DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos Avenue
San Juan Puerto Rico 00901-3223

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August 25, 2015

Ms. Nilsa Martinez, General Manager
Pace Analytical, Inc.
PO Box 325
San German, PR 00683

Reference: Inspection Date(s): 07/06/2015 - 07/09/2015

Location: Pace Analytical, Inc.
El Retiro Industrial Zone,
B Street
San German, PR 00683, US

Dear Ms. Martinez:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 787-729-8506.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Digitally signed by Mayra E. Burgos -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300088400, cn=Mayra E. Burgos -A
Date: 2015.08.25 17:12:29 -04'00'

Enclosure: Establishment Inspection Report (EIR)

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SUMMARY

The inspection of this contract control-testing laboratory was conducted according to SJN- DO FY'15 assignment ID 11470312, Operation ID 7604396, to evaluate the firm's compliance with cGMP's. This inspection was conducted in accordance with Compliance Program Guidance Manuals CPGM 7356.002, "Drug Manufacturing Operations (PAC 56002).

The firm provides contract laboratory testing of various medical products, water, and environmental samples from several pharmaceutical and medical device manufacturers throughout Puerto Rico and Dominican Republic. The profile code covered was CTL (Control Testing Laboratory Only).

The firm's previous FDA inspection of 10/31/2012 did not revealed any cGMP deviations. The inspection was classified NAI.

The current inspection provided coverage of the following Systems: Quality, Laboratory Control and Facilities and Equipment. During the current inspection I covered representative of operations throughout the entire facility on the firm's Quality and Laboratory Controls systems. I reviewed out-of-specification reports, Laboratory Investigations, Deviation Reports, Customer Complaints, Change Control Requests, Corrective and Preventive Actions, Sample Handling and qualification of selected testing methods for raw material testing. Also covered were employee training, computer system validation and data integrity.

The following objectionable conditions were listed in the FDA-483 issued at the end of the inspection: 1) an adequate compendia method verification was not in place for the test for raw material 2-pyrrolidone; 2) There was no secondary review of notebook for notes relating to the limit of benzene compendia verification

Firm's QA Manager promised to correct the observations and to send a written response to the District within three weeks. No refusals were encountered and no samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Pace Analytical, Inc.
Location:	El Retiro Industrial Zone, B Street San German, PR 00683
Phone:	(787) 892-2680
FAX:	(787) 892-1054
Mailing address:	PO Box 325 San German, PR 00683
Dates of inspection:	7/6/2015, 7/7/2015, 7/8/2015, 7/9/2015
Days in the facility:	4
Participants:	Steven P. Donald, Investigator Noreen Muniz, Consumer Safety Officer

Upon arrival to the firm I presented my credentials, explained the purpose of my visit to Kyra Iriarry, Senior QA Specialist and Nilsa Martinez, who identified herself as the most responsible person for day-to-day operations at this firm location. I issued an FDA-482, Notice of Inspection, to Ms. Nilsa Martinez, General Manager of Pace Analytical Services, Inc. San German, PR . During the second day of the inspection, I met with and presented my credentials to Cynthia Hansen, Director of Quality. Ms. Hansen is located at the Oakdale, MN location and is the Director of Quality for both testing locations. Investigator Donald wrote this report, in its entirety.

HISTORY

The firm's history has not changed since the previous FDA inspection.

Pace Anaytical, Inc., operates as a contract control-testing laboratory facility for the drug and medical device pharmaceutical industry. The firm is an independent subsidiary of Pace Analytical Life Sciences, LLC which is located at 1311 Helmo Avenue N., Oakdale, Minnesota.

The firm is registered with the U.S. FDA as a manufacturer of human and veterinary drug products. See **Exhibit # 1** for a copy of the firm's registration.

The firm's administrative hours are Monday to Friday from 8:00am to 5:00pm. The laboratory operates over two shifts, 7:00 am to 04:30 pm and 1:30 pm to 10 pm, Monday through Friday. There is a single weekend shift on Saturday and Sunday from 7:00 am to 04:30 pm Approximately 66 personnel are employed on-site.

Post inspectional correspondence should be addressed to the following address:

Nilsa Martinez, General Manager

Pace Analytical, Inc.

P.O. Box 325

San German, PR 00683.

