March 24, 2005

Mr. Marvin Shacter, Manager
Hoffman Estates Laboratory
Analysts, Inc.
2450 Hassell Road
Hoffman Estates, IL 60195

SUBJECT: NRC INSPECTION REPORT 99901353/2005-201 and NOTICE of NONCONFORMANCE

Dear Mr. Shacter:

On February 22 and 23, 2005, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at the Analysts, Inc., laboratory in Hoffman Estates, Illinois. The enclosed report presents the details of that inspection.

The NRC inspectors reviewed the implementation of selected portions of the Analysts, Inc., quality assurance (QA) program and Analysts' processes for safety-related chemical and physical analyses of diesel fuel and lube oil for NRC-licensed facilities; such analyses being basic components as defined in §21.3, "Definitions," of Part 21, "Reporting of Defects and Noncompliance," of Title 10 of the *Code of Federal Regulations*, (10 CFR Part 21).

During this inspection, the NRC inspectors reviewed selected client procurement documents, Analysts QA and technical documents, test procedures and records; examined measuring and test equipment and specimens; observed testing activities in progress; reviewed personnel qualification and training records, and interviewed key personnel. In addition, the inspectors reviewed procedures, postings and records associated with Analysts's implementation of 10 CFR Part 21 requirements.

The NRC inspectors found instances in which implementation of Analysts's QA program, contractually imposed on Analysts by its nuclear utility customers, failed to meet certain requirements of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." These instances are characterized as nonconformances, are cited in the enclosed Notice of Nonconformance (NON), and are described in detail in the enclosed report. You are requested to respond to the cited nonconformances and you should follow the instructions specified in the enclosed NON when preparing your response.

In addition, the inspectors identified two minor violations of 10 CFR Part 21 requirements; specifically, §21.6, posting requirements, and the procedural requirements of §21.21(a). As these are minor violations, they will be discussed in this report, but no separate notice of violation was issued. Nevertheless, Analysts is required to institute appropriate corrective actions. Corrective action and continued compliance may be reviewed in the future.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures and your response(s) will be placed in the NRC's Public Document Room (PDR). To the extent possible, your response(s) should not include personal, private, proprietary or safeguards information so that your response(s) can be placed in the PDR without redaction. However, should you find it necessary to include such information, you should clearly identify that which you desire not be placed in the PDR and provide the justification for withholding from public disclosure as delineated in 10 CFR 2.790 (recently revised, effective June 16, 2003).

The responses requested by this letter and the enclosed Notice of Nonconformance are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Should you have any questions concerning this inspection, please contact Mr. Stephen Alexander at 301-415-2995 or by e-mail at sda@nrc.gov .

Sincerely,

/RA/

Theodore R. Quay, Chief
Plant Support Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Docket No. 99901353

Enclosures: 1. Notice of Nonconformance
2. Inspection Report 99901353/2005-201

cc/wencl:
Mr. Joel Mountain, MSQA
Corporate Quality Assurance Manager
Analysts, Inc.
3075 Corners North Court, NW
Norcross, GA 30091

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Docket No.: 99901353

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2. Inspection Report 99901353/2005-201

cc/wencl:
Mr. Joel Mountain, MSQA
Corporate Quality Assurance Manager
Analysts, Inc.
3075 Corners North Court, NW
Norcross, GA 30091

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DATE	03/ 24/05	03/24/05	03/24/05

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NOTICE OF NONCONFORMANCE

Analysts Inc. Docket No.: 99901353
Hoffman Estates, IL, Laboratory Inspection Report No.: 2005-201

Based on the results of an inspection conducted on February 22 and 23, 2005, it appeared that certain activities of Analysts, Inc., Hoffman Estates Laboratory (Analysts) were not conducted in accordance with NRC requirements as set forth below:

A. Criterion I, "Organization," of 10 CFR Part 50, Appendix B, states, in part, that the persons performing quality assurance (QA) functions shall have authority and organizational freedom and shall report to a level of management such that this required authority and organizational freedom, including independence from cost and schedule when opposed to safety considerations, is provided.

