licensed staff **must** not interpret ultrasound.
  - **Must** successfully complete a skills checklist before they may perform ultrasound.
- Licensed staff
  - May perform and/or interpret ultrasound examinations. See below for information on which licensed staff may interpret ultrasound for specific services.
  - **Must be** granted clinical privileges to perform and/or interpret ultrasound. Clinical privileges should include separate categories for performing and interpreting each type of ultrasound listed in this section and defined in [redacted] below.

2. Training and Proctoring — All staff (including contractual employees) that perform and/or interpret ultrasounds **must**
   - complete the [redacted] as evidenced by passing the [redacted] OR pass the [redacted] that comes with the [redacted] OR demonstrate completion of an [redacted]
   - participate in hands-on, supervised training OR demonstrate previous hands-on training (not required for staff who interpret only)
     - Hands on training may be performed by any appropriately trained and skilled personnel.
   - be proctored (direct observation in the performance and/or interpretation of ultrasound) until competence has been reached
     - For personnel who will interpret ultrasound, proctoring **must** be done by staff who are privileged to interpret.

FYI — Accessing the [redacted]



Documentation — of training, proctoring, privileges and completed skills checklists **must** be placed in personnel file.

Specific Services — see individual services below for specific personnel issues.

Every affiliate **must** have a quality improvement program. (See [redacted] The quality improvement program **must**

1. Ensure initial proficiency for staff.

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- Document initial training and proficiency. (See
- Process of initial training:
    - o **Must** include a combination of direct observation of scanning technique and submission of scans to program director (or designee) for review.
    - o A minimum of 20 scans **must** be completed by the trainee. The number of scans performed will vary by individual. Each trainee **must** do the number of scans that assures competency.
    - o Discretion on the part of the program director is allowed, especially in cases of trainees with past experience.

2. Evaluate and document ongoing proficiency.
    - Identify problematic areas.
    - Document a corrective action plan.
    - Have a system in place to assess results of corrective actions.
3. Ensure complete evaluation of the Ultrasound program through
    - Review of equipment, medical records and personnel charts.
    - Evaluation of the results of any deficiencies with corrective actions / interventions.
4. Revisit corrective actions / interventions to determine outcome at regular intervals.

Every ultrasound examination **must** be documented and signed by the appropriate affiliate personnel. This may be accomplished by using a flow sheet or within the narrative report of the client encounter.

Pre-Procedure Image — For each pre-procedure ultrasound, a printed image or photograph **must** be taken and maintained as part of the client's medical record.

Intra or Post-Procedure Image — When an intra- or post-procedure image is taken, it **must** be maintained as part of the client's medical record.

Written Report — The written final report, whether provided by the affiliate or an outside facility includes:

1. name(s) of person(s) performing and interpreting the ultrasound
2. special techniques, equipment, media, or medications used, if any
3. whether exam was satisfactory with notation of limitations, if any
4. anatomic areas scanned
5. normal findings and/or abnormalities
6. diagnostic Impression
7. specific findings related to the purpose of the exam (e.g., intrauterine gestation/size, number, IUC) (see also Items below, for documentation for specific types of ultrasound)
8. comparison with previous ultrasounds for the same condition, if applicable

Clients and Ultrasound Images — documentation in the client record **must** include that the client was offered the opportunity to see her ultrasound, her response to the offer, and if she was given a copy of the ultrasound image.

FYI — Options for viewing the ultrasound

Affiliates have shared that they most commonly offer women the option to view the ultrasound in one of two ways — a direct question to the client or indirectly as part of the client intake form. Either way is acceptable.

Document that the option was offered, whether or not the client chose to view the image, and that it was shown to her (if applicable).

Client preferences:
Do you want to see the ultrasound? ____Yes ____No
Do you want to know if there is more than one pregnancy? ____Yes ____No

If the client indicates yes to either question, the record can simply have a checkbox:

____Client shown ultrasound image
____Client given a copy of the image
____Client informed of multiple pregnancies

Prior to the performance of ultrasound — the [redacted] or the [redacted] must be signed or already present in the client's record.

Limitations of the Ultrasound — The client **must** be informed of the limitations of the ultrasound being performed. For example, an ultrasound for pregnancy dating only would not be evaluating fetal anatomy.

1. Information may be given verbally.
2. It **must** be documented in the client's medical record that the information was given.

Personnel

1. **The following affiliate staff may perform** or interpret first or second trimester or **limited ultrasound after meeting** training requirements described above and undergoing appropriate proctoring/privileging.
   - **Performance of ultrasound** — non-licensed personnel, licensed nurses, clinicians, certified sonographers and physicians
   - Interpretation of ultrasound — clinicians and physicians
2. Complex cases — when an abortion-related abnormality, condition, or complication is complex enough to require further ultrasound evaluation, (i.e. the findings of the original ultrasound are unclear or exceed the privileges granted to

the clinician), the ultrasound **must** be interpreted by and usually* performed by the following.

- An affiliate physician with ultrasound privileges related to abortion

or

- An out-of affiliate radiologist or other physician with similar experience and skill for consultation

or

- An emergency facility capable of evaluating and managing abortion-related conditions

*In rare circumstances, when the physician is attending to the needs of the client, the ultrasound may be performed by a privileged non-physician.

Documentation

1. All ultrasound examinations **must** be interpreted and co-signed by a privileged clinician or physician.
2. See [redacted] above, for specifics about the report.

Medication Abortion

1. Pre-abortion first trimester ultrasound is required. A limited post-abortion ultrasound is required if pregnancy termination is not confirmed with serial BhCGs.
2. See [redacted] for specific standards related to medication abortion and the use of ultrasound.
3. Whenever a discrepancy exists between the findings on an ultrasound examination and the client's clinical history, the responsible clinician/physician should repeat the ultrasound procedure in order to confirm the initial findings. In most circumstances, this does not apply to size/date discrepancies when the ultrasound dating is clear.

Surgical Abortion

1. First trimester Abortion
   - First trimester ultrasound **must** be performed in the following circumstances, when:
     - Accurate dating cannot be determined by bimanual pelvic examination or there is a discrepancy between size and dates.
     - There is a possibility that the client may not be pregnant.
     - There is suspicion that the client is beyond 13w 6d gestation.
     - The pelvic examination reveals an abnormality that might interfere with the safe performance of the abortion (*e.g.*, adnexal masses, myomata, congenital uterine anomalies, hyperflexion of the uterus, severe retroversion).
   - Limited ultrasound
     - On-site availability of limited ultrasound is strongly encouraged but not required. When ultrasound is not available on site, a consultant relationship with a qualified provider in the community **must** exist for referral of clients as needed.
     - May be used intra-operatively or post-operatively to evaluate:
       - suspected perforation
       - cervical stenosis
       - confirmation of the evacuation of multiple uterine compartments (septate and bicornuate uterus)
       - completion of a procedure when fetal size is found to be greater than originally estimated

- postabortal problems, particularly in the evaluation of retained products of conception or a continuing intrauterine pregnancy
- immediate confirmation of completion of procedure when POCs are not clearly identified in early surgical abortion

2. Second trimester ultrasound **must** be performed prior to mid-trimester abortion.
3. Whenever a discrepancy exists between the findings on an ultrasound examination and the client's clinical history, the responsible clinician/physician should repeat the ultrasound procedure in order to confirm the initial findings. In most circumstances, this does not apply to size/date discrepancies when the ultrasound dating is clear.