INTERSTATE COMMERCE/JURISDICTION

The firm provides customers with contract laboratory testing. The firm does not manufacture any ingredients or finished goods. Approximately 90% of the firm's analyses are performed for customers within Puerto Rico. The raw materials, finished drug products, and medical devices analyzed on-site are purchased and/or distributed through channels of interstate commerce.The firm provides contract laboratory testing of various active pharmaceutical ingredients, finished drug products, water, and environmental samples from several pharmaceutical and medical device manufacturers throughout Puerto Rico. The laboratory testing is conducted on FDA regulated articles. See **Exhibit # 2** for a listing of the firm's customers and **Exhibit #3** for a listing of analytical services provided by Pace.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Nilsa Martinez identified herself as the General Manager and most responsible person for day-to-day operations conducted at the San German facility. She reviews revenue operations, maintains client relations, and has oversight of the QA division, facility and safety operations and human resources. She accepted Form FDA 482, Notice of Inspection. Nilsa Martinez reports directly to Gregory Kupp, VP, Chief Operating Officer of Pace Analytical Life Sciences, San German, PR. Ms. Martinez accompanied us during the inspection and was available to answer questions at all times.

Cynthia Hansen, Quality Assurance Director for Pace Analytical Life Sciences and has been with Pace since 2006. Ms. Hansen oversees Quality Operation at both the Oakdale and San German facilities, having harmonized the quality operations at both these facilities. Her responsibilities include IT data review, equipment support and document control. Ms. Hansen also reports directly to Gregory Kupp, VP, Chief Operating Officer of Pace Analytical Life Sciences. She was present on the second day of the inspection, through closing, and was available to answer our questions.

Ms. Nazario, the QA manager, was not present during our inspection.

The following personnel from the San German facility were also present and participated in the inspection by providing information, as requested:

Brenda Ojeda, Senior Microbiologist

Bianca Bonilla, Principal Specialist

Janice Billalobos, Microbiologist I

See **Exhibit # 4** for the organizational charts for Pace's Puerto Rico Operations and Pace Analytical Life Sciences, parent company.

FIRM'S TRAINING PROGRAM

The training program is described in SOP 4, Training Program, effective date 19 Feb. 2015; SOP L2, Technique Based Training, effective date 31 Oct. 2014 and SOP L21, Technical Records Review, effective date 10 Dec. 2014. The SOPs describe new hire training, annual cGMP and ethics training, job-specific procedure training and the responsibilities of the trainee, mentor and supervisor. I reviewed the training records, without objection, for Chemist, HT, from 2010 to present, for the training requirements identified in the SOPs above. I also reviewed the records for a laboratory technician DC, start date of 11 Mar. 2013, against the training requirements of SOP 4; all records were complete and consistent with SOP 4 training requirements, except I noted that the employees new position in Administration was never recorded in the training records in that a "new position acknowledgement" was never filed. Ms. Martinez stated that this was an oversight and the this would be corrected.

MANUFACTURING/DESIGN OPERATIONS

The firm does not manufacture any raw materials or finished products. The facilities include areas used for storage and analysis of raw materials, microbiological samples, medical devices and finished products (for chemistry and microbiology); the facilities also include areas used for warehousing of analytical supplies and reagents.

The firm is heavily dependent on electronic records to capture processing data and data transfer to the client. PacePort is a proprietary system used to convey testing results to the client via an online web portal. The client may access the following on PacePort: testing reports, certificates of

analysis, full data packages, including notebook pages, invoices, methods, sample processing data and test results.

See **Laboratory Control System** for a detailed description of sample testing

MANUFACTURING CODES
The logging of samples and assigning of project/sample numbers is performed using the firm's LIMS software. Each sample is assigned a unique, 7-digit Pace project/sample number. The number assigned to each sample upon is coded as follows: the first 2-digits correspond to the Puerto Rico lab location (90) and the next 5-digits consist of a unique sequential number. This information is also described in SOP 21, Sample Management, Effective Date 21 May 2015.

Quality System
As part of the Quality System, I reviewed deviations, laboratory investigations, change control and corrective action tracking.

Deviations
I reviewed the SOP entitled Deviations and Modifications, SOP 17, Effective Date 12 Jan 2015. Deviations are defined as unplanned departures from an approved laboratory method or procedure, while modifications are planned departures from the approved method. QA reviews all deviations/modifications. I reviewed the SOP without objection. I reviewed 5 of 136 deviation reports logged since January 2014 through June 2015.

- DEV 724; load sample weight deviation
- DEV 725; test execution and recording error
- DEV 745; mobile phase preparation documentation error
- DEV 748; organism ID errors in validation exercise
- DEV 765; errors in element analysis; dilution errors.

