

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 7/17/2017-8/18/2017* FEI NUMBER 1525965
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lakshmi N. Gudapakkam , Business Leader and Senior VP CT/AMI
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FIRM NAME Philips Medical Systems (Cleveland) Inc	STREET ADDRESS 595 Miner Rd
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44143-2131	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated and investigated where necessary.

Specifically, you are not adequately investigating complaints. For example:

A.) Out of 133,845 complaints received from July 2016-July 2017, 129,736 complaints were closed based only on the assigned HHM (hazard/harm) symptom code and not further investigated (97%). From January 2016 to present, there were 3,623 complaints (representing 33 HHM symptom codes) that received a low HHM severity level of (b) (4) (less than moderate or no injury), but had a high RMM (risk matrix) severity level (b) (4) potential serious injury or (b) (4) potential death).

Of these 3,623 complaints, 1,792 should have been escalated based upon your "Service Record Reviewer Team (SRRT) Monitoring Work Instruction", #CNV-073105-01 and forwarded to the Complaint Handling Unit (CHU) for further investigation.

Additionally, a query of complaints from Feb 2014 to present for HHM codes related to rescan or reinjection of patients found that codes which meet the criteria for escalation are not always forwarded to the CHU. For example:

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- There were 104 complaints with HHM symptom code (b) (4)
Only 51 of these complaints (49%) were actually escalated.

The remaining 1,831 complaints were closed with no further evaluation or investigation and no documentation explaining the reason no investigation was necessary.

The following are examples of complaints that were closed and not forwarded to the CHU:

- (1) Complaint #5161859, dated 2/24/16: BrightView SPECT imaging system: Table continued to move after letting go of buttons.
- (2) Complaint #5108381, dated 2/9/16: BrightView SPECT imaging system: Table is stuck and estop not working
- (3) Complaint #5176332, dated 2/29/16: SPECT Skylight: unrequested motion error on table
- (4) Complaint #4997407, dated 1/8/16: BR 16 Water: table is free floating
- (5) Complaint #6070916, dated 11/14/16: BrightView SPECT XCT: emergency stop switch "pinged off"

Out of the 1,831 complaints that were not further evaluated or investigated, there were 1,246 complaints that were related to table problems (68%). This data was not analyzed to determine whether further investigation is necessary or if potential corrective/preventive actions are necessary.

B.) The following complaints are examples of incomplete investigations that were escalated to the CHU:

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(b1) Complaint #6772839, dated 5/30/17: Ingenuity TF PET/CT imaging System: The user reported a reconstruction failure that resulted in a rescan and reinjection. The complainant stated that this is occurring monthly. The firm concluded that no MDR was required (based upon your Position Papers: “(b) (4)” dated 12/16/14 and “(b) (4)” dated 12/22/14) and is low risk, and thus no further evaluation or investigation is required and the issue will be monitored through trending. The same location reported this problem on 7/7/14 (Complaint #3139910) and on 7/8/2014 (Complaint #3141512). You stated that the defect was found to be a software defect and will be fixed internally in a future software update. You stated that this update is not planned to be released to the field until (b) (4) (estimated) as a mandatory software upgrade. This site still has not had any corrective action for this reconstruction issue. Since the RMM was deemed “Acceptable”, the issue was not forwarded to CAPA and not assessed by your Product Safety Committee (PSC) for potential Correction or Removal. From 1/22/2013 to present, you have received 22 complaints with the same failure mode.

(b2) Complaint #6700539, dated 5/11/17: Brilliance iCT imaging system. The user reported saving incorrect patient images. You investigated the issue by reviewing system log files. No issue was found and the complaint was closed. However, the complaint stated that engineering should be contacted for a deeper investigation. This was never done. Complaint was closed on 5/18/17 with no further action taken.

(b3) Complaint #6629122, dated 4/21/17: Ingenuity CT imaging system. A customer reported on the CT viewer 2 examinations of 2 different patients are mixed and is happening 2-3 times a year. Your FSE resolved the issue by restarting the host PC. The complaint was not investigated further and was closed based only the resolution of the customer complaint. The complaint was closed on 4/26/17.

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OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, the following are examples of how your complaint processing procedures ["Complaint Handling Standard Operating Procedure", #CNW-073103-00, and "Complaint Handling Work Instruction", #CNV-073103-05, "Service Record Reviewer Team (SRRT) Monitoring Work Instruction", #CNV-073105-01] are not complete and adequately established:

A.) Your procedures for entering complaints do not describe how and when failure codes are entered during the complaint process. You do not have any procedure that defines these failure codes. During complaint processing, you enter a HHM symptom code for all complaints, but only enter a failure code for those complaints that are escalated to the Complaint Handling Unit (CHU). Therefore, you have not entered failure codes for the 97% of complaints received since January 2016 (129,736 complaints).

