TABLE OF CONTENTS

SUMMARY (SLK) ..... 1
ADMINISTRATIVE DATA (SLK) ..... 2
HISTORY (SLK/BPP) ..... 3
INTERSTATE COMMERCE (SLK) ..... 4
JURISDICTION (SLK) ..... 5
INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (SLK) ..... 5
FIRM'S TRAINING PROGRAM (SLK) ..... 6
MANUFACTURING/DESIGN OPERATIONS (SLK/BPP) ..... 7
Design Controls (SLK) ..... 9
Corrective and Preventive Actions (SLK/BPP) ..... 9
Production and Process Controls (SLK) ..... 12
MANUFACTURING CODES (SLK) ..... 13
COMPLAINTS (SLK) ..... 13
RECALL PROCEDURES (SLK/BPP) ..... 13
OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (SLK/BPP) ..... 13
VOLUNTARY CORRECTIONS (SLK/BPP) ..... 25
REFUSALS (SLK) ..... 27
SAMPLES COLLECTED (SLK/BPP) ..... 27
ATTACHMENTS ..... 27
EXHIBITS ..... 27

## SUMMARY (SLK)

This preannounced baseline surveillance inspection of a medical device manufacturer of Diagnostic Imaging Workstations was conducted in accordance with the Los Angeles District FY 2009 work plan. The inspection utilized QSIT and CP7382.845 and is reported under FACTS Assignment ID 993867 and PAC 82845B. The key product code is 90L-Z. Profiles classes ELE, MTL, COH, COS, and SPD were covered. The firm does not manufacture any sterile or tracked devices.

The previous site Establishment Inspection was conducted by the State of California Food and Drug Branch in accordance with the state partnership on 10/12/2005 and was classified NAI. The previous USFDA inspection, conducted 06/7, 8, 10/04, was the initial inspection of the firm. That inspection resulted in issuance of an 8-item FDA-483. Deficiencies cited included: failure to appoint a

Management Representative; conduct and establish procedures for management review; conduct quality audits; provide adequate resources including assignment of trained personnel for management, performance of work, and assessment activities, including internal quality audits; implement quality system procedures; establishment procedures to control the design process of the device; establish controlled, approved procedures for manufacture, testing, packaging and labeling of the device; establish procedures to ensure DHRs are maintained to demonstrate the device is manufactured in accordance with the Device Master Record (DMR) and quality system regulations; establish a DMR; and develop MDR procedures.

The current inspection covered management controls, design controls, corrective and preventive actions, and production and process controls. In addition, follow-up was conducted to assess adequacy of corrective actions implemented by the firm in response to the prior FDA-483 citings. Records reviewed during this inspection included the firm's quality manual, standard operating procedures, service reports, employee training records, and Device History Records. A 7-item FDA-483 was issued at close of the inspection citing the firm for deficiencies including: 1) failure to establish document control procedures designating an individual to review documents for adequacy, approve them prior to issuance, develop a system for document distribution, and a system for document changes; 2) failure to establish complaint handling procedures; 3) incomplete corrective and preventive action procedures; 4) MDR procedures lack an internal system providing for a standardized review process/procedures for determining when an event meets the criteria for reporting, and for designating an individual responsible for investigating MDR events; 5) failure to appoint a management representative, and to define the frequency with which management review meetings are to be held; 6) procedures for identifying training needs were not complete and implemented; and 7) failure to identify valid statistical techniques needed for certain product analyses.

The firm's President stated that corrective action would be taken for each deficiency cited. She did not want the observations annotated but stated that she would instead respond in writing within (b) (4) (b) (4).

No samples were collected and no refusals were encountered during the inspection.

**ADMINISTRATIVE DATA (SLK)**

| | |
|---|---|
| Inspected firm: | Neo Imagery Technologies, Inc |
| Location: | (b) (4) |
| Phone: | 877-528-1698 |
| FAX: | 626-968-8116 |
| Mailing address: | 17128 Colima Road, Suite 888<br>Hacienda Heights, CA 91745 |

| | |
|---|---|
| Dates of inspection: | 4/23/2009, 4/29/2009, 5/1/2009 |
| Days in the facility: | 3 |
| Participants: | Sonya L Karsik, Investigator<br>Brian P. Putz, Investigator |

This inspection was conducted jointly by myself (SLK) and Investigator Brian P. Putz. We were both present on all days of the inspection. Sections of this report written by each of us are identified with our respective initials, SLK or BPP.

On 4-23-09, we presented our credentials and issued a form FDA-482, Notice of Inspection, to Ms. Tina Ting Ting Young, President and Owner of the firm.

A 7-item FDA-483 was issued at close of the inspection to Ms. Young. The FDA-483 was modified at the firm to make a correction.

**HISTORY (SLK/BPP)**

Ms. Young told us the firm was established in 1995 with the (b) (4) spent in product development activities. Ms. Young stated that the firm incorporated in California in 1996. However, the California Business Portal lists the firm being incorporated in California in 1995 with Tina Young as the agent for service of process. The firm's first 510(K) was cleared in July 1997 and a second 510(K), for the InSight Diagnostic Imaging Workstation was cleared in December 1998. The firm is a developer and manufacturer of software used to receive image files from medical scanning devices, such as Computed Tomography (CT) or Magnetic Resonance Imaging (MRI), and perform real-time viewing and image manipulation.

The firm's place of business was moved from their City of Industry, CA location to a location in Walnut, CA and subsequently to a private home in (b) (4) in June 2008. The firm's President stated that the entire home is devoted to the firm's business operations. The company is privately held. There are no related firms.

The firm employs a total of (b) (4) people including Ms. Young. (b) (4) employees are full-time and (b) (4) serves as a Regulatory Consultant. Hours of operation are (b) (4) (b) (4). There is no seasonal variation in hours. Annual sales were estimated at (b) (4)

The firm is registered as a medical device manufacturer with registration number (b) (4) (**exhibit 24**). The device registration and listing were reviewed and the address on the device registration is inaccurate and should list their current location in Hacienda Heights. The firm's President stated

that they are working with their regulatory consultant to have the correct address listed on the registration.

No regulatory actions have been taken against the firm.

Address official correspondence to:
Ms. Tina Ting Ting Young, President
Neo Imagery Technologies, Inc.
17128 Colima Road, Suite 888
Hacienda Heights, CA 91745

**INTERSTATE COMMERCE (SLK)**

Ms. Young stated that while the firm has previously distributed finished devices to (b) (4), (b) (4) and other customers located outside of California, no finished devices have been distributed in interstate commerce within (b) (4). However, Ms. Young stated that her firm continues to service products which have been sold and distributed outside of California.

Ms. Young stated that she purchases all components used in the manufacturing/assembly process in California. The majority of these components are imported by her vendors from (b) (4), but she stated that she makes an effort not to purchase components from (b) (4). She estimated that approximately (b) (4)% of components used in manufacture/assembly of the Imaging Workstations/software move interstate commerce.

The firm's two suppliers were identified as:

1. (b) (4)
2. (b) (4)

A supplier list with addresses is provided as **exhibit 23**.

Primary customers for the finished device are hospitals and MRI/CT Imaging Centers. There is no wholesale marketing of product.