All deviations included documented corrective actions and QA review; all were opened and closed within the appropriate period.

reviewed the report for trending of deviation for the years 2013 and 2014. The report documents the total number of deviations broken down by department, individual, type of incident and method. The total number of tests performed per year is also noted. The deviation rate, compared to the number of tests performed, is very consistent, 0.1% for the last 4 years. I have no objections to the deviations procedure or the method of monitoring and controlling the deviation rate at this facility.

Laboratory Investigations:

I reviewed the following document: Laboratory Investigations, SOP L8, Effective Date 30 Jul 2014. I also reviewed Investigation logs from January 2012 to July 2015 and pulled specific reports for further review. I reviewed 8 of 24 investigation reports occurring from February 2013 to June 2015.

Of this group, four investigations were for environmental monitoring excursions:

- LIR-245; 27 Feb 2013
- LIR-249; 26 Apr 2013
- LIR-286; 21 Nov 2013
- LIR-301; 24 Jan 2014

All excursions occurred in uncontrolled areas and were near the alert and action limits for bacterial counts in these areas (within 2-fold).

Three investigations were issued for failures in filter integrity testing:

- LIR 409; 13 Apr 2015
- LIR 415; 04 May 2015
- LIR 423; 05 June 2015

No laboratory error determined; retesting was not performed; Out of Specification event logged and clients were notified.

One investigation was issued for a water sample for exceeding TOC (total organic carbon) testing limits.

- LIR 375; 23 Dec 2014

No laboratory error determined; retesting was not performed; Out of Specification event logged and the client was notified.

All laboratory investigations were performed according to the SOP and were reviewed by QA. I have no objections to the laboratory investigation procedure or results.

Change Control

I reviewed the Change Control Request log from 2013 to May, 2015. There were 36 requests in 2013, 24 in 2014 and 11 up to May of 2015. I reviewed three of thirty six selected Change Control Reports:

- CRF 178; 07 Mar 2014
- CRF 191; 14 Nov 2014
- CRF 136; 05 Feb 2013

All change control requests include the reason for the change, an impact assessment, a change plan, pre-approval by management and QA, and an implementation record which includes follow-up procedures deemed necessary during the planning phase. The post change review is performed by management and QA. I have no objections to the change control procedure or log of events.

Corrective Action Tracking (CAT)

Actions taken to mitigate the effects of deviations are reported as corrective and preventive actions and entered into the firm's Corrective Action Tracking (CAT) system according to SOP 42, "Corrective Action" Effective Date 4 Apr 2014, consists of a listing of all CAT reports which have been initiated (or remained open) since the previous FDA inspection. I did not review specific CAT reports. The log of reports that remain open identify 15 reports where the current status of each is noted and due date or extension date is listed. All CAT reports appear to be well documented and reviewed in a timely manner. I have no objection to the firm's monitoring of their corrective actions.

Laboratory Control System

The laboratory is organized in three (3) groups based on the testing they perform: Microbiological, Chemistry (raw materials), and Chemistry (finished products). I performed a walk-through of these areas.

Sample Receipt

I asked Ms. Martinez and Ms. Bonilla how samples are handled at this facility, Ms Bonilla Principal Specialist with over 5 years' experience at this company, stated that samples are received at the San German facility, logged in and assigned a unique Pace project/sample number, with bar code, and staged in appropriate storage conditions while awaiting analysis. The logging of samples and assigning of project/sample numbers is performed using the firm's Laboratory Inventory Management System (LIMS). This number is used to track the sample status throughout the testing service. Furthermore, the LIMS keeps track of all testing performed as well as the review status by QA.

Testing and Analysis

As a raw material or product is tested, the technician will generate a worksheet (Control Sheets) that specifies testing requirements and is used to record testing results. These Control Sheets are assigned a unique, sequential number and will be linked to a specific work order (WO) that is associated with the sample number. The Control Sheet is printed on watermark paper and is controlled by QA. The control sheet becomes a part of the official record of testing and will be included in the data package, described later.

Ms. Hansen stated that test results of data processing and analysis (from analytical software like Empower) are entered manually into the LIMS system (Chemware, Horizon 101 version, commercially available), into defined fields, by the analyst. Once completed, the LIMS data report, associated notebook pages and control sheets, are reviewed and approved by QA and are assembled into the data package. All raw and processed data from Empower are retained in the Empower system, and are backed up on company servers.