Early Pregnancy Evaluation and Management of Early Pregnancy Complications

1. See [redacted] for specific standards related to the use of ultrasound.
2. Whenever a discrepancy exists between the findings on an ultrasound examination and the client's clinical history, the responsible clinician/physician should repeat the ultrasound procedure in order to confirm the initial findings.

Types of ultrasound that may be performed

1. First trimester
2. Second trimester
3. Limited — may be used for:
   - actual or potential emergencies, for example, if the woman is bleeding
   - for confirmation of IUP and gestational dating only

Personnel and Documentation

1. Only the following affiliate personnel may perform ultrasound for the purpose of pregnancy diagnosis and gestational dating:
   - Performance of ultrasound — non-licensed personnel, licensed nurses, clinicians, certified sonographers, physicians
   - Interpretation of ultrasound — physicians and clinicians
2. See Subsection VI, above, for specifics about the report.

Ultrasounds that must be referred — Ultrasound examinations that **must** be referred to a qualified radiologist or perinatal specialist and **must not** be performed at the affiliate:

1. Required 18–20 week prenatal ultrasound to assess fetal anatomy
2. Specialized ultrasound for known or suspected fetal abnormalities or other complications including nuchal translucency screening (See [redacted] for more information.)

Ultrasounds that may be performed at the affiliate

1. First trimester prenatal ultrasound
2. Standard second or third trimester prenatal ultrasound
3. Limited prenatal ultrasound (e.g. fetal heart tones are not audible with the doptone)

Personnel and Documentation

1. Only the following affiliate staff may conduct prenatal ultrasound after appropriate training and proctoring:
   - Performance of ultrasound — certified sonographers, radiologists and affiliate physicians with privileges in obstetrical ultrasound
   - Interpretation of ultrasound — radiologists or affiliate physicians with privileges in obstetrical ultrasound
2. See [redacted] above, for specifics about report.

IUC Insertion — Limited ultrasound may be used as an aid in inserting an IUC when palpation/confirmation of uterine position is difficult on bimanual exam.

IUC Localization — Limited ultrasound may be used as an aid in locating an IUC when the string is absent.

1. IUCs are echogenic. The presence of an intrauterine IUC on ultrasound excludes expulsion or translocation into the abdomen.
2. The absence of an intrauterine IUC could be due to expulsion or translocation. In this circumstance, further evaluation is required by a physician — either in the affiliate or by referral.
3. See [redacted] for more information on IUC localization.

Personnel and documentation

1. Only the following affiliate personnel may provide ultrasound for the purpose of IUC localization:
   - Performance of ultrasound — licensed health professional, certified sonographer, radiologist, or affiliate physician privileged in ultrasound for IUC localization
   - Interpretation of ultrasound — radiologist, affiliate physician privileged in ultrasound for IUC localization
     - When confirmation of an <u>intrauterine</u> IUC is made by ultrasound, interpretation may be done by clinician who is privileged in ultrasound interpretation for IUC localization.
2. See [redacted] above, for specifics about report.

Required Approvals — Only affiliates approved for Level II (Expanded Office) GYN and/or Level III (Expanded Surgical) GYN may provide on-site ultrasound for gynecologic conditions.

Referral — When a more comprehensive ultrasound is indicated, the client **must** be referred to an out-of affiliate radiology service for performance and interpretation of the ultrasound.

Transvaginal Probe — If possible, transvaginal probe is preferred for structures within the focal range of the vaginal probe. For structures outside of this range, a transabdominal

ultrasound is required.

Personnel and Documentation

1. Only the following affiliate personnel may provide gynecological ultrasound examinations:
   - Performance of ultrasound — affiliate-employed certified sonographers, affiliate-employed certified radiologists or affiliate physicians privileged in the performance of gynecologic ultrasound
   - Interpretation of ultrasound — Affiliate personnel interpreting and providing final reports for gynecologic ultrasound **must** be:
     - Affiliate-employed certified radiologists
     - Affiliate physicians with the following qualifications:
       - Completion of a United States OB/GYN residency which included at least 300 ultrasounds
       - Other physician with at least 16 hours of Cat I CME in basic and advanced ultrasound, and documentation of a minimum of 100 ultrasounds, at least half being supervised by a physician competent in ultrasound
       - Those physicians who in their practice of medicine have completed 16 hours of Category I CME in basic and advanced ultrasound and have performed and interpreted at least 300 pelvic ultrasounds.
2. See [redacted] above, for specifics about the report.

In addition to those situations specified elsewhere in this section, referral out of the affiliate for ultrasound evaluation or other evaluation and management is required for:

1. poor visualization of anatomical structures with the affiliate ultrasound
2. suspected placenta accreta or percreta in second or third trimester
3. a visualized or suspected complex adnexal mass
4. known malignancy
5. suspected malignancy based on affiliate sonogram

This page has been left blank intentionally.

Ultrasound may be required as part of a variety of affiliate services. Service approval is not required.

Performance vs. Interpretation of Ultrasound

1. Performance of the ultrasound is the act of doing the examination — taking the measurements, creating a printed image, and reporting the findings for interpretation.
2. Interpretation of the ultrasound is reviewing the findings, providing an impression or conclusion, and approving and signing the final written report.

Client Viewing of Ultrasound Images — Any client who undergoes an ultrasound at the affiliate **must be** offered the opportunity to view the ultrasound image.

1. Clients who request a copy of the ultrasound image should be accommodated whenever possible.
2. See [redacted] Documentation, below.

> **FYI — Practice Guidelines**
>
> In 2004 and 2007, the American Institute of Ultrasound in Medicine (AIUM), the American College of Radiology (ACR), and the American College of Obstetricians and Gynecologists (ACOG) published practice guidelines for the performance of pelvic and obstetric ultrasound, respectively. The types, indications and components of ultrasound as outlined in these guidelines is incorporated into this document.

[redacted] DOES NOT PERFORM PELVIC ULTRASOUND EXCEPT FOR POST MEDICAL ABORTION FOLLOWUP

1. Indications – include but are not limited to
   - Evaluation of Level I gynecological conditions including pelvic pain, abnormal uterine bleeding, amenorrhea [redacted]
   - Evaluation of Level II gynecological conditions such as structural abnormalities [redacted]
   - Evaluation and management of of Level III gynecological conditions [redacted]
   - IUC Localization [redacted]
   - Evaluation of postmenopausal bleeding [redacted]
   - Provision of basic infertility services [redacted]
   - Provision of expanded infertility services [redacted]
2. Components – depending upon reason for ultrasound, the following structures should be evaluated as indicated
   - Uterus

4. anatomic areas scanned
5. normal findings and/or abnormalities
6. diagnostic Impression
7. specific findings related to the purpose of the exam (e.g., intrauterine gestation/size, number, IUC)
8. comparison with previous ultrasounds for the same condition, if applicable

Clients and Ultrasound Images — Documentation in the client record **must** include that the client was offered the opportunity to see her ultrasound, her response to the offer, and whether she was given a copy of the ultrasound image.