Finished products are installed at customer's sites by the firm's service personnel.

Interstate documentation was not available at the firm (301k and 301a). See internal email in EIR attachments and affidavit collected from firm's President/Owner.

## JURISDICTION (SLK)

Neo Imagery Technologies, Inc. manufactures a Class II medical device; a diagnostic imaging workstation sold under the brand name Insight. This is the firm's only product. The diagnostic imaging work station was first cleared for distribution under 510(K) (b) (4) on July 3, 1997. At that time, the device was not classified by the U.S. FDA (**exhibit 1**). A second 510(K) for this device, 510(K) (b) (4), providing for volume rendering, was cleared on December 21, 1998. This device was classified into Class II – Special Controls (**exhibit 2**).

The Insight Diagnostic Imaging Workstation receives digital information from scanning devices such as Magnetic Resonance Imaging and Computed Tomography devices and manipulates image data for the purpose of image characterization, enhancement, communication, archiving and real-time 3-dimensional visualization. The product directions for use indicates that the system is designed as an aide to trained medical practitioners in the diagnostic process such as cardiac vessel calcification quantification, performing non-invasive diagnostic procedures via simulated endoscopy on patient images, and to measure distances in 3D reconstructed images of tumors.

Product labeling is provided as **exhibit 36a, 36b, 36c**. Advertising materials are provided as **exhibit 22**.

The firm does not have a product catalogue. The address of the firm's website is: http://www.neoimagery.com.

## INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (SLK)

This inspection was pre-announced to Ms. Tina Ting Ting Young, President and sole owner of the firm. All information contained within this report was provided to us by Ms. Young. The roles and responsibilities of the firm's personnel are as follows:

*Ms. Tina Ting Ting Young, President and Owner* – Ms. Young continues to be the most responsible person at the firm. She stated that she established the firm in 1995, and has held her current position at the firm since its inception. She earned B.S. degrees in biomedical engineering and electromechanical engineering, and a Master's degree in electrical engineering. Her day-to-day responsibilities include overseeing day-to-day operations at the firm, ensuring production of the firm's diagnostic imaging workstations when orders are received, taking customer orders, performing equipment demonstrations for potential customers, on-site device installation, field servicing, review and approval of device history records, and review and approval of internal operating procedures. Ms. Young said she is also responsible for handling service requests and

customer complaints, and she serves as the firm's Quality Assurance Supervisor. She has the authority to make hiring and firing decisions, and may make capital expenditures. Ms. Young has (b) (4) direct reports. Both the FDA-482 and FDA-483 were issued to her.

*Mr. Alexander D. Tong, Support Engineer (Technical Support)* – Mr. Tong has been employed at the firm for approximately 8 years. He studied electrical engineering through his junior year of college but did not earn a degree. He has 15 years experience working with computer hardware. His day-to-day responsibilities at the firm include on-site device installation at customer sites, providing technical support to customers, field service, and performing diagnostic work. Mr. Tong may not make hiring and firing decisions, and may not make capital expenditures. He does not have any direct reports. Mr. Tong reports to Ms. Young with dotted-line reporting to Mr. Michael Young. Mr. Tong was present throughout the inspection with the exception of the inspection close-out meeting.

*Michael T. Young, Vice President of Research and Development* – Mr. Michael Young, who serves as the firm's Technology Officer, began his employment with the firm in 2005. He assumed the responsibilities of (b) (6), who is no longer employed at the firm. Mr. Michael Young's responsibilities include overseeing software development. At each year-end, he participates in Management Review Meetings. He does not work in the office on a daily basis, but instead works remotely. He is responsible for product design. Mr. Young does not have authority to hire and fire personnel, and may not make capital expenditures. He reports to Ms. Tina Young. Mr. Young was not present during the inspection.

(b) (4)

The firm's Regulatory Consultant was identified as (b) (6).

(b) (6), *Vice President of Research and Development* – Ms. Young told us that (b) (6) (b) (6), who was previously responsible for product design, testing, and specification development, is no longer employed by the firm.

An organizational chart for the firm is provided as **exhibit 6.**

**FIRM'S TRAINING PROGRAM (SLK)**

The firm's training procedure, titled "Employee Training Procedure", revision A, dated 8-15-04, is provided as **exhibit 14**. The procedure applies to all personnel including production, quality and administrative staff. We noted that this procedure requires that receptionists, managers,

representatives, salespersons, and other employees likely to receive complaints be trained in complaint handling procedures applicable to their functions, however, the firm has not established a complaint handling procedure (**see FDA-483 item 6A and related exhibits**).

We reviewed employee training records and noted that Ms. Young, who told us that she also serves as the firm's Quality Assurance Supervisor, had not been trained in the firm's Quality Assurance Procedures or Quality System Instructions (**see FDA-483 item 6B and related exhibits**). Note that Ms. Young is responsible for training other employees in these procedures.

## MANUFACTURING/DESIGN OPERATIONS (SLK/BPP)

### Management Controls (SLK)

The firm has a Quality Policy and a "Statement of Commitment" which are both included within the Quality Manual. We reviewed the firm's Quality Manual, revision 100B, which was approved by the firm's President (b) (4) . The manual includes procedures for management review; internal audits, design control; control of purchased material; non-conforming articles; corrective action; final inspection and test; sampling inspection; and packing, shipping, preservation, and marking.

Per the firm's President, the dates shown in the Quality Manual Table of Contents are the effective dates for each of the documents contained within. We noted that all of the procedures contained within this manual were assigned effective dates before the quality manual was approved (b) (4) (b) (4).

In addition, we noted the following documents have no indication of document approval date and signature of approving official for the following documents: 1) QAP No. 9, titled Corrective Action (**exhibit 10**); 2) QAP 13, titled Receiving Inspection (**exhibit 29**); 3) QAP 15, titled Final Inspection and Test (**exhibit 25**); 4) QAP, titled Sampling Inspection (**exhibit 31**); 5) QAP 17, titled Packaging, Shipping, Preservation, and Marking (**exhibit 32**); 6) QAP 22, titled Quality Control Audit (**exhibit 18**); 7) Medical Device Reporting (MDR) Procedure (**exhibit 9**) (**see FDA-483 item 1B and related exhibits**).

We also noted that the following individual procedures lack any individual change control records documenting initial release, justification for changes, signature(s) of approval official(s), approval dates, or other change control/approval records with exception of over-arching approval for the specific version of the quality manual:1) QAP No. 9, titled Corrective Actions (**exhibit 10 and exhibit 12**); 2) Management Review Procedure (**exhibit 7 and 8**); 3) QAP 15, titled Final Inspection and Test (**exhibit 25 and exhibit 28**); 4) QAP 17, titled Packaging, Shipping, Preservation, and Marking (**exhibit 32 and 35**); 5) QAP 22, titled Quality Control Audit (**exhibit 18 and 20**). (**see FDA-483 item 1C and related exhibits**).

We inquired whether the firm has a document change control procedure, and noted that a change control procedure is listed in the Table of Contents for the firm's Quality Manual. Ms. Young responded saying that if a change needs to be made, she makes the change electronically, stores the revised document on the server, and prints out a revised quality manual as a whole, even if only one procedure within the manual has been revised. We pointed out that medical device manufactures are responsible for establishing document control procedures to include systems for tracking changes, describing justification for changes, establishing a document approval scheme, effective dates, and issuance and retrieval of controlled documents. Ms. Young acknowledged our comments and then responded telling us that her firm does not have any written procedures for document change control (**see FDA-483 item 1A and related exhibits**).