Contrary to the above, prior to the hiring (a few months before the inspection) of a separate individual to serve as the Analysts Hoffman Estates Laboratory onsite QA Manager, the Laboratory Manager had been for some time performing the duties of the onsite QA manager himself, with some assistance during visits from time to time by the Analysts Corporate QA Manager based in Atlanta, Georgia. Therefore, the person performing QA functions onsite did not have sufficient independence from cost and schedule considerations. Nonconformance 99901353/2005-201-01

B. Criterion V, "Instructions, Procedures, and Drawings," of 10 CFR Part 50, Appendix B, states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to the above, as of February 23, 2003, Analysts was using some procedures that were not appropriate to the circumstances to prescribe activities affecting quality and some procedures did not have adequate qualitative or quantitative acceptance criteria. Although Analysts personnel were expected to comply with the existing procedures, there were instances of noncompliance. Nonconformance 99901353/2005-201-02.

C. Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, requires, in part, that a test program be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents...Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

Contrary to the above, as of February 23, 2005, certain Analysts test procedures, test equipment and laboratory practices were not consistent with the applicable industry standards with which the laboratory certifies compliance, in that procedures did not always specify appropriate measuring and test equipment, test equipment was not set up in accordance with the procedure or applicable standard, or procedures lacked adequate specificity when prescribing certain test steps, test parameters or acceptance criteria. Nonconformance 99901353/2005-201-03.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Plant Support Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 24th day of March, 2005

INSPECTION REPORT
Plant Support Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

INSPECTION OF:	Analysts, Inc.
FACILITY:	Hoffman Estates Laboratory
INSPECTION DATES:	February 22-23, 2005
DOCKET/REPORT NO.:	999001353/2005-201
VENDOR CONTACT:	Marvin Shacter, Laboratory Manager (800) 222 - 0071 (847) 884 - 7877
ADDRESS:	2450 Hassell Road Hoffman Estates, IL 60195
INSPECTION TYPE:	ANNOUNCED, REACTIVE
TEAM MEMBERS:	Stephen Alexander, NRR/DIPM/IPSB, Team Leader Carolyn Lauron, NRR/DE/EMCB Jessica Umaña, NRR/DIPM/IPSB
INSPECTION BASES:	10 CFR Part 21 10 CFR Part 50, Appendix B
SCOPE:	10 CFR Part 21: procedures, posting, records 10 CFR Part 50, Appendix B:QA manual, QA procedures, internal QA audit records, external QA audits, handling of discrepancies, corrective action (Criteria XV and XVI), procurement and dedication, QA organization, lab travelers, sample identification, documentation of results, M & TE QA, calibration

SUBMITTED: ***/RA/*** Date 3/24/05
Stephen D. Alexander, Lead Inspector

APPROVED: ***/RA/*** Date 3/24/05
Dale F. Thatcher, Chief, QMS/IPSB

Enclosure 2

1.0 INSPECTION SUMMARY

The purpose of this inspection was to evaluate the implementation of selected portions of the quality assurance (QA) program of the Analysts, Inc., Hoffman Estates, IL, Laboratory (Analysts), in the area of safety-related chemical and physical analyses of diesel fuel and lube oil that it provides as basic component services to NRC-licensed facilities of the commercial nuclear power industry. The inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50, Appendix B)

- 10 CFR Part 21, "Reporting of Defects and Noncompliance"

- Applicable industry standards on diesel fuel and lube oil analyses

The inspectors identified nonconformances with respect to three criteria of 10 CFR Part 50, Appendix B: Criterion I, “Organization,” Criterion V, “Instructions, Procedures, and Drawings,” and Criterion XI, “Test Control.” The inspectors also identified specific deficiencies with respect to applicable industry standards.