FYI — Options for viewing the ultrasound

Affiliates have shared that they most commonly offer women the option to view the ultrasound in one of two ways — a direct question to the client or indirectly as part of the client intake form. Either way is acceptable.
document that the option was offered, whether or not the client chose to view the image, and that it was shown to her (if applicable).

Client preferences:
Do you want to see the ultrasound? ____Yes ____No
Do you want to know if there is more than one pregnancy? ____Yes ____No

If the client indicates yes to either question, the record can simply have a checkbox:

____Client shown ultrasound image
____Client given a copy of the image
____Client informed of multiple pregnancies

Prior to the Performance of Ultrasound — The Request for Medical Services or the Request for Surgery or Other Special Services/Procedures **must** be signed or already present in the client's record.

Limitations of the Ultrasound — The client **must** be informed of the limitations of the ultrasound being performed. For example, an ultrasound for pregnancy dating only would not be evaluating fetal anatomy:
1. Information may be given verbally.
2. It **must** be documented in the client's medical record that the information was given.

Referral out of the affiliate for ultrasound evaluation or other evaluation and management is required for
1. when a more comprehensive ultrasound is indicated

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Plan of Correction to Complain

ID Prefix Tag: T2114

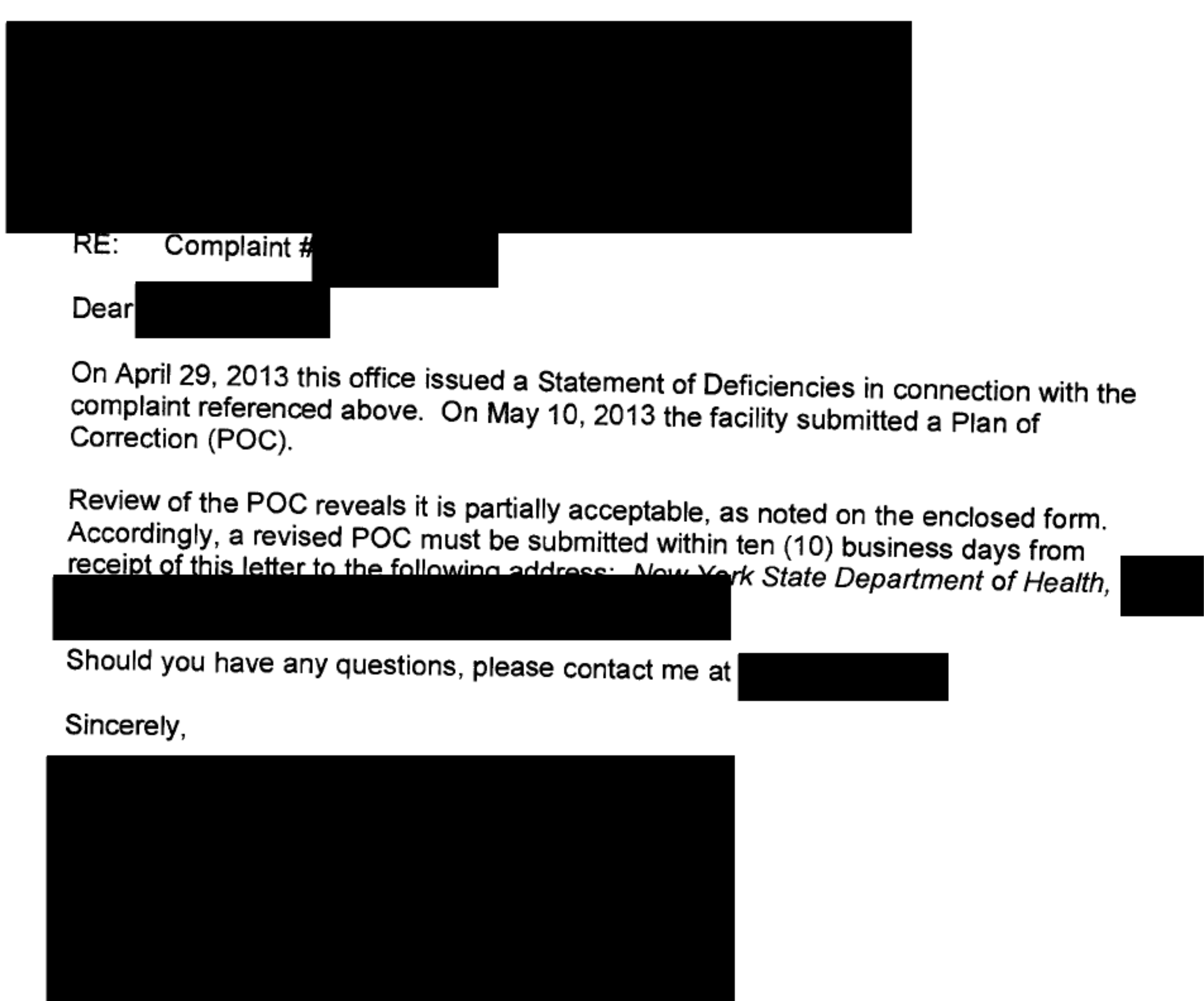
Statement of Deficiency	Plan of Correction	Implementation and Monitoring
The MR for Patient A lacks complete information regarding an that wa during an emergency, (se pertinent findings in T 2008)		Managers to conduct Emergency drills and audit every 6 months with a report to ommittee
Also, the US reports in Patients A's and other patient's lack complete information and legible signatures., (see the findings in tags T2008 and T2056)	Please refer to T2008 and T2056	Please refer to T2008 and T2056

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

August 23, 2013



RE: Complaint #

Dear

On April 29, 2013 this office issued a Statement of Deficiencies in connection with the complaint referenced above. On May 10, 2013 the facility submitted a Plan of Correction (POC).

Review of the POC reveals it is partially acceptable, as noted on the enclosed form. Accordingly, a revised POC must be submitted within ten (10) business days from receipt of this letter to the following address: *New York State Department of Health,*

Should you have any questions, please contact me at

Sincerely,

COMPLAINT
STATEMENT OF DEFICIENCIES ISSUED ON APRIL 29, 2013
RESPONSE TO THE PLAN OF CORRECTION DATED MAY 10, 2013

Corrective action(s) are developed to fix/address the identified cause of the deficient practice cited and to prevent recurrence of that deficient practice.

Monitoring plans involve mechanisms or processes you will use to evaluate in a timely manner whether or not the corrective actions are effective, i.e., the plan must describe actions (steps) that will be taken by specified individuals (identified by position/title) soon after corrective actions are completed, and then periodically, to determine if they are working.