Management review meetings are conducted in accordance with quality manual document titled "Management Review Procedure", revision B, effective 10-20-05. Topics to be reviewed at Management Review Meetings include audit results, design control documents, corrective and preventive actions, testing records from verification and validation processes, control of procurement, and non-conformances. While Ms. Young told us that Management Review Meetings are held (b) (4) , the procedure does not indicate any timeframe or frequency with which these meetings are to be held (**see FDA-483 item 5 and related exhibits**). We inquired where the minimum required frequency for these meetings is documented. Ms. Young pointed to the firm's internal audit procedure, QAP 22, titled "Quality Control Audit" stating that the procedure provides for (b) (4) audits of manufacturing, quality control, sales, purchasing and/or estimating. Investigator Putz explained that the firm appears to have a schedule for quality audits but that quality audits are not the same as management review meetings.

The firm's Management Review Procedure, revision B indicates that Mr. Michael Young, as the firm's Quality Manager, will oversee or appoint a member in Neo Imagery who will ensure that quality system requirements are effectively established and effectively maintained in accordance with Quality System Regulations, and for reporting on the performance of the quality system to management with executive responsibility. However, there was no documentation indicating who has been appointed as the firm's Management Representative (**see FDA-483 item 5 and related exhibits**).

We reviewed documentation showing that the last Management Review Meeting was held on (b) (4) (b) (4). The firm's President and Mr. Young were both in attendance.

Internal quality audits are conducted in accordance with QAP 22, titled "Quality Control Audit". The procedure provides for annual audits. Audits are to be conducted by personnel responsible for manufacturing, quality control, sales, purchasing and/or estimating. The procedure requires that the results of each audit and any required corrective action, are to be submitted to the President of the firm for review.

The firm uses audit checklists for each internal audit conducted.

In our review of systems audited, we noted that the purchasing process was audited on (b) (4) by Ms. Tina Young. Investigator Putz explained to Ms. Young that auditors should be independent and free of any bias or potential bias. Investigator Putz noted that Ms. Young is involved in the purchasing processes (responsible for ordering goods) and thus the potential for bias was present in the conduct of this audit.

## DESIGN CONTROLS (SLK)

Per Ms. Young, the last design change to the firm's product was made in (b) (4). Ms. Young then corrected herself and said that there have been no software changes (changes to the Insight product) since (b) (4).

We reviewed the firm's design control procedures which include the following documents:

1. "Design Process Flowchart", revision A, effective 8-12-04
2. "Design Control Instruction 1", revision A, revision date 8-12-04
3. "Design Control Instruction 2 – Design Change Control Instructions, revision A, revision date 8-12-04.

No deficiencies were noted in this regard.

## CORRECTIVE AND PREVENTIVE ACTIONS (SLK/BPP)

### CAPAs

Corrective and preventive actions are handled in accordance with QAP No. 9 titled "Corrective Action" and QSI No. 9-1, titled "Corrective Action Request Instructions". Ms. Young identified quality data sources feeding into the firm's CAPA system as results of product testing, testing of new hardware platforms (mother boards), customer complaints, and customer feedback. We noted that neither the procedure nor instructions included requirements for analyzing internal quality audit results, supplier quality audit results, customer complaints, or service records to identify existing and potential causes of quality problems. Additionally, the procedure does not include provisions for verifying or validating corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device (**see FDA-483 item 3 and related exhibits**).

We asked whether the firm had initiated any corrective and/or preventive actions. Ms. Young said that the firm had. We reviewed the following Corrective and Preventive Action reports (**exhibit 13**):

| Report No. | Date of Request | Date of Completion | Description of | Corrective Action |
|---|---|---|---|---|

| | | | Problem | Requested |
|---|---|---|---|---|
| (b) (4) | 9/9/05 | 9/13/05 | System power drain to large and causes system to be unstable | Use larger power supply. |
| (b) (4) | 12/21/05 | 1/12/06 | (b) (4) personal firewall and (b) (4) Anti-virus blocks remote support. | Do not enable (b) (4) personal firewall and do not upgrade anti-virus software. |
| (b) (4) | 2/06/2006 | 02/09/2006 | Network controller on server not working | Replaced with 8 port (b) (4) Switch Copper version (b) (4) |
| (b) (4) | 6/9/06 | 6/15/06 | (b) (4) switch room died after local thunderstorm | Replaced (b) (4) switch and moved network traffic to parallel switch |
| (b) (4) | 5/21/07 | 5/23/07 | (b) (4) write to disk function interferes with system archiving | Remove (b) (4) from archiving station |
| (b) (4) | 9/5/08 | 9/10/2008 | (b) (4) (b) (4) score does not record to the access database for some patients | Found out the doctor name has apostrophe. Fixed (b) (4) so the data with apostrophe will go to the access database. |

**MDRs**

We selected Medical Device Reports and customer complaints as two quality data sources for review. We reviewed the firm's procedure titled "Medical Device Reporting Procedure". This procedure has no assigned document number, revision date, or approval signatures (**see FDA-483 item 1 and related exhibits**). This procedure was incomplete in that it lacked a system providing for a standardized review process for determining when an event meets the criteria for reporting. Additionally, the procedure lacks designation of an individual who is responsible for promptly reviewing, evaluating, and investigating an MDR reportable event (**see FDA-483 item 4 and related exhibits**).

We asked whether the firm had filed any MDRs within the last two years. Ms. Young responded saying that no reports had been filed, and that it was not possible for her product to cause a death or serious injury as the product does not come into contact with patients. I (SLK) explained that if the firm's device malfunctioned (failed to meet performance specifications), and if a recurrence of the malfunction could result in serious injury or death, then a MDR should be filed. I (SLK) told Ms. Young that I understood her to say that her firm's software performs volume rendering and calcification quantification. As an example, I said that use of erroneous volume rendering data or calcification quantification data may result in incorrect patient diagnosis and possible inappropriate or inadequate treatment of a patient. Ms. Young responded saying that an incorrect diagnosis is not possible because the physician makes the diagnosis not the software. I (SLK) pointed out that data generated by the software is utilized by the physician in making the diagnosis and treatment

decisions. I also explained the use of decision trees for MDR reporting decisions, and Investigator Putz directed Ms. Young to part 803 of Title 21 of the Code of Federal Regulations. At this point, Ms. Young stated that her Regulatory Consultant had discussed the use of decision trees with her in the past.

## COMPLAINTS

We asked to review the firm's complaint handling procedure and Ms. Young responded explaining that her system for complaint handling is incorporated into her Medical Device Reporting procedure.