In addition, the inspectors identified two minor violations of 10 CFR Part 21 requirements; specifically, §21.6, posting requirements, and the procedural requirements of §21.21(a). As these are minor violations, they will be discussed in this report, but no separate notice of violation will be issued. Nevertheless, Analysts will be expected to institute appropriate corrective actions.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There have been no previous NRC inspections of this facility.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

The inspectors reviewed procedures, records and other documents, including nuclear plant client procurement documents to verify the adequacy of Analysts’ 10 CFR Part 21 program and its implementation, and the adequacy of the Appendix B QA program and its implementation. In addition, the inspectors reviewed selected lab procedures, observed lab practices, examined measuring and test equipment (M&TE) and other laboratory analysis apparatus and test samples, reviewed control and calibration of M&TE, reviewed technician training and qualification, observed analyses in progress and interviewed personnel to confirm adequate laboratory practices.

3.1 Quality Assurance Program

a. Inspection Scope:

The inspectors reviewed purchase orders of the nuclear customers. For safety related sample analyses, the contract release specified requirements for “Safety Related (ASME & NON-

ASME)" and that 10 CFR Part 21 applied. In addition, clients typically imposed the requirements of Analysts, Inc.'s client-approved QA programs that should meet the requirements of 10 CFR Part 50, Appendix B. The inspectors reviewed selected QA procedures and the QA manual. The inspectors also checked on the certification of the Hoffman Estates and Atlanta labs to receive and handle potentially radioactively contaminated oil samples.

b. Findings and Observations:

The inspectors found that the Hoffman Estates Laboratory had not had a separate individual, with adequate independence from cost and schedule considerations, permanently assigned as onsite QA Supervisor until a few months prior to this inspection. At most other times, with the exception of one or two brief periods, and contrary to Criterion 1, "Organization," of Appendix B to 10 CFR Part 50, the laboratory manager himself had acted in this capacity with occasional assistance from the Analysts Corporate QA Manager during periodic visits to the Hoffman Estates lab. The inspectors determined that the individual who was permanently assigned as onsite QA Manager at the time of our inspection had been hired recently, in part, to correct this QA deficiency and was receiving on-the-job training and gaining experience in that position.

With regard to handling of potentially radioactively contaminated oil samples, the inspectors determined that both the Hoffman Estates laboratory and the Atlanta laboratory had been certified to receive potentially radioactively contaminated samples and that the Hoffman Estates laboratory did occasionally receive such samples. However Analysts stated that it was not their practice to send potentially contaminated samples received at Hoffman Estates to the Atlanta laboratory because they were usually quite able to handle all they received in house.

c. Conclusions:

Criterion I, "Organization," of 10 CFR Part 50, Appendix B, states, in part, that the persons performing quality assurance (QA) functions shall have authority and organizational freedom and shall report to a level of management such that this required authority and organizational freedom, including independence from cost and schedule when opposed to safety considerations, is provided. The person serving as QA manager not having sufficient independence from cost and schedule considerations is a nonconformance with respect to this Appendix B requirement. Accordingly, Nonconformance 99901353/2005-201-01 was cited.

3.2 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed Analysts's procedures and posting related to the implementation of its program established to comply with the requirements of 10 CFR Part 21 (Part 21). Analysts produced no records of evaluations or notifications, stating there had been none, but the inspectors reviewed its records of customers to whom it had supplied basic components.

b. Findings and Observations:

Part 21 Procedure: The latest revision of Analysts, Inc., Hoffman Estates Procedure IL 1035-Defects; Reporting of Defects and Non-Compliance; 10 CFR Part 21, Revision 0, dated November 1, 1993, was not adequate to prescribe the actions required by §21.21(a). Specifically, even though it was dated 1993, it did not reflect the changes to 21.21(a) made in 1991 that are required to be in Part 21 procedures, i.e., completion of 21.21(a)(1) evaluations within 60 days of discovery, an interim report to the NRC within 60 days of discovery if the evaluation cannot be completed within the 60 days per 21.21(a)(2), and the notification of a director or responsible officer within 5 working days of completion of the evaluation per 21.21(a)(3) if there are defects or failures to comply involving substantial safety hazards in basic components (including services) supplied to NRC-licensed facilities.