KEY:

ACOG = American College of Obstetricians and Gynecologists
ACR = American College of Radiology
AIUM = American Institute of Ultrasound in Medicine
US = Ultrasound
POC = Plan of Correction
P&P = Policy and Procedures

TAG #	CITATION	FINDING	COMMENTS/REQUIREMENTS
T 2008	751.2 ORGANIZATION AND ADMINISTRATION (b) Operator	PARTIALLY ACCEPTABLE	The revised POC must: - include a revised P&P which addresses the following: • a requirement that US reports include all obtained during the procedure and, when repeat US is advised, a clear explanation of why the repeat US is necessary; and • a requirement that final reports in patients' medical records include an official interpretation by a physician.

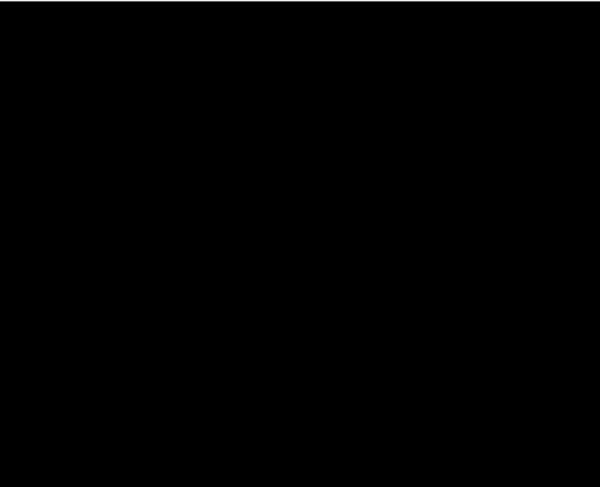
TAG #	CITATION	FINDING	COMMENTS/REQUIREMENTS
			(NOTE: This is required by the nationally recognized AIUM in its Standards and Guidelines for the Accreditation of Ultrasound Practices, dated 11/5/11. In this document the AIUM specifically states, "The rendering of a final diagnosis of ultrasound studies represents the practice of medicine and, therefore, is the responsibility of the supervising physician."); - include a written P&P describing equirements and process for training and credentialing sonographers; - include a revised which includes provisions for recording the following information (as required by the ACR-ACOG – AIUM Practice Guideline for the Performance of Obstetrical Ultrasound, last revised 2007):

TAG #	CITATION	FINDING	COMMENTS/REQUIREMENTS
			- include description of the corrective action used to
			- include a revise
			1)
			2)
			3)
			- describe a specific frequency for audit/inspection of the emergency cart and contents (e.g., monthly and after each procedure), and indicate the inspections will be documented;
			- indicate that P&Ps no longer in effect will be removed from circulation and all staff will be informed when this happens; and
			- indicate that staff competencies in the performance of checks, and will be evaluated during orientation and documented.

COMPLAINT
STATEMENT OF DEFICIENCIES ISSUED ON APRIL 29, 2013
RESPONSE TO THE PLAN OF CORRECTION DATED MAY 10, 2013

TAG #	CITATION	FINDING	COMMENTS/REQUIREMENTS
T2056	751.5 ORGANIZATION AND ADMINISTRATION (a)	PARTIALLY ACCEPTABLE	See Comments / requirements under Tag 2008 regarding US services, training, credentialing and reports.
T 2114	751.7 ORGANIZATION AND ADMINISTRATION (d)	NOT ACCEPTABLE	The revised POC must: - describe how the facility will ensure all documentation in medical records is legible.

For all tags referenced above, describe timely monitoring plans for evaluating the effectiveness of the corrective actions submitted. (Please see description of Monitoring Plans at the beginning of this document.)