- From January 1, 2016 to present you have 855 complaints that have received an "(b) (4)" failure code. The "(b) (4)" failure code defines the category of the complaint (i.e.: console, gantry, couch). The Tier 2 codes further defines the failure. These codes are used for data analysis and to determine if further actions are needed (i.e.: CAPA). In your recent "Complaint Trending Report June 2017", your top failure code for "Console Acquisition" was "(b) (4)". The "(b) (4)" code does not provide sufficient detail on what the defect was in order to analyze this data to determine if further action is necessary.

Additionally, there is no procedure on when to add a code or when an "(b) (4)" code should be further defined and additional codes added.

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B.) Your complaint procedures are not clear on when a complaint requires investigation and what level of investigation is needed. Section 5.1.1 of the Complaint Handling SOP states that the SRRT (Service Record Review Team) assigns symptom codes (also called HHM ID #). These codes are based on the severity of actual harm occurring, not the potential severity of the hazard. All HHM symptom codes which are assigned a severity level of "2" or greater are automatically forwarded to the CHU for further evaluation or investigation. Symptom codes assigned a severity of "1" (306 of 412 codes (74%)) are then divided into one of three categories: 1) close, no further evaluation, 2) close, no further evaluation but meets an escalation criteria (per "Service Record Reviewer Team (SRRT) Monitoring Work Instruction", #CNV-073105-01, Rev 05 dated 6/14/17 procedure) to be forwarded to the CHU, 3) forward to the CHU.

C.) Revision 04 of the SRRT Work Instructions (dated 11/12/2015) removed nine (9) HHM symptoms codes which required escalation to the CHU for further evaluation and investigation. These nine (9) codes included issues relating to: electric shock, patient leakage current, motorized movement issues or falling parts. Since 11/12/2015, there have been 4,251 complaints which were not escalated to the CHU for further evaluation or investigation because these codes were removed. You have no documented rationale why these codes were removed.

OBSERVATION 3

Procedures for corrective and preventive action have not been adequately established.

Specifically, you have not adequately established your "Corrective and Preventive Action Standard Operating Procedure", CNW-073100-00 Rev 08, dated 3/1/17. For example:

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A.) Complaints and non-conformances (QNs & CTUDTs) are only evaluated for potential corrective/preventive actions when an escalation criteria is met. These criteria are incomplete & vague and do not ensure consistent escalation of your data sources. For example:

(a1) Item #2 of section 4.3.3 states that one reason to escalate is because of a “*violation of an applicable regulation*”, e.g: 21 CFR 820. Most of your data sources would appear to meet these criteria, but have not escalated to a CAPA.

(a2) Item #4 defines another escalation criteria as: “*As a result of Product and Process Metrics Management*”. This “Product and Process Metrics Management Standard Operating Procedure” does not provide triggers on when a CAPA should be considered. For example:

Your data analyses (trending) does not contain sufficient information to allow consideration into your CAPA System. For example, your following two data analysis reports are not complete or adequate:

- Complaint Data Analysis: You only analyze the (b) (4) symptom codes and failure codes (by number of occurrences) for the (b) (4) for CAPA consideration per “Complaints Trending Work Instruction”. This is not based upon the risk level associated with the symptom or failure code, but only upon total numbers.

Your analysis of these (b) (4) complaints is not based upon an appropriate statistical methodology. You have not established acceptable levels for these (b) (4) codes or symptoms. For example, you base your decision to further evaluate issues based on a two standard deviation from the mean of occurrences over a (b) (4) period. Your statistical methodology allows for an upward trend in the mean value which may not trigger further action.

- Non-conformances (QN) Data Analysis: Your QN Trend Report (data gathered from June 2016-June 2017) does not include meaningful data that could generate corrective actions.

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For example, you assign “*cause codes*” for each QN per your “Nonconforming Product Control Standard Operating Procedure”, #CNW-073114-00, section 4.3.1.10. However, you do not use this data to monitor and analyze as a potential data source to CAPA.

This QN Trend Report noted an “(b) (4)” trend of “QN Closure Timeliness”. The documented action planned was “*Evaluate QNs for a path forward*”. There has been no further action taken. Your data analysis for the “Top System QN Descriptions” (compiled from a (b) (4)) indicated that there were “(b) (4)” trends found related to the iCT Systems and Ingenuity Systems. This was an upward trend of your (b) (4) QNs opened against these systems. You have not taken any actions to address these trends.