Although designation of the facility-specific director or responsible officer is not explicitly required to be part of Part 21 procedures, IL-1035 did so, which is useful, except that it designated the laboratory manager as the responsible officer, which did not meet the definition in 21.3, and contained out-of-date NRC notification requirements. IL-1035 did contain several other non-required, but useful and desirable provisions regarding posting, procurement documents and training. However, the posting provision was not correct in that it did not specify the posting of IL-1035 itself per 21.6(a), nor did it prescribe the contents of the alternative notice correctly in accordance with 21.6(b).

Section 21.21(b) of Part 21: Section 21.21(b) of Part 21 states that if a deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation per §21.21(a)(1), then the supplier must inform the purchasers or affected NRC licensees within five working days of this determination so that they may evaluate the deviation or failure to comply. Analysts stated that in all cases it would not be capable of performing a 21.21(a)(1) evaluation; therefore its standard practice is to inform its customers in accordance with §21.21(b) of any deviations or failures to comply of which it may become aware in basic components supplied by Analysts. Although 21.21(b) notification is not required by 21.21(a) to be in procedures, in practice, 21.21(b) would be the only meaningful way in which Analysts could comply with the reporting requirements of Part 21. Therefore, since analysts had appropriately included it its procedures other provisions for implementation of Part 21 requirements, Analysts stated that this elective provision would also be included among the revisions to their Part 21 procedure to correct the identified deficiencies in both required and non-required provisions as noted above.

Part 21 Posting: Pursuant to §21.6, Analysts had posted in an appropriate location a copy of the procedures adopted to implement the provisions of 10 CFR Part 21, and a copy of 10 CFR Part 21 itself. However, the posting did not comply with the provisions of the Analysts Part 21 procedure, nor the requirements of 21.6, in that it did not include a copy of Section 206 of the Energy Reorganization Act of 1974.

Part 21 Records: Analysts had no records of Part 21 notifications to its clients or to the NRC. However, the inspectors did not identify any instances in which such notifications should have been made. Analysts did have records of analysis results reported to clients, including reports

of analyses of samples routinely taken from diesel fuel tanker trucks bound for client plants. In some cases, the results were unsatisfactory and the client plants were advised to reject the fuel shipment. The inspectors identified no concerns in this area.

c. Conclusions

The inspectors concluded that Analysts's Procedure IL-1035, Revision 0, dated November 1, 1993, was not adequate to ensure that the specified requirements in 21.21(a) are satisfactorily implemented. This was a minor violation of 21.21(a). Analysts Corporate QA Manager promptly commenced preparation of a revision to the procedure during the inspection to correct the violation as well as the incorrect elective provisions and presented a rough draft for the inspectors' review. The inspectors explained some additional revisions that would be needed to fully correct the violation and the QA Manager committed to effect those revisions. In addition, the omission of Section 206 of ERA-74 from the Part 21 posting was a minor violation of 10 CFR 21.6. Analysts posted Section 206 prior to the exit meeting to correct the violation.

3.3 Personnel Training and Qualification, Working Environment and Safety Culture

a. Inspection Scope:

The NRC inspectors interviewed Analysts inspection and test personnel. As part of the interviews, the inspectors asked the Analysts employees whether they felt intimidated or uncomfortable raising concerns with their supervisors or felt pressured into accepting components without adequately verifying the quality attributes.

b. Findings and Observations:

Interviews with test and inspection personnel revealed that employees were generally satisfied in their jobs and were comfortable with raising issues to their supervision. The employees interviewed indicated that while there was some pressure placed on them to finish jobs as expeditiously as practicable, they did not feel pressure to take shortcuts.