We again reviewed the MDR procedure, titled "Medical Device Reporting Procedure" (**exhibit 9**). We noted that the only information pertaining to complaints was the inclusion of the definition of a complaint (**exhibit 9, page 2**). There were no written instructions indicating who is responsible for receiving and logging complaints, what information is to be collected from complainants including documenting name of the complainant, product model number, serial number, description of the event, appointment of an individual or individuals responsible for determining whether an investigation is required, or any requirement for determining whether the event was reportable per the MDR regulations. We showed this to Ms. Young who stated that her Consultant had written the procedure for her and she assumed it was adequate. Investigator Putz pointed out to Ms. Young that her firm had had a complaint handling procedure at the time of the last U.S. FDA inspection in 2004 even though the procedure was not a controlled document. Ms. Young stated she was not aware of the location of that procedure and had believed that the documents put in place by her Consultant were adequate, particularly since she had submitted them to the U.S. FDA as part of the corrective action for the prior 2004 inspection with no negative comments forthcoming (**see FDA-483 item 2 and related exhibits**).

Ms. Young then told us that while the firm does not have a complaint handling procedure as described in the regulations, complaints are handled by the firm in the same manner as customer service requests and are documented on Insight Service Report Forms. We reviewed these forms and noted that they lack fields for capturing several elements required for customer complaints.

We asked whether there is any requirement for servicing of the Insight Diagnostic Imaging Workstation. Ms. Young responded saying there are no service requirements for the product. We also noted that Operator's Manual does not indicate servicing is required but simply that any servicing performed is to be conducted by the manufacturer. We asked Ms. Young if the firm had a written procedure for servicing of the device. She responded saying that the firm has no written procedure.

The firm received a total of (b) (4) requests for servicing within the past (b) (4). Using QSIT binomial staged sampling plan, Table 1, row A, column 1, ucl .30, we randomly selected 11 Insight Service Reports for review (**exhibit 17**):

| Case # | Date | Site | Incidence Reported | Advised Action |
|---|---|---|---|---|
| (b) (4) | 6/28/2007 | (b) (4) | InSight workstation DVD RAM can't read | Replace InSight6 DVD RAM drive |
| (b) (4) | 10/1/2007 | | Workstation does not update patient image list | Copy imagelist.sys to workstation |
| (b) (4) | 7/5/2008 | | Workstation keep rebooting | Clone the master drive using the image from standby drive. |
| (b) (4) | 11/21/2008 | | Does not fetch calcium score into access database | Add (b) (4) from C:\insight folder |
| (b) (4) | 12/22/2008 | | (b) (4) can't archive | Replace DVD RAM |
| (b) (4) | 1/26/2009 | | InSight can't update image list | Copy imagelist.sys |
| (b) (4) | 4/23/2009 | | Can't turn on system | System returned for repair, still open |
| (b) (4) | 9/26/2008 | | InSight can't see data | Relocate the InSight directory |
| (b) (4) | 9/26/2007 | | The system does not boot | Push the cable to the hard drive housing |
| (b) (4) | 5/8/2007 | | Need a new disk number | Edit ins.ini |
| (b) (4) | 11/28/2007 | | Receiver light running | Leave program running |

Investigator Putz asked Ms. Young if the firm trends their quality source data. Ms. Young responded saying that she does trend quality data but that this is only done electronically, and no trend analysis reports are maintained (either electronic or hardcopy reports). Investigator Putz asked whether the firm has a procedure describing the statistical analysis methodology used for trending, assigning responsibility, and requiring that results of trend analysis be reviewed at periodic Management Review Meetings. Ms. Young stated that she performs trend analysis by scrolling through her firm's electronic service reports for key words, and, if a trend is found, a CAPA is opened (**see FDA-483 item 7 and related exhibits**). Investigator Karsik explained that without retention of trend analysis data and results, the firm is unable to provide any evidence that trend analysis of quality source data is actually being conducted.

## PRODUCTION AND PROCESS CONTROLS (SLK)

Ms. Young told us that the firm has not sold a device since (b) (4), and that no orders for product have been received since that time. Accordingly, no manufacturing, assembly, or installation operations were in effect for review.

The firm has established a Device Master Record for the Insight Diagnostic Imaging Workstation which includes a list of components, and flowcharts. The firm has also established QAP titled "Final Inspection and test Procedure". This procedure requires performance of comprehensive software regression testing to ensure software specifications are satisfied, and functional verification of Insight Workstation specifications as it is fully integrated with each customer's existing information technology system.

We reviewed the DHR for the last unit produced and sold (serial number (b) (4) sold to (b) (4) (b) (4). No deficiencies were noted in this regard.

We also reviewed the firm's procedure for receiving of components, QAP-13, titled "Receiving Inspection". This procedure includes provisions for return of materials and components which do not meet acceptance specifications to the supplier.

**MANUFACTURING CODES (SLK)**

The firm's finished diagnostic imaging workstations are accompanied by a (b) (4) (b) (4) unique serial number. This number is provided to the firm by the manufacturer (b) (4) which is intended to prevent pirating of the firm's software by personnel outside of their firm.

**COMPLAINTS (SLK)**

There were no complaints on file with the U.S. FDA for this firm. See the Corrective and Preventive Actions section of this report for information on the firm's complaint handling methods.

**RECALL PROCEDURES (SLK/BPP)**

The firm does not have a written system for management of product recalls. Ms. Young stated that the firm does not need a recall procedure because each workstation is tested prior to installation. In addition, Ms. Young stated that the firm has never had a recall of any of their workstations.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (SLK/BPP)**

At the close of the inspection on May 1, 2009, we issued the FDA-483, Inspectional Observations, to Ms. Young. Also present from the firm during issuance of the FDA-483 was (b) (6) (b) (6).

Investigator Putz prefaced discussion of the FDA-483 by stating that objectionable conditions listed on the FDA-483 were our observations and our observations only. He explained that items listed on

the FDA-483 were not intended to be an all-inclusive list of objectionable conditions that could be present at the firm, and that the firm is responsible for conducting internal self-audits to detect and correct any deficiencies which may be present.

Investigator Putz informed Ms. Young that upon further review by the U.S. FDA, the conditions listed might be considered violations and he explained the legal sanctions available to the FDA should the conditions remain uncorrected.

Investigator Putz explained the firm's option to have the FDA-483 observations annotated, and the choices of annotation available. He also explained the option to respond to the FDA-483 in writing, and that any written response should be directed to the attention of the Los Angeles District Director, Alonza Cruse.

Investigator Putz then read each observation aloud and provided firm management an opportunity to respond to each item. Ms. Young acknowledged each observation, and stated that corrective action would be taken for each observation. She stated that she would respond to the U.S. FDA in writing within (b) (4), and did not want the FDA-483 observations annotated.

During reading and discussion of the FDA-483 observations, Ms. Young identified one error in observation number 2. This error was corrected by modification of the FDA-483 prior to our departure from the firm.

**Observations listed on form FDA 483**

---

**OBSERVATION 1**

Document control procedures were not established, defined, documented, complete, and implemented.