PacePort Upload

The data package is reviewed by QA before uploading to PacePort. PacePort will interface with the Empower and LIMS systems to access specified data for upload. Client access to PacePort is

password protected. Ms. Hansen stated that the PacePort system has been validated for security. Assembly of the data package is not validated but she demonstrated how the Paceport looks for a file to uploads by a naming convention. If this file is not found, an error message is shown. Also, she stated that QA will review the data before assembly so the risk of sending the wrong data are low.

Investigator Data Package Review

Ms. Bianca Bonilla provided a hard copy of a data package for Povidone testing (Work Order #s 9034532, 9034591 and 9034611). The control sheets for testing will identify specific equipment and reagent preparation information, including expiration dates, that was used in testing. Weights with balance tape are documented, methods are identified, equipment qualification dates are verified, HPLC columns are identified, flow rate, injection volume and temperature are also recorded here. In the results summary for the HPLC runs, the analyst provides comments and example calculations for one sample while the remainder calculations for the other samples are performed by the analytical software (Empower in this case). The analyst sign-off (4-digit code) makes reference to the Empower data set, so the Empower data are linked to the worksheet data through this code. HPLC peak integration is performed by Apex Track, an algorithm for peak integration, defined by input parameters (retention time, minimum peak area and height, peak width, detection threshold, etc.) which is part of the Empower software package. I asked Ms. Bonilla if manual integration could be performed. She stated that manual integration may be performed under certain circumstances per Chromatography SOP C-1 (not reviewed), but was not performed here for these samples.

I compared the data in the above data package to what is on PacePort for the above work orders. The data for 2-pyrrolidone content in the Povidone samples were the same in both locations.

I looked at several test worksheets in the data package and noted the testing information provided on each. The worksheet for Impurity 2-pyrrolidone determination referenced the compendia method verification for Povidone testing, including determination of LOD, LOQ, Linearity and Accuracy (**Exhibit 5**). The method verification was completed on 20 Jun 2012. I reviewed this procedure in notebook 00061 for WO 9013513, Notebook date 20 June 2012. The data in the notebook for curve area values agree with summary data in the compendia method verification. The method is per USP35/NF30. The method is 2-pyrrolidone (detection). I also checked the Empower data set for the same scan data in the notebook, and the data agree.

On page 14, notebook 00061 for WO 9013513, it is stated " notes from this linearity and quantitation limits standard were .... to be appended to WO 9010139" (**Exhibit 6**). Ms. Martinez provided a copy of the earlier compendia method transfer, dated 27 Dec 2011. This compendia test method transfer appeared to list only specificity and detection requirements (**Exhibit 7**), not LOQ, Linearity and Accuracy. It appears that the firm did not have a valid compendia transfer method in place for the period of 27 Dec 2011 to 20 Jun 2012 (See **OBJECTIONABLE CONDITIONS AND MANAGEMENTS RESPONSE**).

Laboratory Walk-Through

On the walk-through through the chemistry area, I checked various pieces of equipment for calibration dates and logs for daily checks (if applicable); all equipment noted was within its calibration date. I checked the chemical storage areas for expired material and solution preparations for expiration dates and technician identification. I observed that all chemicals and solutions in this area were properly labeled. In the chemistry wet-lab, I noticed a biuret set up for titration directly below an air vent. I advised that this is not the best location for this procedure as the air from the vent can increase evaporation of the solutions (See **General Discussions with Management**).

I examined a notebook used by technician HT (Notebook 00074). The entries for August 8, 2014 were signed by the technician but not by a second reviewer (See OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE, #1). See Facilities and Equipment for further information.

Facilities and Equipment System

Equipment calibration Program is described in SOP L17, Effective date 09 JUN 2015. I requested and reviewed a list entitled Equipment Events Due. This is a list of equipment, by name, description and the upcoming service that is required and the due date. Laboratory equipment in the analytical laboratory (GC, AA, refrigerators, HVAC) is included in a preventive maintenance program. The company or department performing the service is also identified. I reviewed the most recent service for the following equipment:

- Balance PADC-Balace-013, Date of Calibration 20Jan2015, by Mettler Toledo, San Juan.
- TOC Analyzer PADC INOR-029, #US13182009, Date of Calibration: 27 Mar2015
- HPLC Waters Alliance 2695, PADC-CL-005; (this HPLC was used in the determination of 2-pyrrolidone in Povidone testing, discussed above) . Annual requalification was performed per SOP QP72 (not reviewed) in February, 2015 and was approved 28 Mar 2015. I reviewed a summary of the testing procedure, acceptance criteria and results.