Copy
2nd POC

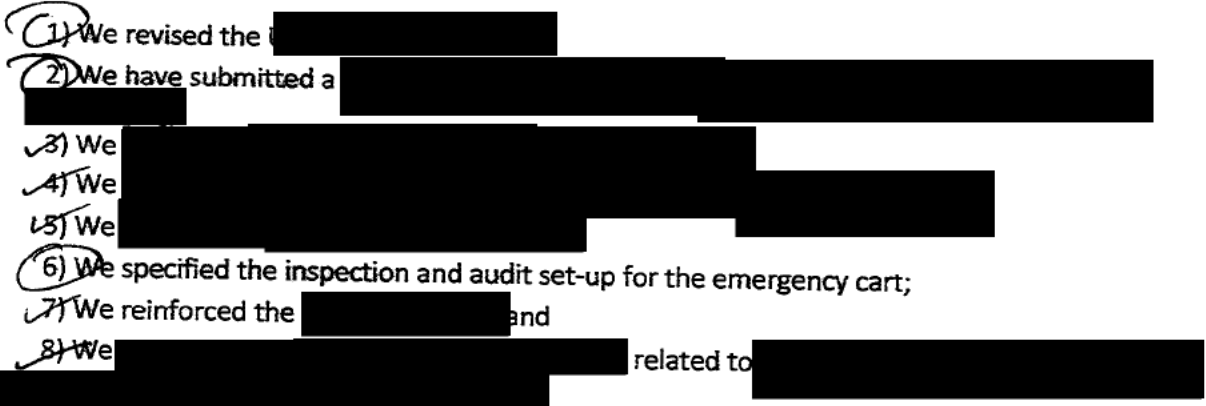
September 6, 2013

Re: Complaint #

Dear

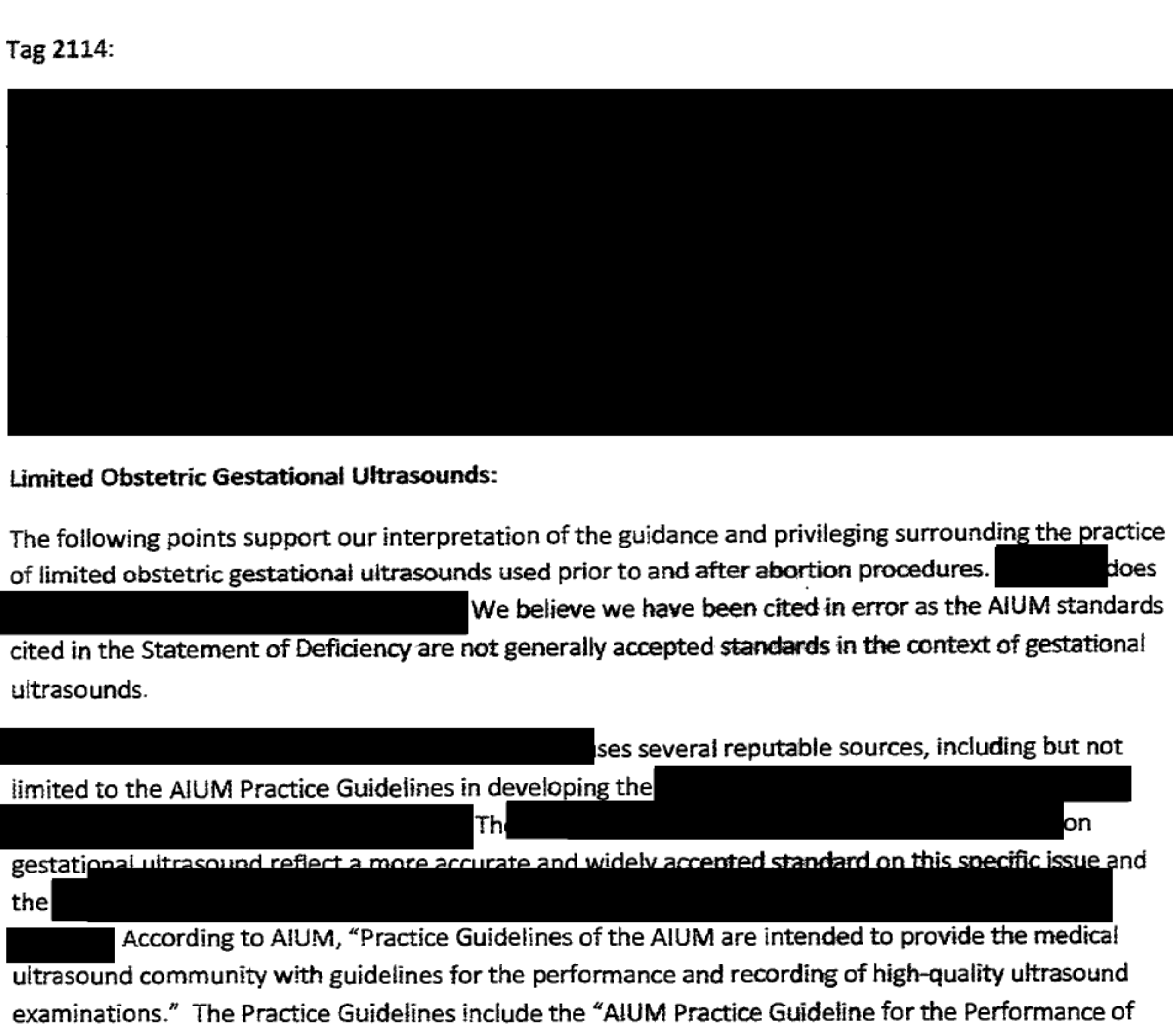
In response to your letter of August 23, 2013, we have made revisions to the plan of correction related to the subject complaint. You will find in the attached file the following changes in policies and procedures and forms. We also respectfully offer a response to the question you raised about which level of clinical staff can interpret gestational ultrasounds and the AIUM guidelines.

Tags 2008 and 2056:



1) We revised the
2) We have submitted a
3) We
4) We
5) We
6) We specified the inspection and audit set-up for the emergency cart;
7) We reinforced the and
8) We related to

Tag 2114:



Limited Obstetric Gestational Ultrasounds:

The following points support our interpretation of the guidance and privileging surrounding the practice of limited obstetric gestational ultrasounds used prior to and after abortion procedures. does We believe we have been cited in error as the AIUM standards cited in the Statement of Deficiency are not generally accepted standards in the context of gestational ultrasounds.

ses several reputable sources, including but not limited to the AIUM Practice Guidelines in developing the Th on gestational ultrasound reflect a more accurate and widely accepted standard on this specific issue and the According to AIUM, "Practice Guidelines of the AIUM are intended to provide the medical ultrasound community with guidelines for the performance and recording of high-quality ultrasound examinations." The Practice Guidelines include the "AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations" which does not state who can and cannot interpret ultrasound. The "Standards and Guidelines for the Accreditation of Ultrasound Practices" which goes into some detail about who can interpret ultrasound, is not a practice guideline. It is the rules around which an Ultrasound Practice can become accredited by AIUM. Many office-based practices are not accredited by AIUM. These AIUM guidelines recognize that "deviations from the guideline will be needed in some cases depending on patient needs and available equipment." Moreover, an approach that differs from the guidelines, standing alone, does not necessarily imply the approach is below the standards of care.

We submit that the are an acceptable protocol. A review of the

The [redacted] outlined in [redacted] inserted on the following page) states that physicians and clinicians can interpret ultrasound for the purpose of abortion. Only physicians may interpret prenatal ultrasound [redacted] **does not** perform [redacted] We agree fully that advanced practice staff need appropriate training, proctoring, as well as privileging and we have clarified our policy and procedure related to training and privileging as noted above.

The [redacted] states:

- Licensed staff
  - May perform and/or interpret ultrasound examinations. See [redacted] below, for information on which licensed staff may perform and interpret ultrasound for specific services.
  - Must be granted clinical privileges to perform and/or interpret ultrasound. Clinical privileges should include separate categories for performing and interpreting each type of ultrasound listed.

Type of Service	**[illegible] who may perform**	[illegible]
▪ Other Gynecologic Conditions (Levels 1,2, 3) [redacted] A-1) ▪ Menopause [redacted] ▪ Infertility (Levels 1, 2) [redacted]	▪ certified sonographers ▪ certified radiologists ▪ affiliate physicians	▪ certified radiologists ▪ affiliate physicians with the following qualifications o completion of a United States OB/GYN residency which included at least 300 ultrasounds OR o completion of at least 16 hours of Cat I CME in basic and advanced ultrasound, and documentation of a minimum of 100
▪ IUC localization [redacted]	▪ licensed health professional ▪ certified sonographer ▪ radiologist	▪ radiologist ▪ affiliate physician When confirmation of an intrauterine IUC is made by ultrasound, interpretation may be done by clinician
▪ Abortion (Sections [redacted] ▪ Early Pregnancy Evaluation ([redacted]	▪ non-licensed personnel ▪ licensed nurses ▪ clinicians ▪ certified sonographers ▪ physicians	▪ clinicians ▪ physicians
▪ Prenatal Care [redacted]	▪ certified sonographers ▪ radiologists ▪ affiliate physicians	▪ radiologists ▪ affiliate physicians

[redacted]s devoted to providing the full range of reproductive health services in the [redacted] to our community where the needs are great. Towards this end, we believe the revisions we have made in our policies and procedures and forms and the standards and guidelines we follow related to interpretation of ultrasound are responsive to the concerns raised in the complaint.

Should you have any questions or comments on the material we have submitted please do not hesitate to contact me.