Specifically,

A. The firm does not have a written document control procedure providing a system that designates an individual to review documents for adequacy, approve them prior to issuance, a system for distribution, and a system for document changes. Note that the firm's product, the Insight Diagnostic Imaging Work Station, indicated for receiving of image files from medical scanning devices, such as CT or MRI, and performing real-time viewing, image manipulation, three or four dimensional visualization, communication, archiving, cardiac vessel calcification quantification and simulated endoscopy providing non-invasive diagnosis, has been manufactured and distributed by the firm since (b) (4)

B. There was no documentation indicating document approval date and signature of approving official for the following documents: 1) QAP No. 9, titled Corrective Action; 2) QAP 13, titled Receiving Inspection; 3) QAP 15, titled Final Inspection and Test; 4) QAP 16, titled Sampling Inspection; 5) QAP 17, titled Packaging, Shipping, Preservation, and Marking; 6) QAP 22, titled Quality Control Audit; and 7) Medical Device Reporting (MDR) Procedure.

C. There are no records of changes to documents providing a description of the change, identification of the affected documents, the signature of the approving official, and the approval date for the following procedures: 1) QAP No. 9, titled Corrective Actions; 2) Management Review Procedure, Rev. B, effective date 10/20/05; 3) QAP 15, titled Final Inspection and Test; 4) QAP 17, titled Packaging, Shipping, Preservation, and Marking; and 5) QAP 22, titled Quality Control Audit.

---

*Annotation:*

Reference: 21 CFR 820.40

**Supporting Evidence for A, B, and C (SLK/BPP)**:

A.

**Exhibit 1** is a copy of 510(k) (b) (4) clearance letter dated July 3, 1997 from the FDA to Neo Imagery Technologies, Inc.

**Exhibit 2** is a copy of 510(k) (b) (4) clearance letter dated December 21, 1998 from FDA to Neo Imagery Technologies, Inc. Note: The InSight Diagnostic Imaging Workstation was classified as a class II medical device.

**Exhibit 36a** is a copy of the user manual for the InSight Diagnostic Imaging Workstation.

**Exhibit 24** is Neo Imagery and Technologies, Inc. registration and device listing for 2009. The device listing indicates the firm holds a 510(k) for product code LLZ, device name: system, image processing, radiological, premarket submission number: (b) (4) .

**Exhibit 4** is the Quality Assurance Manual Control #100B Coversheet dated 8/30/04.

**Exhibit 5** is the Quality Assurance Manual Table of Contents.

B. The following documents have no indication of document approval date and signature of approving official for the following documents: 1) QAP No. 9, titled Corrective Action (**exhibit 10**); 2) QAP 13, titled Receiving Inspection (**exhibit 29**); 3) QAP 15, titled Final Inspection and Test (**exhibit 25**); 4) QAP, titled Sampling Inspection (**exhibit 31**); 5) QAP 17, titled Packaging, Shipping, Preservation, and Marking (**exhibit 32**); 6) QAP 22, titled Quality Control Audit (**exhibit 18**); 7) Medical Device Reporting (MDR) Procedure (**exhibit 9**)

C. The following documents did not have any records of changes: 1) QAP No. 9, titled Corrective Actions (**exhibit 10 and exhibit 12**); 2) Management Review Procedure (**exhibit 7 and 8**); 3) QAP 15, titled Final Inspection and Test (**exhibit 25 and exhibit 28**); 4) QAP 17, titled Packaging, Shipping, Preservation, and Marking (**exhibit 32 and 35**); 5) QAP 22, titled Quality Control Audit (**exhibit 18 and 20**).

**Relevance for A, B, and C (SLK/BPP):**

Medical device manufacturers are required to maintain document control procedures to help ensure content of documents is appropriate for their intended use and that obsolete versions are removed from potential use. These procedures are to provide a system to distinguish different versions of the same document, provide a written justification for changes to documents, designate an individual(s) with authority to approve document content and for documenting the date approved. Without these procedures and controls in place, it is not possible to verify that the documents currently in use were approved by a designated individual, are the most current versions, and are suitable for their intended use. Additionally, without a document control procedure, there is no assurance that invalid or obsolete documents are being removed from locations where they may potentially be used.

**Discussion with Management for A, B, and C (SLK/BPP):**

Investigator Putz asked Ms. Young if she had a document control procedure or any other document that addresses how to handle controlled documents. Ms. Young stated that while the firm does not maintain a document control procedure, she does have a system in place. She informed us that she had developed a system with her Regulatory Consultant, (b) (6) in which the date of approval of the Quality Assurance Manual was intended to also serve as the date of approval for all individual procedures contained in the manual, however there is no procedure indicating this (**exhibit 5**). Additionally, we noted that the dates listed on the Quality Assurance Manual Table of Contents were described to us as the effective dates of each individual document. None of the document effective dates listed in the table of contents are consistent with the approval date (b) (4) (b) (4) shown on the Quality Assurance Manual Coversheet and all of the effective dates proceed the approval date for the manual itself.

Investigator Putz then asked her why all of the dates listed on the Quality Assurance Manual Table of Contents are all dated prior to the approval date (b) (4). Ms. Young stated that the documents were transferred back and forth from the Neo Imagery Technologies, Inc. site and her Regulatory Consultant and she approved the manual as a whole when all individual procedures had been completed. Investigator Putz again asked if this procedure is documented and she stated that it was not.

We explained to Ms. Young that controlled documents should not be placed into effect before they are approved for use.

Note that the firm does list a change control procedure in the Quality Assurance Manual, but Ms. Young did not provide it to us when we requested a document control procedure.

Ms. Young told us that she is the only person that looks at the documents and she has a system in place to ensure that the obsolete documents are no longer available for use. She told us that the obsolete documents that have been changed are put into a three ring binder (b) (4) (b) (4). When reviewing the *Corrective Action* procedure, we observed that it was listed as revision B in the Quality Assurance Manual Table of Contents (**exhibits 10 and 5, respectively**). Investigator Putz asked Ms. Young if we could see revision A of the *Corrective Action* procedure. She provided us with a *Corrective Action* procedure with an "obsolete" sticker on it (**exhibit 10**). We reviewed this procedure and noted that the procedure lacked a revision code and it was not possible to identify the differences between the obsolete procedure and the current version without comparing and contrasting each line of the two documents.

Investigator Putz then asked Ms. Young what the differences in the two documents were. Ms. Young told us that she would have to read the documents to determine what the differences were, but she believed that the document was changed when the firm put their QSI (Quality System Instructions) in place. She told us that every time she needed to revise a procedure or document, she would printout a new Quality Manual and places the obsolete documents in the obsolete binder.

Ms. Young stated that the firm is planning on correcting the observation and will respond to the observation in writing to the FDA in (b) (4). Investigator Putz showed Ms. Young the section in the Code of Federal Regulations that addresses document controls. She asked if she could make a copy of the CFR section so that she could reference it in the future. Investigator Putz also informed her that she could find the Code of Federal Regulations on online at www.fda.gov.

**OBSERVATION 2**

Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been established.

Specifically, the firm does not have a written complaint handling procedure. The firm's President stated that customer complaints are treated in the same manner as service requests, and are documented electronically on InSight Service Report forms. The InSight Service Report forms do not delineate which customer reports are complaints and which customer reports are service requests.

Note there is no documentation in the user manual specifying that servicing is a requirement for the Insight Diagnostic Imaging Workstation. Additionally, the firm does not have a service report procedure.