Additionally, you are not following your “Product and Process Metrics Management Standard Operating Procedure” section 4.1.1, in that you have not defined any “*Action/Alert limits*” for non-conformances that could trigger further action.

B.) In January 2017, you updated your “(b) (4) Quality Notification (QN) Material Review Board (MRB) Evaluation & Disposition Work Instruction, #CNV-073406-00, Rev 11 to remove a failure/occurrence metric for non-conformances which would trigger a CAPA Request. This metric was: “*Three or more similar component failures/occurrences in 30 days or six in six months*”. You do not have any documented rationale why this metric was removed and why it is no longer used as a CAPA trigger.

C.) The following CAPAs reviewed were not complete and were closed before adequate corrective actions were taken:

(c1) CAPA #3668989, dated 9/2/15: This CAPA was opened as a result of a complaint that reported: “*Brain CT data exhibited ring artifact which were initially misintepreteted as a brain hemmorage*”. An MDR #1525965-2012-00122 was submitted, dated 12/5/2012. The CAPA

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concluded that this is a known issue due to embrittlement of the (b) (4) within the (b) (4) (b) (4) over time due to long-term radiation exposure. You concluded in your CAPA investigation that this was an "acceptable" failure ((b) (4) 1) and no further product corrective actions were needed. You also concluded that the PM schedule was appropriate to detect these failures. However, your (b) (4) analysis conducted as part of the CAPA investigation found 59 similar complaints related to this issue. You have no documented rationale why these are acceptable even though you believe the PM schedule is adequate to detect this failure. After you closed the CAPA, you reran your data analysis on 8/11/17 for complaints and found from 2/4/16-8/11/17 that there were an additional 117 complaints related to this failure mode.

During the course of your CAPA investigation, you decided to open a SCAR because you found that your (b) (4) suppliers of the (b) (4) were using different control checklists for evaluating and repairing this part [SCAR, # (b) (4) , dated 1/27/16]. The CAPA was closed on 2/5/16 and the SCAR was closed on 2/29/16 with no further actions taken.

(c2) CAPA #4702449, dated 10/12/2015: This CAPA was opened due to "software anomaly escapes" relating to software versions 4.1.3 and 4.1.4. You concluded that after you implemented all your remediation corrective actions (1/2015), your complaint rate of software defects decreased by 60% and you closed the CAPA based upon "the premise that there was a statistical difference in the pre and post test groups". You did not investigate into the root cause why the defects were not caught during design and development or even what specifically changed in your remediation process that caused this improvement. After remediation activities were implemented in 1/2015, you reported 23 recalls related to software defects.

D.) From February 2014 to the present, you have reported to the FDA 30 recalls (all Class II) related to software defects and you concluded that the cause of these were due to "software design controls".

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You have not initiated any further corrective action to identify the problem with design controls and if your (b) (4) testing is adequate and robust enough to detect defects prior to market release. You have recalled every version of the 4.1.x software (4.1.0, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5 and 4.1.6) which is used on your iCT and Ingenuity CT imaging systems.

- This is a repeat observation from the FDA-483 issued on 1/28/2014.

OBSERVATION 4

Risk analysis is inadequate and is incomplete.

Specifically,

A.) Your firm uses a Hazard Harm Matrix (HHM) to determine if complaints originating from service orders (SOs) are forwarded to the complaint handling unit (CHU) for potential investigation. The HHM uses "symptom codes", based on actual events occurring, and only assigns a severity level (no probability).

Per your Risk Management Periodic Review procedures (CNW-073106-03, Rev 2), you perform an annual review of the Risk Management Matrix (RMM) and the HHM to confirm the hazards are aligned.

(a1) Data extracted from the 2016 Risk Management Periodic (b) (4) reviews for the Brilliance iCT and Ingenuity systems found 56 discrepancies between the HHM and RMM regarding the assigned severity levels. Thirty three (33) of the discrepancies were assigned an HHM severity of (b) (4) (less than moderate or no injury) and the associated RMM had assigned a potential severity of (b) (4) (serious injury) or (b) (4) (death). Twenty four (24) of the thirty three (33) symptom codes are not forwarded to the CHU for further evaluation or investigation.

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(a2) According to RMM-HHM Alignment (b) (4) all RMM hazards which have a severity of (b) (4) (serious injury or death), must have at least 1 HHM entry which would require escalation to the CHU (complaint handling unit). In the report, you concluded that this criteria was met. This inspection found 11 entries which did NOT have a corresponding HHM entry which would require escalation to the CHU.

(a3) It is unclear why some of the symptom codes which are assigned a severity level of (b) (4) are forwarded to the CHU and why some are not.