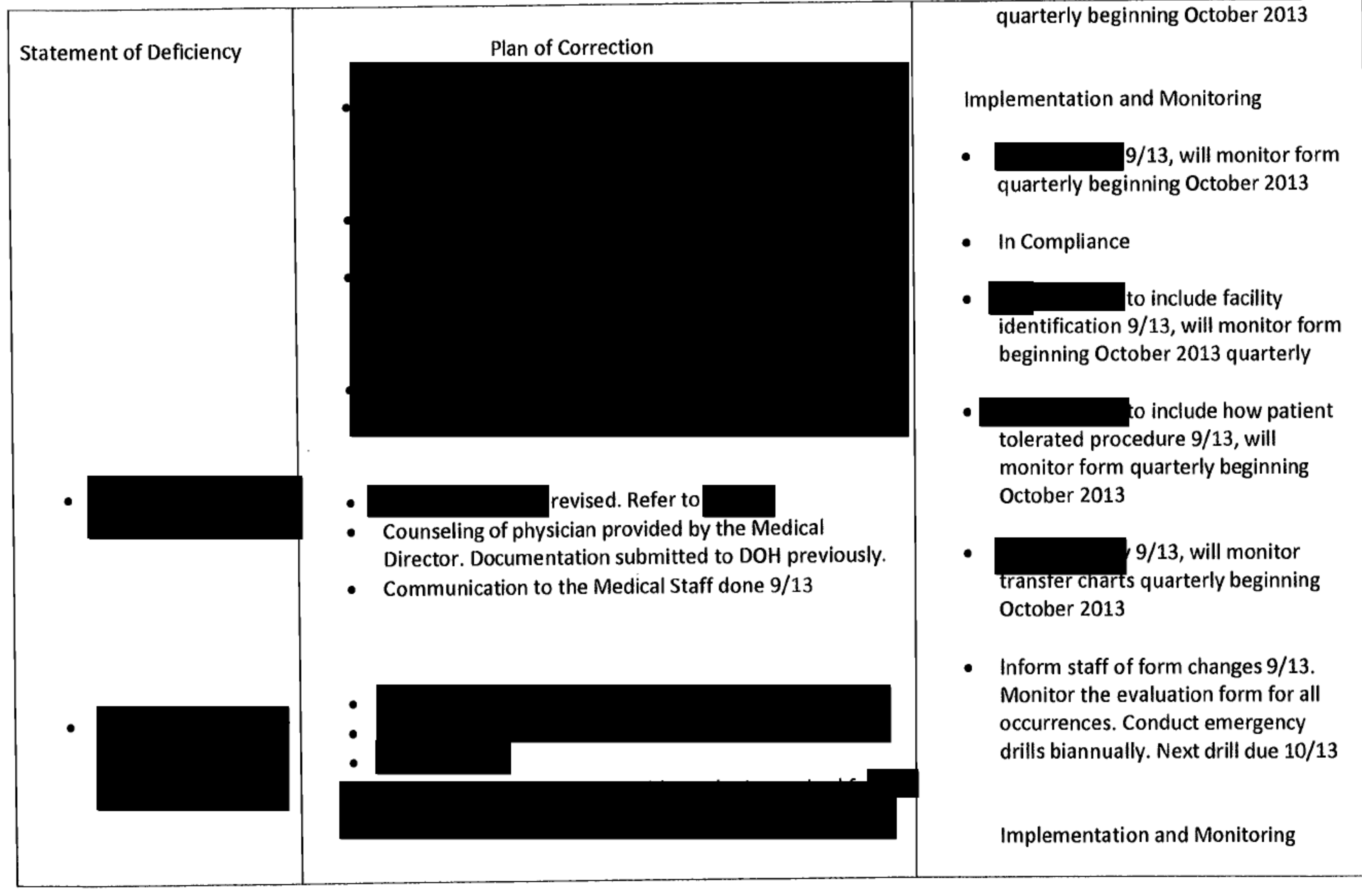
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint:

ID PREFIX TAG: T 2008

Statement of Deficiency	Plan of Correction	Implementation and Monitoring
• Requirement that US reports include all measurements • Documentation of repeat US	• Refer to pages • Refer to page	• has been following measurement guidelines per policy • Revision to policy 9/13, Lead clinician and Medical Director will monitor repeat scans quarterly beginning October 2013
• Interpretation of US images	• AIUM provides guidelines that are not intended to establish legal standards of care. s not required to be AIUM accredited. is in compliance by adhering to the established policy for interpretation of US images. Refer to	• In compliance
• Training and Credentialing	• Training of sonographers is stated in the Refer to page US policy revised to include credentialing of sonographers. Refer to	• Credentialing of sonogram privileges for providers is being presented and granted by the Board of Directors. In compliance. Will monitor as each new provider is granted privileges. • In compliance
•	• •	• Inform staff of form changes 9/13. 9/13, will monitor form

Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint

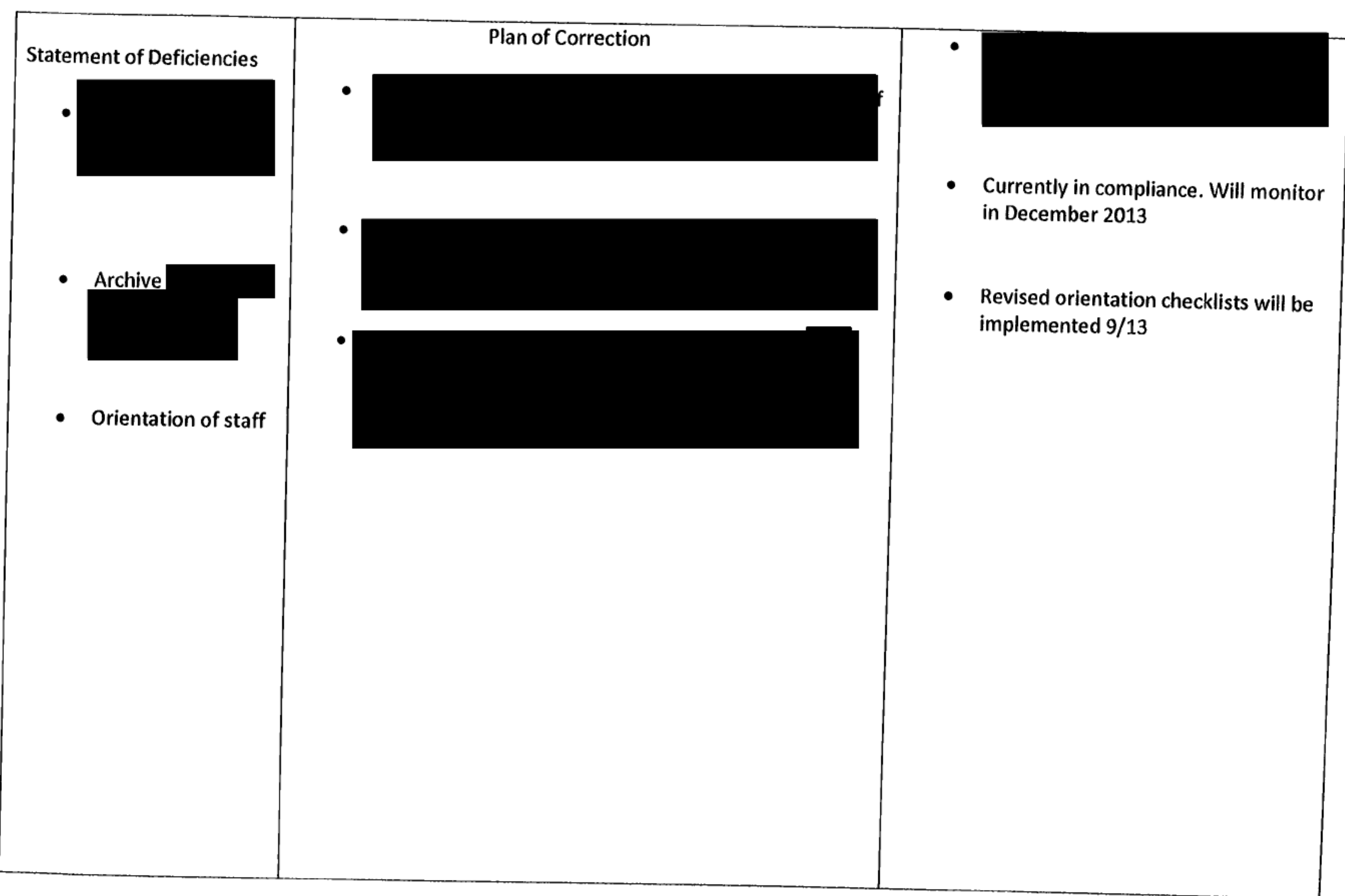
ID PREFIX TAG: T 2008



Statement of Deficiency	Plan of Correction	
		quarterly beginning October 2013
	• • • •	Implementation and Monitoring • 9/13, will monitor form quarterly beginning October 2013 • In Compliance • to include facility identification 9/13, will monitor form beginning October 2013 quarterly • to include how patient tolerated procedure 9/13, will monitor form quarterly beginning October 2013
•	• revised. Refer to • Counseling of physician provided by the Medical Director. Documentation submitted to DOH previously. • Communication to the Medical Staff done 9/13	• 9/13, will monitor transfer charts quarterly beginning October 2013
•	• • •	• Inform staff of form changes 9/13. Monitor the evaluation form for all occurrences. Conduct emergency drills biannually. Next drill due 10/13 Implementation and Monitoring

Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint

ID PREFIX TAG: T 2008



Statement of Deficiencies	Plan of Correction	
•	•	•
		• Currently in compliance. Will monitor in December 2013
• Archive	•	
• Orientation of staff	•	• Revised orientation checklists will be implemented 9/13

Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint:

ID PREFIX TAG: T 2008

Plan of Correction in Response to Statement of Deficiencies issued on August 23,2013
Regarding Complaint: [redacted]

ID PREFIX TAG: 2056

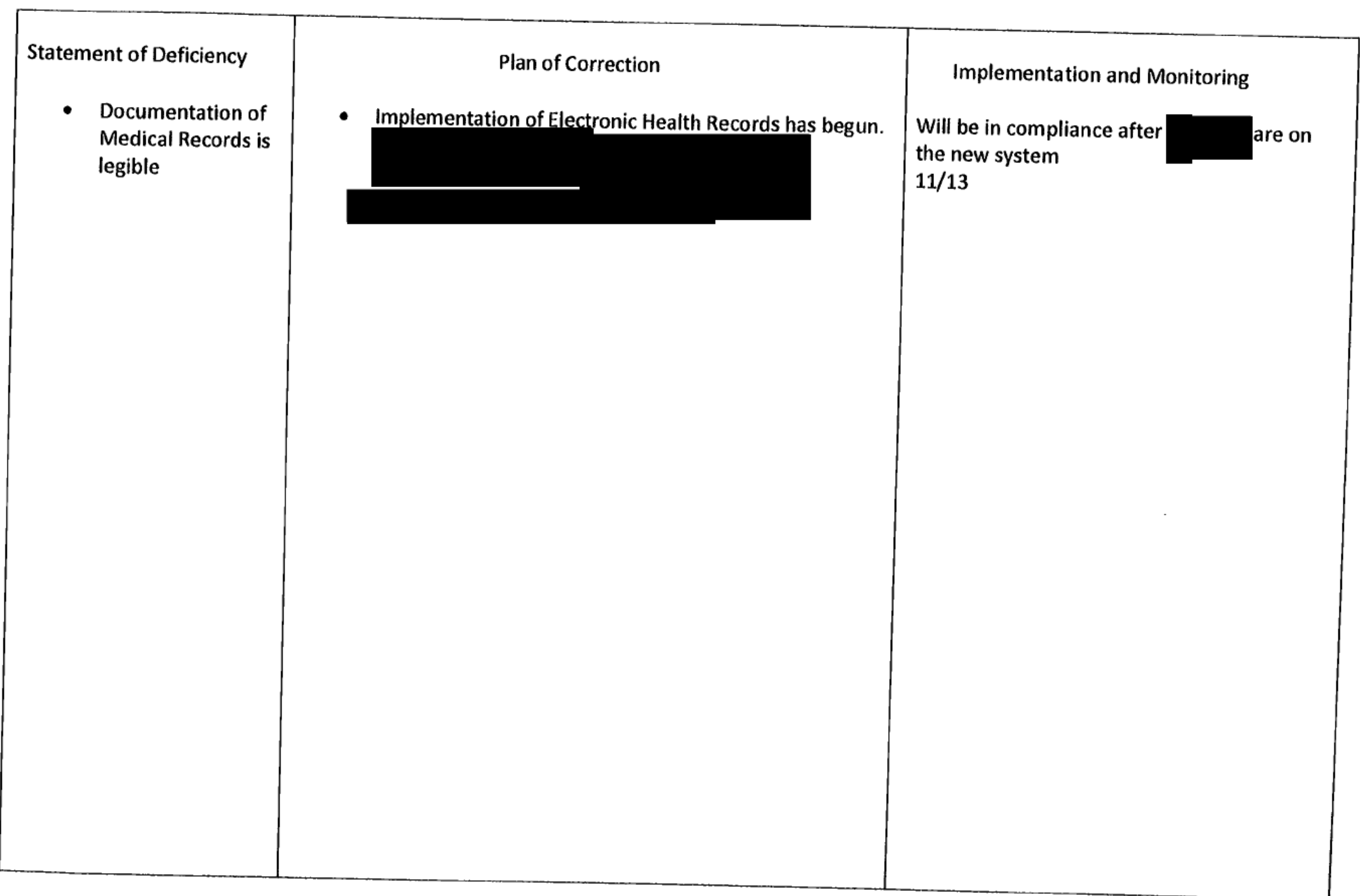
Statement of Deficiency	Plan of Correction	Implementation and Monitoring
• US services training, credentialing and reports	• Refer to Tag 2008	• Refer to Tag 2008

Plan of Correction in Response to Statement of Deficiencies issued on August 23,2013
Regarding Complaint

ID PREFIX TAG: 2056

Plan of Correction in Response to Statement of Deficiencies issued on August 23,2013
Regarding Complaint:

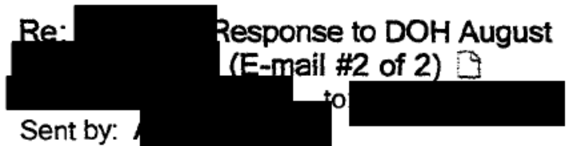
ID PREFIX TAG: 2114



Statement of Deficiency	Plan of Correction	Implementation and Monitoring
• Documentation of Medical Records is legible	• Implementation of Electronic Health Records has begun.	Will be in compliance after are on the new system 11/13

Plan of Correction in Response to Statement of Deficiencies issued on August 23,2013
Regarding Complaint

ID PREFIX TAG: 2114



Re: Response to DOH August 24, 2013 Request: Complaint (E-mail #2 of 2)

to 09/09/2013 10:07 AM

Sent by:

Received - thank you!