Deficiencies observed during review of 11 InSight Service Reports include the following:

a. 11 of 11 InSight Service Reports do not include the ~~name of the device,~~ specific model number and control numbers used.

b. 11 of 11 InSight Service Reports do not include the address of the complainant.

c. There is no assurance that hard copy printouts of 5 of 11 InSight Service Reports reviewed are exact copies of

information input into the electronic service reports at time of receipt because text boxes on the printouts do not contain all the information displayed on the electronic forms. Per the firm's President, any one of the firm's employees can make changes to the computer-based InSight Service Report system. The firm's President stated the master InSight Service Report files are the hard copies kept in the customer folders.

d. 11 of 11 InSight Service Reports where no investigation was made do not include the reason why and the name of the individual responsible for the decision not to investigate the complaint.

e. 11 of 11 InSight Service Reports do not have a section for documenting any investigation which may be conducted.

f. 11 of 11 InSight Service Reports do not have a section to document corrective action taken, if any.

g. 11 of 11 InSight Service Reports do not include a determination as to whether the complaint represents an event which is required to be reported to the FDA as a Medical Device Report.

---

*Annotation:*

Reference: 21 CFR 820.198(a)

**Supporting Evidence and Relevance (SLK/BPP)**:
**Exhibit 36a** is the user manual for InSight Diagnostic Imaging Workstation
**Exhibit 17** is InSight Service Reports

Investigator Putz explained to Ms. Young that medical device manufacturers are required to establish and maintain a complaint-handling procedure and complaint files. Procedures are to include systems for receiving, reviewing, and evaluating complaints to ensure that complaints are processed in a uniform and timely manner and are evaluated to determine if they meet requirements for MDR reporting. In addition, Investigator Karsik explained that medical device manufacturers are required to review and evaluate all complaints to determine whether investigations are necessary, and if no investigation is conducted, the firm is to document the reason no investigation was conducted along with the name of the individual who made that decision.

Without a system for complaint handling, there is no assurance that: 1) All required information is captured, 2) any events which may be MDR reportable are being investigated, evaluated and reported, where appropriate, and 3) that this quality data source is trended to identify, correct, and prevent recurrence of any negative trends which may be detected.

**Discussion with Management (SLK/BPP)**:
We asked to review the complaint handling procedure. Ms. Young proceeded to look for the complaint handling procedure and was unable to locate it. Investigator Putz explained to Ms. Young that during the previous FDA inspection the firm did have a Complaint Handling Procedure. Ms. Young looked for the procedure again, but was unable to locate the Complaint Handling Procedure. Ms. Young then told us that while the firm did not have a separate complaint handling procedure they did have a complaint procedure as part of the Medical Device Reporting procedure (**exhibit 9**

**page 2**). Investigator Putz told Ms. Young that the MDR procedure does not define how the firm will handle a complaint and that the complaint section in the MDR procedure is simply a definition.

Investigator Putz asked Ms. Young if the firm had received any complaints within the last two years. Ms. Young responded saying that the firm has not received complaints within the last two years, but that they do receive service calls.

Ms. Young told us that the firm had (b) (4) InSight Service Reports from April 2007 – present. Investigator Putz asked Ms. Young how the firm handles complaints that are received. Ms. Young responded saying that customer complaints are treated in the same manner as service requests, and are documented electronically on InSight Service Report forms. Additionally, Ms. Young stated that the firm does not delineate which customer reports are complaints and which customer reports are service requests.

We asked Ms. Young if there was a servicing requirement for the workstation noting that the user manual for the InSight Diagnostic Imaging Workstation does not specify that servicing is a requirement. Ms. Young replied saying that there is no service requirement for her product. Investigator Putz asked her if the firm had a written service report procedure. Ms. Young stated that the firm does not have a procedure and that the firm's employees simply fill out the text boxes on the electronic InSight Service Report screen.

---

**OBSERVATION 3**

The procedures for implementing corrective and preventive actions were not complete.

Specifically, the firm's procedures QAP No. 9, titled Corrective Action and QSI No. 9-1, titled Corrective Action Request Instructions do not include requirements for analyzing internal quality audit results, supplier quality audit results, complaints, and service records to identify existing and potential causes of quality problems.

Additionally, these procedures do not include provisions for verifying or validating corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device. Further, procedures do not include provisions for submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

---

*Annotation:*

Reference: 21 CFR 820.100(a)

**Supporting Evidence and Relevance (SLK/BPP)**:
**Exhibit 10** is QAP No. 9, titled Corrective Action

**Exhibit 11** is QSI No. 9-1, titled Corrective Action Request Instructions
**Exhibit 13** is corrective actions from 9/13/05-9/10/08

Manufacturers are required to maintain procedures for implementing corrective and preventive action. The procedures must include the following requirements: 1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of quality problems. Without input of all quality data sources into the firm's CAPA system, the firms' ability to detect recurring quality problems and identify actions needed to correct and prevent recurrence is limited. Additionally, without requirements for verifying and/or validating effectiveness of CAPA actions taken, there is no assurance the actions taken corrected the underlying problem and that the device was not adversely affected. There is no assurance that there is a review of actions taken without the procedures addressing the need for management review of identified quality problems to judge the effectiveness and adequacy of the firm's quality system.

**Discussion with Management (SLK/BPP)**:

During the course of the inspection, Investigator Putz asked to review the firm's Corrective and Preventive Action procedure. Ms. Young provided me with the QAP No. 9, titled *Corrective Action* and QSI No. 9-1, titled *Corrective Action Request Instructions*. The procedure identifies quality data sources feeding into CAPA as discrepant material from manufacturing processes or vendor supplied parts or services.

Investigator Putz asked Ms. Young if there are any other quality data sources feeding into her Corrective Action Procedure. Ms. Young identified other quality data sources as service reports, final product testing, and installation testing. Investigator Putz pointed out to Ms. Young that these quality data sources are not listed in the firm's Corrective Action procedure and since these sources are not identified there is no assurance that they are entered into the CAPA system where appropriate. Investigator Putz also explained to Ms. Young in the close-out meeting that the firm's Corrective Action Procedure does not address all of the required elements of the regulation, including the need to have a procedure for preventive action.

Ms. Young requested to look at the section in the CFR that showed the requirements for Corrective and Preventive Action. Investigator Putz showed Ms. Young 21 CFR 820.100 which addresses Corrective and Preventive Action. Ms. Young then proceeded to make a copy of the section for further reference. Ms. Young told us that she plans to correct the observation and will respond in writing to the agency in (b) (4).

**OBSERVATION 4**

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, the firm's procedure titled, Medical Device Reporting (MDR) Procedure lacks a standardized review process for determining when an event meets reporting criteria, and does not designate an individual to promptly review, evaluate, and investigate a MDR reportable event.

*Annotation:*

Reference: 21 CFR 803.17(a)(2)

**Supporting Evidence and Relevance (SLK/BPP)**:
**Exhibit 9** is the *Medical Device Reporting Procedure*. Note: The firm was cited during the last FDA inspection in 2004 for failure to develop written MDR procedures. During the current FDA inspection the firm was also cited for the MDR procedure lacking an approval date and signature of approving official (**see observation 1**).

Medical Device Manufacturers are required to develop, maintain, and implement written MDR procedures including a standardized review process or procedure for determining when an event meets the criteria for reporting. The standardized review process/procedure assists firms in prompt identification of events meeting reporting criteria and identifying rationale for not submitting a report to the FDA. Without a structured system for review, evaluation, and investigation there is no assurance that any reportable events are being handled in accordance with the regulations.