The inspectors interviewed the lead lab technician and several others. The inspectors toured the lab and the lead lab technician explained the function and the type of analysis conducted at each station (e.g., particulate count, viscosity, etc.). The inspectors asked about the procedures used in the lab. The technicians were asked if they took any shortcuts, bypassed any of the procedures in order to process the samples faster and whether it was possible for them to estimate the results of the analyses conducted. The lead technician exhibited the procedures and explained the steps. She said that there was no way to take shortcuts because they cannot guess the outcome of the analyses and they cannot force the results. They are also not given the acceptance criteria. Only the data analysts have access to those. The technicians are just supposed to record results, and in many cases, the results of the tests are recorded automatically by the equipment. She also stated that there would be no incentive to take shortcuts because if an analysis showed an anomalous, erroneous, or out-of-specification result, then they are required to rerun the sample, which in some cases might require the technician to stay past normal working hours. Two other technicians were asked if they ever took shortcuts. They both said that there is no way to take shortcuts with the procedures being used. If an error is shown in a sample then the analysis would have to be performed again.

The inspectors determined that English is a second language for most of the laboratory technicians. Many of them did not read English well, and at the time of the inspection, the procedures were written in English only. However, the inspectors determined that by means of verbal explanation of the procedures to the technicians in conjunction with demonstrations of the desired techniques, supervisors who were more fluent in both English and Spanish were able to ensure that the Spanish-speaking technicians understood the procedures and could perform them properly. There was also supervision in the lab as well as separate scrutiny of results by the data analysts to monitor performance. The inspectors also determined that technicians were familiar with the procedures by virtue of training and experience. Nevertheless, Analysts, Inc., agreed to have translations prepared as necessary so that technicians could refer to written procedures more readily with less reliance upon supervision.

c. Conclusions

The inspectors concluded that Analysts's inspection and test personnel had adequate training for their assigned duties, but that not having procedures appropriate to the circumstances, i.e., that could be read and understood by technicians without the need for undue reliance on assistance from supervisors, constituted a nonconformance with respect to Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50. However, the inspectors further concluded that although proper translations of procedures should be made available for ready reference by lab technicians, the lack of them appeared to have impacted efficiency only. The inspectors could not conclude that any deficiencies in quality were attributable to lack of procedures in Spanish. Finally, the inspectors concluded that while they did identify certain technical and QA deficiencies, there was no indication of undue production pressure or short cuts being used that would significantly impugn the technical integrity of Analysts process or results. Nonconformance 99901393/2005-201-02 was cited.

3.4 Test Procedures, Equipment and Laboratory Practice

3.4.1 Test Procedures

The analyses of diesel fuel oil data is based on ASTM D975-98b, "Standard Specification for Diesel Fuel Oils." Specifications for the diesel fuel oil samples are listed in the final report along with the test results from the laboratory analyses. Based on discussions with the laboratory manager, these specifications were provided by the client upon agreement of contractual services for diesel fuel oil testing. The inspectors noted that these specifications are consistent with the ASTM standard.

a. Inspection Scope

The NRC inspectors reviewed selected Analysts laboratory procedures to verify technical and quality adequacy, including appropriate approvals, change control, control of M&TE, references, technical basis, and acceptance criteria. To aid in evaluating procedural effectiveness, the inspectors also reviewed analysis results and records, examined apparatus and samples, observed analyses being performed and interviewed lab technicians using the procedures.

Analysis procedures reviewed included the latest revisions of the following:

1. IL-9000-WSCENT, "Water and Sediment in Middle Distillation Fuels by Centrifugation." Original issue date: 12/15/95 Short lab-specific procedure based on ASTM D2709, "Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge".

2. IL-ASTM-CONT. (D4176), "Feed Water and Particulate Contamination," Revision 0, dated 11/30/02, stamped "Obsolete" Cover page with ASTM D4176, "Standard Test Method for Free Water and Particulate Contamination in Distillate Fuels (Visual Inspection Procedures)," attached.

3. IL-ASTM-FUEL CONT (D5452), "Particulate Contamination in Aviation Fuels," Rev. 0, dated: 11/30/02, stamped "Obsolete" Cover page with ASTM D5452, "Standard Test Method for Particulate Contamination in Aviation Fuels by Laboratory Filtration," attached.