I found the equipment calibration/requalification/maintenance records acceptable. During the walk-through, the above equipment was in use during the current calibration period.

In the microbiology area, the cabinet for the storage of Rodac environmental testing plates contained bags of plates purchased by a vendor, expiration date 29 Nov 2015l Lot 132511, manufacturer: EMZ. I examined the Certificate of Analysis for this product and it indicated that growth promotion testing was performed per USP <61>. Brenda Ojeda, Microbiologist, stated that they will also perform a growth confirmation test on these media. If the media are untested, the bag is labeled with a red sticker; if the media are tested, the bag is labeled with a green sticker. Both bags are stored on the same shelf in the Rodac cabinet (**See General Discussions with Management**). I also noted that all incubators, hoods and benchtop equipment were within calibration dates identified on the equipment tags. See Environmental Monitoring, discussed below, for more information regarding this area.

Regarding environmental monitoring (EM), Ms. Ojeda stated that non-viable monitoring is performed twice per year in the microbiology testing area; viable air and surface testing is performed monthly and areas limited to immediate working areas (biological cabinets and hoods) are tested daily for viable air and surface. I reviewed EM data from testing locations in Rooms 1023 C and D for the years 2012 through the first two months of 2015. All results were within acceptable, predefined action and alert limits, except, on a few occasions in 2012 where action limits in uncontrolled areas were achieved. The establishment of Alert and Action levels is documented in SOP Q7, Cleanroom Environmental Monitoring Alert and Action Level Determination, Effective date 4 APR 2014. Environmental monitoring is performed per SOP LM 229, Cleanroom Monitoring, Effective Date 14 MAR 2014. Environmental monitoring appears to be performed according to their procedures and the results appear to be acceptable; I have no objections.

Ms. Martinez stated that as of February 2015, no sterility testing is performed at this facility; all sterility testing samples are sent to Pace testing labs in Ogden, MN.

LIMS validation was performed in 2010 in Oakdale and here in May of 2010. I reviewed a report titled "Validation of Horizon 10 Laboratory Information Management System (LIMS) Installation Qualification, VP 96, Version 1, dated 31 July 2009. A script is provided documenting test procedure and acceptable results. All acceptance criteria were met.

Installation of the Empower software was performed by the vendor. Operational qualification was performed by Pace. I reviewed the Operational Qualification testing of the Empower 2 system, dated May 2011. Specifically, I reviewed the data acquisition section (5.1) verifying raw data, application method, results, date and time stamp, data locking (non-modifiable, based on user group) and audit trail capture. Additional sections reviewed included process verification, data management and security verification. Acceptance criteria were listed for each section. All acceptance criteria were met.

COMPLAINTS

Pace only performs testing on products manufactured at other industrial facilities. The firm does not receive external complaints for drug products or medical devices. I verified that there were no complaints on file for this firm in the San Juan District Office establishment file or in FACTS.

Procedure SOP 30, "Complaint Handling" (ver. 3, previously reviewed), describes the firm's procedures for handling of complaints from clients and includes provisions for trending of complaints by category. I reviewed a list of 5 complaints received by the firm, two in 2014 and three in 2013. There were no deficiencies observed in the firm's handling of these complaints.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically,
An adequate compendia method verification was not in place for the test for 2-pyrrolidone. In a compendia method verification prepared on 27 December 2011, work order 9010139, testing for specificity and detection limit was performed for 2-pyrrolidone testing. In a subsequent compendia method verification prepared 20 June 2012, work order 9013513, testing for specificity, detection limit quantitation limit and linearity was performed. In the intervening period there was no complete compendia method verification necessary for the testing of 2-pyrrolidone. The subsequent compendia method verification of 20 June 2012 did not assess the impact of the required change, document the change or provide any reason for the change. Furthermore there was no assessment of potential impact on tests conducted on samples, if any, before the subsequent compendia method verification was initiated.

Reference: 21 CFR 211.160(b)

Supporting Evidence and Relevance:
SOP L3, Verification of Compendia Procedure, Effective Date 26 Jun 2015, provides a procedure for conducting the compendia procedures and includes the testing that is required. However, the SOP does not provide for the capture of key information when retesting is required or requested. For example, the reason for the change or the impact on tested samples, either before or after the change is not recorded. See **Exhibit 8** for the current SOP referenced above.