**Discussion with Management (SLK/BPP)**:
We explained to Ms. Young that the majority of the MDR procedure is comprised of definitions and it does not address the need to have a system for determining when an event meets the criteria for reporting. Investigator Karsik told Ms. Young that many firms utilize a decision tree to meet the requirement of having a standard review process. Ms. Young responded that her consultant showed a decision tree to her in the past. Ms. Young did not elaborate on why she did not implement a decision tree in the firm's MDR procedure. Ms. Young told us that she plans to correct the observation and she will respond to the agency in writing in (b) (4) .

**OBSERVATION 5**

Procedures for management review are not complete.

Specifically, the firm's Management Review Procedure, rev. B., effective date: 10/20/2005 does not state with what frequency meetings will be held. Further, neither the Management Review Procedure, Rev. B, effective date: 10/20/2005 nor any other document specifies who has been appointed as the firm's Management Representative.

*Annotation:*

Reference: 21 CFR 820.20(c)

**Supporting Evidence and Relevance (SLK/BPP)**:
**Exhibit 8** is Management Review Procedure, Rev. B, Effective date: 10/20/05

Medical Device Manufacturers are required to establish procedures for Management Review meetings defining intervals with which meetings will be held. In addition, management with executive responsibility must appoint, and document a member of management to act as the management representative.

Management Reviews are intended to measure the firms systems against the quality system regulations, and these meetings should be held frequently enough to keep management with executive responsibility informed of ongoing quality issues and problems. This feedback system increases the likelihood that firms will produce devices as intended.

Medical Device Manufacturers are required to appoint a Management Representative who is responsible for ensuring that the quality system is effectively established and maintained. This individual is also responsible for reporting on performance of the system to management with executive responsibility. The appointment is required to be documented. The lack of an appointed management representative in conjunction with lack of a document control system, complaint handling procedure, incomplete CAPA procedures brings into question whether Management Review meetings may be ineffective in adequately assessing the ongoing suitability and effectiveness of the firm's quality system.

**Discussion with Management (SLK/BPP)**:
During the inspection, we reviewed the firm's Management Review Procedure. Investigator Putz

told Ms. Young that the procedure does not define the frequency with which Management Review Meetings will be held. Ms. Young told us that the frequency of the meetings is defined and they are conducted (b) (4) . She told us that the frequency of the meetings is not located in the Management Review Procedure but in another document. She referred us to QAP 22, titled *Quality Control Audit* section 5. Ms. Young then pointed to section 5, QSI 22-2 (Quality System Audit) Annually (**exhibit 18, page 2**).

Both myself (BPP) and Investigator Karsik told Ms. Young that quality audits are not the same as management review meetings. Investigator Karsik stated that management review is a broader review of the organization as a whole to ensure the quality policy is implemented and quality system remains effective in meeting the firm's quality objectives. Ms. Young stated she will correct the observation and respond to the agency in writing within (b) (4).

---

**OBSERVATION 6**

Procedures for identifying training needs were not complete and implemented.

Specifically,

A. The Customer Complaints Section in the Employee Training Procedure, titled *Employee Training,* Revision A, with approval date 8/15/04 specifies that employees likely to receive complaints are to be trained in complaint handling procedures applicable to their functions; however the firm does not have a Complaint Handling Procedure.

B. There is no documentation that the firm's President/Owner was trained in the firm's Quality Assurance Procedures or Quality System Instructions.

---

*Annotation:*

Reference: 21 CFR 820.25(b)

**Supporting Evidence and Relevance (SLK/BPP)**:

A. **Exhibit 14** is the firm's Employee Training Procedure, Rev. A, Date 8/15/2004.

During the inspection, we reviewed the *Employee Training Procedure*. We observed that the procedure states that receptionists, managers, representatives, salespersons, and other employees likely to receive complaints are trained in complaint handling procedures applicable to their functions (**exhibit 14, page 1**). Investigator Putz asked Ms. Young how does the firm train employees in the complaint handling procedure when the firm does not have one in place (**see**

**observation 2**). Ms. Young did not clearly respond to the statement. Note the firm was cited in the last FDA inspection for not having a training procedure.

We noted that the firm's Employee Training procedure was approved 8/15/2004. By implementing a training procedure which requires training of employees in a complaint handling procedure that does not exist, brings into question the validity of the training procedure as a whole. The training procedure has been in place for more that four years and this inconsistency was not identified by the firm.

Medical Device Manufacturers are required to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. A training program to ensure that personnel adequately perform their assigned responsibilities also should include information about the cGMP requirements and how particular job functions relate to the overall quality system.

B. **Exhibit 15** is the firm's Employee Training Record.

We reviewed the firm's Employee Training Records (**exhibit 15**). Ms. Young stated that the employee training record documents the firm's entire employee training since the training procedure was put into effect. I asked to see documentation that Ms. Young was trained in the firm's Quality Assurance Procedure and Quality System Instructions. Ms. Young showed us where she had signed the Employee Training Record, supervisor/trainer section. Investigator Putz told her that she also needs to be trained in the procedures particularly because Ms. Young told us many of the procedures were developed by an outside consultant and not written by her.

Manufacturers must ensure that persons assigned to particular functions are properly equipped and possess the necessary education, background, training, and experience to perform their functions correctly.

**Discussion with Management A and B (SLK/BPP)**:
Ms. Young promised to correct the observation and stated that she will respond to the agency in writing in (b) (4) .

**OBSERVATION 7**

Procedures to identify valid statistical techniques needed for certain product analyses have not been established.

Specifically, the firm's President/Owner stated that the firm does not have a procedure to address the statistical methodology for analysis of quality data sources including service records, final product test results, and installation test results. Additionally, while the President states that the firm performs trend analysis of quality data sources neither the analyses nor the results are documented.

---

*Annotation:*

Reference: 21 CFR 820.250(a)

**Supporting Evidence and Relevance (SLK/BPP)**:
No evidence was available in support of this observation.

Investigator Karsik asked Ms. Young how does her firm perform statistical analysis of their quality data sources, including service records, final product test results, and installation test results. Ms. Young stated that for the service records analysis, they scan the existing documents looking for any trends; however they do not document the analyses or the results. Ms. Young stated that by scanning the service reports they were able to find a service report trend that generated a Corrective Action (**exhibit 13, page 5**). In addition, Ms. Young stated that the firm does not have procedures addressing statistical analysis.

Medical Device Manufacturers are required to maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

**Discussion with Management (SLK/BPP)**:
Ms. Young told us that she did not believe that it was possible to conduct any type of statistical analysis because the firm has such a small population of quality data sources. Ms. Young stated that for example the firm only receives (b) (4) service call (b) (4) and that you could not conduct statistical analysis on that small of a population. Investigator Karsik told her that the firm needs to be at least documenting what kind of analyses they are doing and what are the results of the analyses. Ms. Young promised to correct the observation and stated that she will respond to the agency in writing in (b) (4).

**VOLUNTARY CORRECTIONS (SLK/BPP)**
The following observations were from the last FDA inspection on 6/2004. Each observation is summarized below followed by an assessment of the adequacy of the actions taken.

1. Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.
    a. A Management Representative has not been appointed to ensure that quality system requirements are met and to report to management on the performance of the quality system.

    ***Adequacy***: Corrective action was inadequate. (**see observation 5 and related exhibits**)

b. Management Reviews have not been conducted and procedures for Management Reviews have not been established

*Adequacy*: Corrective action was inadequate (**see observation 5 and related exhibits**). I verified that firm now has a Management Review Procedure; however the firm was confusing a quality audit with a Management Review Meetings, and their Management Review Procedure does not define a minimum frequency with which these meetings will be held.

c. Quality Audits have not been conducted to verify that the Quality System is effective.

*Adequacy*: Corrective action was adequate. I verified that this item has been corrected; however the firm still seems to have some confusion on the differences between a Management Review Meeting and an Internal Quality Audit. The firm implemented procedure QAP 22, titled Quality Control Audit (**exhibit 18**). However, the procedure implemented by the firm, QAP 22, lacked records of changes, identification of the affected documents, the signature of approving official, and approval date (**see observation 1c and related exhibits**).

d. Adequate resources have not been provided, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits.

*Adequacy*: Corrective action appears to be adequate. I verified that this item was corrected.

2. Quality Systems procedures were not implemented.

*Adequacy*: Corrective action was adequate. **Exhibit 5** is the firm's Quality Assurance Manual Table of Contents and lists the firm's Quality System Procedures.

3. Procedures for identifying training needs were not established.

*Adequacy*: Corrective action was not adequate. The firm has developed training procedures and employee training records. However, the training procedures that were written were not complete and fully implemented (**see observation 6 and related exhibits**).

4. Procedures to control the design process of the device were not established.

*Adequacy*: Corrective Action appears to be adequate. The firm has a Design Process Flowchart, Rev. A, Effective Date 8/12/04 (**exhibit 16**).

5. Process control procedures that describe any process controls necessary to ensure conformance to specifications were not established. In addition, the firm's two procedures which pertain to the manufacture, testing, packaging and labeling of the device, are uncontrolled documents which do not contain approval signatures or effective dates.

*Adequacy*: Corrective action is not adequate. During the current inspection we verified that the firm had implemented process control procedures, however the procedures still lacked approval signatures or effective dates (**exhibits 25, 31, 32**) (**see observation 1 and related exhibits**).

6. Procedures have not been established to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems regulation.

***Adequacy***: Corrective action appears to be adequate. During the current inspection, we verified that the DHR reviewed included manufacturing dates and primary identification label and labeling (**exhibit 39**). In addition, the firm had developed a Device Master Record (**exhibit 21**).

7. Procedures for acceptance activities were not implemented.

   ***Adequacy***: Corrective action appears to be adequate. I verified that the firm currently has two procedures in place titled Control of Purchase material and Receiving Inspection (**exhibit 29**).

8. Written MDR procedures have not been developed.

   ***Adequacy***: Corrective action is not adequate. The firm has developed an MDR procedure however we did find deficiencies with the procedure (**see observation 4 and related exhibits**).

**REFUSALS (SLK)**
No refusals were encountered during the inspection.

**SAMPLES COLLECTED (SLK/BPP)**
No samples were collected.

**ATTACHMENTS**

1. FDA-482 Dated 4-23-09
2. FDA-483 Dated 5-1-09
3. Modified FDA-483 Dated 5-1-09
4. FDA 463a Affidavit signed by Tina Ting Ting Young, President/Owner
5. FACTS Assignment Sheet ID: 993867
6. Email seeking guidance on interstate documentation issue from LOS-CB

**EXHIBITS**

1. 510(K) (b) (4) Clearance Letter Dated July 3, 1997 (4 pages)
2. 510(K) (b) (4) Clearance Letter Dated December 21, 1998 (2 pages)
3. Neo Imagery Technologies, Inc. Statement of Commitment and Policy (2 pages)
4. Quality Assurance Manual Control#100B Coversheet dated 8/30/04 (1 page)
5. Quality Assurance Manual Table of Contents (1 page)
6. Organization Chart effective date 1/1/2005 (1 page)
7. Management Review Procedure, Rev. B, Effective Date: 10/20/05 (2 pages)
8. Management Review Procedure, Rev. A, Effective Date: 8/10/04 (1 page)
9. Medical Device Reporting Procedure (10 pages)

10. QAP No. 9, titled Corrective Action (2 pages)
11. QSI No. 9-1, titled Corrective Action Request Instructions, Rev. A, Effective Date 6/28/04 ( 2 pages)
12. QAP No. 9, titled Corrective Action – with obsolete sticker (2 pages)
13. Corrective Action Request Forms from 9/13/05 – 9/10/08 (6 pages)
14. Employee Training Procedure, Rev. A, Date 8/15/2004 (2 pages)
15. Employee Training Record (1 page)
16. Design Process Flowchart, Rev. A, Effective Date 8/12/2004 (7 pages)
17. InSight Service Reports (11 pages)
18. QAP 22, titled Quality Control Audit (2 pages)
19. QSI No. 22-1, titled Quality System Audit Procedures, Rev. A, Effective Date 8/10/04 (5 pages)
20. QAP 22, titled Quality Control Audit – with obsolete sticker (1 page)
21. Device Master Record Manual Control# 100A (25 pages)
22. Neo Imagery Technologies, Inc. Promotional Brochures (4 pages)
23. Supplier List (1 page)
24. FDA Registration and Listing (2 pages)
25. QAP 15, titled Final Inspection and Test (1 page)
26. QSI 15-1, titled Insight Verification & Validation Instructions, Rev. A, Effective Date 6/28/04 (10 pages)
27. QSI 15-2, titled Insight Workstation Final Check List Instructions, Rev. A, Effective Date 6/28/04 (3 pages)
28. QAP 15, titled Final Inspection and Test – with obsolete sticker (1 page)
29. QAP 13, titled Receiving Inspection (1 page)
30. QSI No. 13-1, titled Receiving Inspection Instructions, Rev. A, Effective Date 6/28/04 (2 pages)
31. QAP 16, titled Sampling Inspection (1 page)
32. QAP 17; titled Packaging, Shipping, Preservation and Marking (1 page)
33. QSI No. 17-1, titled Packing List Instructions, Rev. A, Effective Date 6/28/04 (2 pages)
34. QSI No. 17-2, titled Shipping Label Instructions, Rev. A, Effective Date 6/28/04 (1 page)
35. QAP 17, titled Packing, Shipping, Preservation and Marking – with obsolete sticker (2 pages)

36a. User Manual for InSight Diagnostic Imaging Workstation (55 pages)
36b. InSight System Labels (1 page)
36c. InSight Diagnostic Imaging Workstation (b) (4) Labeling (1 page)
36d. Adhesive Metal Label for the InSight Diagnostic Imaging Workstation (1 page)

37. Section of 510(k) application (17 pages)
38. Resume for Michael T.Y. Young (3 pages)
39. Device History Record for Serial No. B64 (32 pages)

Sonya L. Karsik, Investigator
Los Angeles District, Ontario Resident Post

Brian P. Putz, Investigator
Los Angeles District, Ontario Resident Post