4. IL-9010, "Procedure: ASTM D2276-89 (Lab Method): Standard Test for Particulate Contamination in Aviation Fuel," Revision 0.
   Original issue date: 09/12/98
   ASTM D2276, "Standard Test Method for Particulate Contaminant in Aviation Fuel by Line Sampling".

b. Findings and Observations:

Copies of the laboratory procedures for various fuel oil analyses were provided for review prior to the lab tour. Most of the procedures consisted of a cover page attached to a copy of an ASTM standard. The cover page included the procedure number, procedure title, issue date, and revision. The inspectors noted that an ASTM standard attached to a cover page and assigned a procedure number is not a laboratory procedure. The ASTM fuel oil analysis standard provides the method for testing; however, procedural steps specific to the equipment and reagents used in the laboratory are not included in the standard. Laboratory procedures typically address calibration of equipment and specific reagents to use for the analyses. In addition, laboratory procedures include best practices and conventions applicable to the analyses.

Some of the procedures were updated within the 4 weeks of the inspection. These procedures consisted of a cover page which included procedure number, title, issue date, and revision. Subsequent pages included headings such as description, test method, apparatus, and calculations. Under each heading, "see ASTM standard" was listed. The appropriate ASTM standard was also attached to the procedure. Based on discussions with the lab manager and the corporate quality assurance (QA) manager, these procedures are a product of the laboratory's process of adopting International Standard Organization (ISO) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The inspectors noted that the reference to the ASTM standard is an insufficient laboratory procedure since it does not include laboratory and specific equipment considerations. A few of the procedures consisted of simplified steps that did not provide sufficient detail to ensure proper completion of the analysis and were also not adequate for training and qualification of laboratory technicians.

c. Conclusions:

The inspectors concluded that the procedural deficiencies cited above constitute additional examples of a nonconformance with respect to Criterion V, “Instructions, Procedures and Drawings,” of 10 CFR Part 50, Appendix B, in that certain procedures were not appropriate to the circumstances, and did not have appropriate qualitative and/or quantitative acceptance criteria. Accordingly, Nonconformance 99901353/2005-201-02 was cited.

3.4.2 Laboratory Practices

a. Inspection Scope:

The inspectors observed several analyses being performed including the following:

1. Sulfur test based on ASTM D4294-03, "Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectrometry."

2. Particulate by filtration based on ASTM D5452, "Standard Test Method for Particulate Contamination in Aviation Fuels by Laboratory Filtration."

3. Particulate and water by centrifugation based on ASTM D2709, "Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge."

4. Clear and bright based on ASTM D4176-93, "Standard Test Method for Free Water and Particulate Contamination in Distillate Fuels (Visual Inspection Procedures)."

5. Viscosity based on ASTM D445-03, "Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity)."

6. API gravity based on ASTM D1298-99, "Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method."

7. Distillation of Petroleum Products based on ASTM D86, "Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure."

8. Ramsbottom carbon residue based on ASTM D524, "Standard Test Method for Ramsbottom Carbon Residue of Petroleum Products."

9. Density by hydrometer based on ASTM D1298, "Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method."

b. Findings and Observations:

The inspectors identified technical deficiencies in the performance of several analysis procedures including procedural compliance, use and calibration of M&TE, analytical

techniques (e.g., reading volumes, quantitative transfer), data recording methods, calculational methods, an sample segregation as illustrated in the following examples.

In observing the water content by direct heating (hotplate) method, the inspectors found that there were no objective acceptance criteria, but they confirmed that this test was not performed on any safety-related samples.