Discussion with Management:
I asked why the two verification procedures were not linked and why the repeated testing was necessary in the first place. I said it appears that the firm had no mechanism in place to assure the effectiveness and reliability of the method transfer for product testing. Furthermore, without documenting the change, there is no method to assess the effect of the change on product tested, either before or after the change. Ms. Hansen said it was not clear why this information was not captured and that it may be in another investigation system (like work orders for previous Providone testing) but that information was not recorded. Ms. Hansen stated that in the future, a mechanism to record any retest could be covered in a revision of the SOP for the method verification. Ms. Hansen stated they would look into a mechanism to capture this information.

OBSERVATION 2

The establishment of laboratory control mechanisms including any changes thereto, are not reviewed and approved by the quality control unit.

Specifically,
There was no secondary review of notebook 00074, from August 6, 2014 to August 8, 2014, pages 38 to 42, for notes relating to the limit of benzene compendia verification. A note on page 40 of the notebook, made by the technician, states that testing was "not valid" as the test solution was not prepared. At the bottom of page 42, it is stated that the "run failed" because there is a peak in the blank. According to SOP 11, Good Documentation Practices, management is to review and approve all invalidations and to identify affected process. The Quality group had not signed off on the invalidation at the time discovery, by this investigator, on July 6, 2015.

Reference: 21 CFR 211.160(a)

Supporting Evidence and Relevance:
In review of other, unrelated information in Notebook 00061, page 14, dated 18 Jun 2012, the technician made a note indicating that the "linearity and quantitation limits standards were voided and will not be used for the completion of the addendum..." This page was reviewed and signed by a secondary reviewer. SOPL21, Technical Records review, effective date 10 Dec 2014 does not provide a mechanism to eliminate secondary review. This information contradicts Ms. Bonilla's statement that voided data do not require secondary review.

Discussion with Management:
I stated that all data acquired during testing should be reviewed, whether related to a failed testing procedure, or not. Without a secondary review, it is conceivable that valid testing data may be inappropriately omitted. Ms. Hansen agreed with the assessment that all data should be reviewed and said that the lack of a secondary reviewer for laboratory notebooks was not a normal process. She said they would look into the matter to determine how widespread the practice is, and would then devise an approach to the eliminate the problem.

REFUSALS
There are no refusals to report for this inspection.

GENERAL DISCUSSION WITH MANAGEMENT
At the conclusion of the inspection, I had an exit meeting with Ms. Hansen and Ms. Martinez to discuss the inspectional observations listed in the FDA-483 issued at the same time. Ms. Hansen reiterated Pace's commitment to comply with the regulations and said they intended to send a written response to describe a plan to implement corrective actions to SJN-DO within 3 weeks.

Throughout the course of the inspection I brought the following items to management's attention and each point was re-stated at the closing meeting:

In reviewing the training records for DC, it was noted that the employees new position in Administration was never recorded in the training records and that a "new position acknowledgement" was never filed, as required by the training SOP 4. Ms. Martinez produced such a document, date 8 Jul 2015 who said that this document will be added to the employee's training file.

Regarding the storage cabinet for RODAC media plates, I stated that a better procedure would be to separate approved (released) and unapproved (untested) media plates that are used in environmental monitoring. Ms. Martinez and Ms. Hansen agreed and indicated that they would look into providing separate space for the untested media.

Prior to the conclusion of the inspection, I warned Ms. Hansen that the observations listed on the FDA-483 could be considered by FDA as deviations of the FD&C Act. No other issues were discussed and the inspection was concluded.

SAMPLES COLLECTED

No samples were collected throughout the course of this inspection.

VOLUNTARY CORRECTIONS

There were no objectionable observations made during the previous inspection

EXHIBITS COLLECTED

1. Pace Analytical, Inc., FDA Registration, (1 page)
2. Pace Analytical, Inc., customer list, (3 pages)
3. Pace Analytical, Inc., product list, (9 pages)
4. Pace Analytical, Inc., corporate chart, (4 pages)
5. Compendia Method Verification, 8 of June 2012, (5 pages)
6. Notebook 00061 notes, (6 pages)
7. Compendia Methods Verification, worksheet and supporting data, (27 pages)
8. SOP L3, Verification of Compendia Procedures, Effective Date 26 Jun 2015, (8 pages)

ATTACHMENTS

1. FDA Form 482, Notice of Inspection, (3 pages)
2. FDA Form 483, Inspectional Observations, (1 page)

Steven P. Donald, Investigator

Noreen Muniz, Investigator