B.) A review of 36 complaint records and associated MDR files found:

(b1) Not all hazards associated with the complaints were identified in the records. Out of the 36 complaint/MDR files reviewed, 21 complaint files (representing 28 different hazards) did not have all the possible associated hazards. These hazards are used as part of your data analyses in order to initiate potential corrective/preventive actions. For example, complaint 2599340 only listed hazard 0266 2.11.11 (loose set screws holding the spline hub) as part of the file where hazard 0266 2.7.1.1 (uncontrolled up/down motion due to mechanical failure) is also applicable. Both hazards are assigned a potential severity of (b) (4) or serious injury.

(b2) Per your Senior Systems Engineer and Risk Management Procedures, the same hazard risk identification for similar systems should have the same risk factors. This inspection found that not all hazards associated with the 36 complaint files were fully aligned (potential severity and or probability) with similar imaging systems. There were a total of 75 hazards which were not (b) (4) implemented" to other systems. If properly aligned, you identified twenty three (23) hazards would now be considered "unacceptable" and would require further analyses/mitigation.

(b3) Not all complaint records had an associated RMM hazard assigned. Two complaints (numbers 2637836 and 4074943) had no associated hazard documented in the complaint file. This RMM

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assignment is used by the complaint handling unit to perform data analyses (trending) for possible corrective/preventive actions.

C.) According to your Risk Management procedure, CNW-073106-00, Rev 09, risk levels are assigned using severity and probability. To determine the residual probability in your Risk Management Matrix (RMM) documents, you (b) (4)

(b) (4) Therefore, if an actual injury has never occurred, you assign your (b) (4) The implication being that the number of occurrences (P1) for hazards which have an assigned (b) (4) value of (b) (4) will always be "0". No hazards with residual (b) (4) probability ratings ((b) (4) (b) (4), would result in an unacceptable risk level.

For example, your 2016 Periodic Review of Complaints & Human factors (b) (4), identifies 16 complaints in the past year regarding uncontrolled vertical couch motion. These complaints were identified as linked to RMM hazard number 2.7.1.1. with an assigned potential severity level of (b) (4) (serious injury: life threatening or permanent impairment). None of the complaints involved actual injury, as such, none counted towards the probability score.

➤ This is a repeat observation from the FDA-483 issued on 1/28/2014.

OBSERVATION 5

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

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CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44143-2131	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	

Specifically, your procedure, "Supplier Selection, Classification and Approval Standard Operating Procedure," CNW-140100-00, Revision 11, does not ensure control of your suppliers.

Your procedure states if a supplier is on probation, the Risk Assessment form must be completed. For example, Supplier A is a Class I (highest risk) contract manufacturer of your patient supports and partial gantry for the iCT and CT product lines. This supplier has been on probation since June 1, 2015 and a Supplier Risk Mitigation Form has been completed, per your SOP "Supplier Oversight and Monitoring Process Standard Operating Procedure," CNW-140101-00, Revision 11. However, this supplier currently has been issued 12 of (b) (4) of the open SCARs, spanning January 2016 to present, and 683 of (b) (4) of non-conformances, or Quality Notices, since 2016 were created for their products. Additionally, on May 27, 2016, you reported a recall to the FDA, where the root cause was found to be supplier controls over this supplier. Prior to that, this part has been recalled 3 times since February 2014, due to supplier controls over Supplier A.

- This is a repeat observation from the FDA-483 issued on 1/28/2014.

OBSERVATION 6

Procedures for acceptance of incoming product have not been adequately established.

Specifically, your "Receiving Inspection Plan (RIP) for (b) (4) , (b) (4) , Revision 02 and "Receiving Inspection Plan (RIP) for (b) (4) , Revision 02, is inadequate.

The (b) (4) is used to conduct receiving inspections for 82 of (b) (4) risk components, (b) (4) . The RIP includes only visual inspection, and verifying shipping and part numbers and the Certificate of Analysis. Additionally, at least (b) (4) of your suppliers

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 7/17/2017-8/18/2017*
		FBI NUMBER 1525965
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of the (b) (4) risk components, including Supplier A in Observation 5, are currently on probationary status and use the (b) (4) RIP. The partial gantry, a (b) (4) risk part on the (b) (4) RIP, from Supplier A had (b) (4) non-conformances, or Quality Notices, in 2016. (b) (4) of those Quality Notices were created during production, after passing receiving inspection.