The inspectors found that in the Karl Fischer titration for water in lube oil, the lab's method of cleaning or flushing of sample tubes between specimens was inadequate. There would be two plausible potential effects on the validity of the analysis in this case due to sample cross-contamination because of the deficient cleaning: (1) introduction of extraneous impurities from the residue of one specimen into a subsequent, "cleaner" specimen and (2) potential dilution of a specimen with an unacceptable level of impurities by the residue from a previous specimen that may have been much cleaner. However, the inspectors found that any residual material would be of very small volume such that only significant impurity levels in residue could conceivably make a subsequent specimen appear to have more water than it really had, which is conservative, even if not accurate; whereas there would not be enough volume of residue of a clean sample to cause any significant dilution of a subsequent specimen such that its impurity content might be significantly underestimated. Therefore, although Analysts will be upgrading their practice, the adverse impact of this deficiency would not be safety significant.

The inspectors also observed that the method being used to measure the amount of sample used in the Karl Fischer titration was not adequately controlled. Also the uncertainty of this parameter and its effect on the accuracy of the analysis had not been analyzed. In addition, observation of the ASTM D2709 water and solids by centrifuge analysis revealed that the uncertainty of the measurement of the 100 ml to be centrifuged for the analysis was also not established, controlled or its effect on analysis accuracy analyzed.

The inspectors observed analyses on different diesel fuel oil samples and noted that the methods used were generally consistent with ASTM standards, in some cases, the laboratory technicians were performing the analyses without laboratory procedures. Obsolete laboratory procedures were later provided to the inspectors while observing the subsequent analyses. Based on discussions with the laboratory technicians and the laboratory manager, the laboratory procedures for these analyses were recently removed and replaced with a copy of the ASTM standards. The inspectors noted that although the laboratory technicians efficiently performed the analyses, there were no procedures followed to ensure that important steps in the analyses had been completed satisfactorily.

In addition, the inspectors noted that the laboratory technicians had various methods for documenting results. One documented the results of her analyses on a client-specified worksheet before transferring the information to a laboratory analyses traveler. The data in the laboratory analyses traveler is later entered into the laboratory's database for data analyses, trending, and reporting. A second laboratory technician documented the results of his analyses in a laboratory notebook, performed the calculation, and transferred his results to the laboratory analyses traveler. The data in the laboratory analyses traveler is also entered into the laboratory's database for data analyses, trending and reporting. The inspectors reviewed a sample of completed laboratory analyses travelers and the reports generated based on the data and did not note any discrepancies among the information provided on the various data sheets.

In addition, the rounding convention in use in calculations this part of the lab did not call for rounding to the even number when the significant digit being truncated is exactly 5 to avoid accumulation of rounding error as is conventional scientific practice. The lab did not have a procedure that prescribed standard computation protocols.

During the laboratory tour, the inspectors noted that some of the diesel fuel oil samples are labeled to include pre-designated diesel fuel oil analyses to be performed. In addition, some of the sample labels are hand-marked indicating different and/or additional analyses to be performed. Upon receipt of the samples, a traveler document is created by entering information on the labels into the laboratory's database. The client-designated identifier on the sample's label (called an “EPN”) is linked to the diesel fuel oil analyses to be performed. During this process, the inspectors noted that there was no verification of the information on the labels with the information generated by the database upon entry of the EPN identifier. Upon further discussion with laboratory manager and the corporate QA manager, the inspectors learned that there is extensive discussion between the laboratory personnel and the clients when any discrepancies arise. In addition, reportedly, there are also discussions between the laboratory technicians and the clients when the traveler documentation does not match the sample's label. The inspectors did not observe any of these discussions, but found that the laboratory appeared to have an ad hoc method to handle sample identification, source and requested analysis discrepancies. The assurance of quality in lab’s processing of samples could be improved by controlling this area with standard procedures.

c. Conclusions:

The inspectors concluded that the noted deficiencies in laboratory practices constituted examples of the nonconformances with respect to Criteria V and XI of 10 CFR Part 50, Appendix B. Nonconformances 99901353/2005-201-02 and 03 were cited. The inspectors further concluded that some of the deficiencies observed would either have a negligible effect on the validity of the analyses or a conservative effect. However, in all cases, Analysts staff stated their intention to take corrective actions.