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

Attached are the additional materials r... 09/06/2013 04:31:37 PM

Response to DOH August 24, 2013 Request: Complaint (E-mail #2 of 2)

to: 09/06/2013 04:31 PM

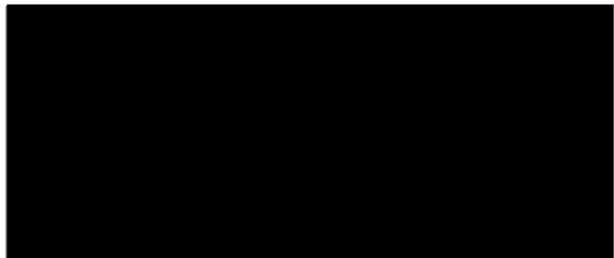
Cc:

Attached are the additional materials requested. Please confirm receipt.

Many thanks,

DOH Response.zip

December 5, 2013

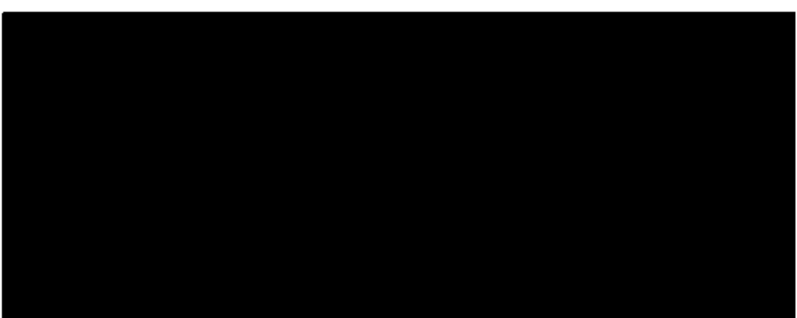


Dear

This note is to submit as requested the documentation related to Plan of Correction #2, Addendum #2. Including materials related to Tag # 2008 and Article 28 survey.

Please do not hesitate to call me with any questions or comments on the materials submitted.

Sincerely,



Document Index for POC #2, Addendum#2

1. Cover Letter

2. [redacted]

3. T2008 Monitoring plan revised to include more comprehensive monitoring

4. [redacted]

5. [redacted]

6. Plan of Correction for Infection Control Program: plan has been revised to include more comprehensive and intensive monitoring of program

7. [redacted] revised to include [redacted]

8. [redacted]

9. [redacted]

Nirav R. Shah, M.D., M.P.H.
Commissioner

NEW YORK
state department of
HEALTH

Sue Kelly
Executive Deputy Commissioner

January 13, 2014

RE: Complaint

Dear

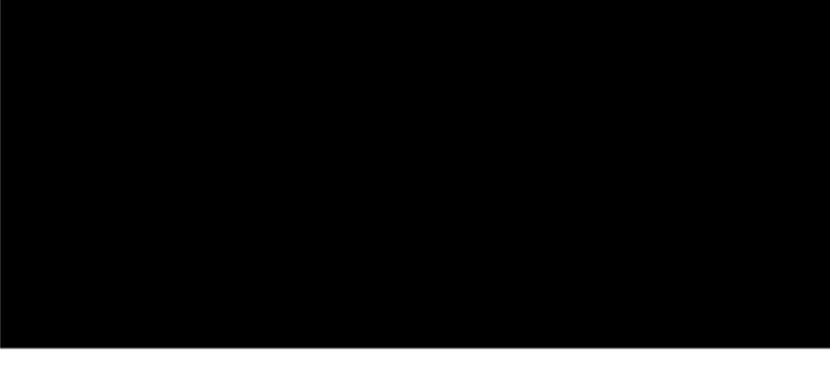
On April 29, 2013 this office issued a Statement of Deficiencies in connection with the complaint referenced above. On May 10, 2013 the facility submitted a Plan of Correction (POC).

On August 23, 2013 this office responded that the POC was only partially acceptable. On September 6, 2013 the facility submitted a second POC. Addendum to the second POC were submitted on November 6, 2013, December 15, 2013, and January 3, 2014.

Review of the Second POC reveals it is acceptable, as noted on the enclosed form. Please continue implementation of the plan as this office will monitor compliance during future surveillance activities.

Should you have any questions, please contact me at

Sincerely,



COMPLAINT
STATEMENT OF DEFICIENCIES ISSUED ON APRIL 29, 2013
RESPONSE TO THE PLAN OF CORRECTION DATED MAY 10, 2013
AND ADDENDUM DATED NOVEMBER 6, 2013, DECEMBER 15, 2013 AND JANURARY 3, 2014

TAG #	CITATION	FINDING	COMMENTS/REQUIREMENTS
T 2008	751.2 ORGANIZATION AND ADMINISTRATION (b) Operator	ACCEPTABLE	
T2056	751.5 ORGANIZATION AND ADMINISTRATION	ACCEPTABLE	
T 2114	751.7 ORGANIZATION AND ADMINISTRATION	ACCEPTABLE	

Plan of Correction for T 2008
POC #2 Addendum #2
December 5, 2013

Objectives	KEY ACTION/Compliance Goal	Monitoring Plan	RESPONSIBLE STAFF	COMPLETION DATE
A. Meet required components for measurement of	A. Reviewed required components with staff who perform/interpret US 5 scans per quarter following completion of the initial 20 scan training, will be sent to the US Program Director for review. Compliance Goal: 100%	A . Staff performing US will send 5 scans quarterly to the US Program Director for review. The US Director will review any deviations from the required components with the staff member. If additional training is identified, direct proctoring will be implemented by credentialed provider. (This applies to Letter C as well)	A. US Program Director	A. Quarterly With no end date Increased the frequency of quarterly submissions 10/13
	Compliance Goal: 100 %	B.Will review charts for repeat scans to determine compliance quarterly. Noncompliance will be reviewed with the staff and reported to the Committee.	B. Lead Clinician and Medical Director	B. Quarterly With no end date Implement: 10/13
C. Meet requirements for Training and Credentialing to Perform/ Interpret	C.All staff who begin to train for US will be proctored under direct supervision of a credentialed US provider and submit 20 scans to the US Program Director for review. After staff have been credentialed to perform US, they will submit 5 scans quarterly to the US Program Director for review. Compliance Goal: 100%	C.The US Program Director will review 20 scans to determine and recommend credentialing to the Board of Directors for US privileges. The US Program Director will review 5 scans quarterly for credentialed staff. The VPPS and the Lead Clinician will review the documentation that 20 scans were submitted and then 5 scans quarterly after credentialed. Noncompliance will be reported to the Committee.	C. US Program Director, VPPS and Lead Clinician	C. Quarterly With no end date Increased the frequency of quarterly submissions 10/13
D. Meet requirements for documentation on the		D. and staff education provided. Quarterly chart audits will be performed and noncompliance will be	D. Lead Clinician	D. Quarterly With no end date Implemented

	Compliance Goal: 100%	reviewed with the staff and reported to the Committee.		9/13