The (b) (4) RIP is used to conduct receiving inspections for 223 (b) (4) (b) (4) risk components, which is your (b) (4) risk category. The RIP includes only visual inspection, and verifying shipping and part numbers and the Certificate of Analysis. There are no requirements for performing incoming testing or measurements. Additionally, at least (b) (4) of your suppliers of the (b) (4) risk components are currently on probationary status, including Supplier B, and use the (b) (4) Risk Class RIP. The (b) (4) system, an (b) (4) risk part on the (b) (4) RIP, from Supplier B had (b) (4) non-conformances, or Quality Notices, in 2016. All of these Quality Notices were created during production, after passing receiving inspection.

During the incoming inspection, I observed a receiving technician when receiving an Ingenuity Extended Patient Support from Supplier A. Per the receiving inspection plan, the receiving technician did not use the vendor specification "(b) (4)", (b) (4), to check 2 of (b) (4) Critical To Quality elements (CTQs) on the Certificate of Analysis from Supplier A.

OBSERVATION 7

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically,

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Your pFMEA work instructions, CNV-073143-01, Rev 6., describe inputs including post market data (associated defects, CAPA, complaints and service work orders) which are to be reviewed (b) (4) for potential pFMEA updates.

Your most recent annual review for the Ingenuity CT system ((b) (4)) pFMEA Review (b) (4), ((b) (4)) did not include complaints/post market data as a data source for the potential updates to the pFMEA.

OBSERVATION 8

Procedures for design change have not been adequately established.

Specifically, your procedure "Defect Management Standard Operating Procedure," CNW-030700-01, Revision 05, has not been adequately implemented. For example,

A.) Your process for handling duplicate Anomaly Reports is not clearly defined. Section 3.4, step 1.1 of your procedure states "Check For Duplicates... If a duplicate record is found skip this entry." However, there is no further definition of updating the duplicate record to include information about the recurrence of the anomaly report. Step 2.4, 7.3, 10.4 and 12.3 all outline the closing of records, if duplicates are found, but do not further define updating the duplicate record. You were unable to provide me with a procedure that defines this process, but your Senior Manager of the Systems Group stated it routinely occurs and is one of the methods for anomaly reports that have been postponed to be reopened and reinvestigated or fixed.

B.) Your Senior Manager of the Systems Group stated your History Review Technical Review Records use a time frame (b) (4) for considering ARs for inclusion in the software updates. However, there are currently 101 ARs not closed that were submitted earlier than (b) (4), which would not be considered for inclusion in a software update.

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C.) Your firm currently uses the terms "Anomaly Report" and "Provisionally Unacceptable." However, neither of these terms are adequately defined in this procedure.

OBSERVATION 9

The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting.

Specifically, your "Adverse Event Reporting Standard Operating Procedure", #CNW-073108-00 (MDR SOP) does not clearly define when malfunction events are reportable under 21 CFR 803. Section 4.3.2 of this procedure states if the malfunction did not cause or contribute to a death or serious injury, but could possibly cause or contribute to a death of serious injury if the malfunction were to recur, you have to "*Review Risk RMM*". There are no further procedures on what you are looking for in the RMM or what data in the RMM would require an MDR submission.

Additionally, your "Hazard Harm Matrix Standard Operating Procedure" #CNW-073107-01 states that the CHU is to utilize this HHM as guidance to assist with regulatory reporting. However, your Manager of the Complaint Handling Unit stated that you do not use the HHM to determine if an MDR is required. Also, your MDR SOP does not address the HHM or how it's used for regulatory reporting.

Annotations to Observations

Observation 1: Under consideration

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Observation 2: Under consideration

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Observation 3: Annotation Intentionally Left Blank

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Observation 4: Annotation Intentionally Left Blank

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Observation 5: Annotation Intentionally Left Blank

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Observation 6: Promised to correct

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Observation 7: Promised to correct

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Observation 8: Promised to correct by 12/22/2017

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 Observation 9: Promised to correct
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~~Promised to correct within 90 Days~~

***DATES OF INSPECTION**

7/17/2017(Mon),7/18/2017(Tue),7/19/2017(Wed),7/20/2017(Thu),7/21/2017(Fri),7/24/2017(Mon),7/25/2017(Tue),7/26/2017(Wed),7/27/2017(Thu),7/28/2017(Fri),7/31/2017(Mon),8/01/2017(Tue),8/02/2017(Wed),8/03/2017(Thu),8/04/2017(Fri),8/07/2017(Mon),8/08/2017(Tue),8/09/2017(Wed),8/10/2017(Thu),8/11/2017(Fri),8/14/2017(Mon),8/15/2017(Tue),8/16/2017(Wed),8/17/2017(Thu),8/18/2017(Fri)

X Laureen M Geniusz
Investigator
Signed By: Laureen M. Geniusz -S
Date Signed: 8/18/2017

X Christina L Bigham
Investigator
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