3.4.3 Measuring and Test Equipment (M&TE)

a. Inspection Scope:

The inspectors examined M&TE and other laboratory apparatus to evaluate use of proper equipment and to evaluate operation and calibration of M&TE. To aid in evaluating M&TE, the inspectors also reviewed procedural or standards M&TE specifications, analysis results and records, examined samples, observed analyses being performed and interviewed lab technicians using the M&TE.

b. Findings and Observations:

During the laboratory tour and observations of the fuel oil analyses, the inspectors noted that laboratory procedures did not address the calibration of equipment used for the analyses. However, upon request of the inspectors, recent calibration records for the centrifuge and scale were made available. In addition, the inspectors observed that the calibration labels on the equipment used for viscosity and distillation measurements were up to date. Based on

discussions with the laboratory manager and the corporate QA manager, the inspectors noted that laboratory procedures should include initial steps to verify that the equipment used for analyses are calibrated and ready for use.

Examination of the apparatus used for the fuel particulate filtration analysis revealed that the apparatus was not set up in accordance with ASTM-D5452 as required. Specifically, the flushing fluid container did not have a 0.45-micron filter unit fitted and the flushing fluid, petroleum solvent, had not been filtered to that level of purity as required by the standard. In addition, the filtration apparatus under the flame hood did not have ground wires installed through collection and isolation flasks as required by the standard and the vacuum pump motor was not explosion proof.

Observation of the sulfur test per ASTM D4294-03, "Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectrometry" revealed that the instrument calibration procedures in use were not formalized. The method of determining correction factors and calculating corrections was not consistent with the instrument manual and there were no procedures that prescribed the process as it was being done. The technician used a calibration check process involving standard samples of known sulfur content to check calibration of the EDXF spectrometer that were not unreasonable, but were not consistent with the instrument's manual, which itself was difficult to interpret. The procedure formerly used to prescribe the sulfur test was marked obsolete and was more specific to the lab's methods, but it did not prescribe the calibration check procedure in enough detail to ensure repeatability. The practice in use may have been acceptable, but that could not be readily confirmed. Analysts committed to review and revise the procedures for this test and the instrument calibration checks as necessary.

c. Conclusions:

The inspectors concluded that the deficiencies described above constitute a nonconformance with respect to Criterion XI, "Test Control," of 10 CFR Part 50, Appendix B, in that written test procedures and actual practice did not always incorporate the requirements and acceptance limits contained in applicable design documents, i.e., applicable industry standards certified to, and in that test procedures did not always include provisions for assuring that all prerequisites for the given test have been met or that adequate test instrumentation was available and used. Accordingly, Nonconformance 99901353/2005-201-03 was cited. However, the inspectors concluded that the deficiency in the flushing fluid filtration for the fuel filtration test would be conservative in any effect it might have. Also, the other deficiencies in the apparatus may pose a safety hazard with the highly volatile flushing fluid, but would not adversely affect the analysis.

4.0 MANAGEMENT MEETINGS AND PERSONNEL CONTACTED

4.1 Entrance and Exit Meetings:

In the entrance meeting on February 22, 2005, the NRC Inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with Analysts staff. In the exit meeting on February 23, 2005, the NRC Inspectors discussed the findings and observations with Analysts staff.

4.2 Personnel Contacted:

Marvin Shacter	Laboratory Manager	*
Joel Mountain	Corporate QA Manager	*
Torrance Clark	QA Manager	*
Timothy Gibbons	Lead Data Analyst	*
Richard Graham	Data Analyst	*
Betty Jimerson	Incoming Materials Inspection and Documentation Clerk	*
Wylet Khamis	Senior Laboratory Technician	*
Steven Kullas	Laboratory Technician	*
Consuelo Lara	Senior Laboratory Technician	*
Marguerita Lara	Laboratory Technician	**
Judith Aroyo	Laboratory Technician	**

* Attended entrance and exit meeting.
** Attended exit meeting only.