



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

September 30, 2004

Mr. Paul S. Prev y III, President
Lambda Research, Incorporated
5521 Fair Lane
Cincinnati, Ohio 45227

SUBJECT: NRC INSPECTION REPORT 99901345/2004-201

Dear Mr. Prev y:

On September 27-28, 2004, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at the Lambda Research, Incorporated (Lambda) facility in Cincinnati, Ohio. The enclosed report presents the details of that inspection.

The NRC inspectors reviewed the implementation of selected portions of the Lambda quality assurance program, and evaluated the effectiveness and control of the salient portions of Lambda's 10 CFR Part 21 (Part 21) controls. During this inspection, the NRC inspectors focused on Lambda's control of deviations and failures to comply that relate to its 10 CFR Part 50, Appendix B, safety-related services.

The inspectors concluded that the control of selected portions of Lambda's quality assurance and Part 21 controls regarding its safety-related activities was found to be generally acceptable with some exceptions. As discussed with you during our exit meeting, my inspectors identified some concerns with Lambda's Part 21 procedure and its recent Part 21 training module. Although your Part 21 procedure was found to be in violation of the requirements, the inspectors identified that the inconsistency with your Part 21 procedure did not cause any Part 21 violations to occur and was found to be minor. Therefore, the identified violation will not be cited and no response to this letter is required.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC's Public Document Room (PDR).

Sincerely,

(Original /s/ by T. R. Quay)

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

Docket No. 99901345

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DATE	09/30/04	09/30/04	09/30/04	09/30/04	

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**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION**

Report No: 99901345/2004-201

Organization: Lambda Research, Incorporated
5521 Fair Lane
Cincinnati, Ohio 45227

Vendor Contact: Ms. Sandy Messerly
Quality Assurance Administrator
(513) 561-0883

Nuclear Industry: Lambda Research, Incorporated (Lambda) is an independent laboratory specializing in x-ray diffraction and related methods of material testing. Lambda focuses its testing in the areas of residual stress measurement, texture analysis, and quantitative phase analysis of polycrystalline and ceramic materials. Additionally, Lambda performs x-ray diffraction crystallographic texture analysis of zircalloy products for nuclear industry customers.

Inspection Dates: September 27-28, 2004

Inspectors:

(Original /s/ by J. Petrosino)
Joseph J. Petrosino, IPSB/DIPM/NRR
Inspection Team Leader

Date: 09/30/04

(Original /s/ by G. C. Cwalina)
Gregory C. Cwalina, IPSB/DIPM/NRR

Date: 09/30/04

Approved by:

(Original /s/ by D. F. Thatcher)
Dale F. Thatcher, Section Chief
Plant Support Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Date: 09/30/04

ENCLOSURE

1.0 INSPECTION SUMMARY

The purpose of this inspection was to evaluate selected portions of the quality assurance (QA) and 10 CFR Part 21 (Part 21) controls that Lambda Research, Incorporated (Lambda) has established and implemented. The inspection was conducted at Lambda's office and laboratory facility in Cincinnati, Ohio. 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 (Appendix B), and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There were no NRC inspections or technical reviews performed at the Lambda facility prior to this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 10 CFR PART 21 PROGRAM

a. Inspection Scope

The NRC inspectors reviewed Lambda Procedure 3P5001.01, "Reporting of Defects and Noncompliance-10CFR21," associated documents and records related to the implementation of its program that had been established to comply with the requirements of Part 21.

b. Observations and Findings

The NRC inspectors noted Section III.A of Procedure 3P5001 requires personnel to report identified problems to the Quality Assurance Administrator. However, a review of the Part 21 training module indicates that personnel are instructed to report problems to the Director of Research. The inconsistency was discussed with Lambda staff who stated the Director of Research or the Vice President, Director of Laboratories, were the correct persons to whom reports should be made. During the inspection, the training module was revised to add the Vice President, Director of Laboratories as a recipient of reports. In addition, Lambda revised Procedure 3P5001 to require reporting to the Director of Research or the Vice President, Director of Laboratories, consistent with the training module.

The inspectors also noted that Lambda's procedure requires informing clients whenever a deviation is discovered, as Lambda does not have the capability to determine if a deviation could cause a substantial safety hazard as discussed in §21.21(b) of Part 21.

The inspectors found the Lambda approach acceptable and appropriate for the establishment of Lambda's Part 21 procedure since Lambda does not know the application of its x-ray diffraction crystallographic texture analyses of zircalloy products for nuclear industry customers and, therefore, could not perform the §21.21(a) required evaluation of deviations or failures to comply associated with substantial safety hazards.

However, contrary to the Part 21 requirements, Lambda did not include in its Part 21 procedure the required time limits, i.e., clients should be informed within 5 working days of the discovery of the deviation. In addition, Section III.D of Lambda's procedure discusses notification of the NRC, however, time limits for that notification are also not included. During the inspection, Lambda provided the inspectors a revised procedure 3P5001 for their review and the inspectors found the procedure to include appropriate time limits and to be acceptable for the scope of Lambda's §21.21(b) responsibilities. That is, §21.21(b) of Part 21 states:

If the 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 to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to §21.21(a).

The inspectors reviewed a listing of Quality Assurance Incident Reports (QAIRs) and some selected reports back to 1998 in order to determine if Lambda had been appropriately implementing its Part 21 responsibilities regarding informing end users of deviations. The inspectors were not able to identify any QAIR records relating to a 10 CFR Part 50, Appendix B purchase order. Therefore, in order to evaluate Lambda's typical process regarding the identification of deviations and its practice of informing customers, the inspectors selected a QAIR related to erroneous data reported to a client. Although the client is a nuclear industry customer, the purchase order reviewed had not imposed any 10 CFR Part 50, Appendix B safety-related or Part 21 requirements. That is, Part 21 was not applicable to the Lambda activities performed for the specific testing.

The selected record showed that Lambda issued a final report to their client reporting the results of an x-ray diffraction crystallographic texture analysis dated June 10, 1999. The report noted the texture was, "not typical of the texture of tubes for analysis in the past." According to Lambda records, the client requested Lambda to recheck the analysis. Lambda began setting up for the re-analysis on June 18, 1999, and issued a second report on July 2, 1999, which identified that the original report provided erroneous results due to a sample mounting error of the original specimen.

The inspectors determined that a draft QAIR was provided on July 16, 1999 (Note: the (first) draft Attachment 1 to the draft QAIR was dated July 15, 1999. The draft QAIR provided a description of the problem, cause, solution and proposed corrective actions. The draft QAIR noted the client had been informed of the problem and a corrected report issued. The inspectors noted that some of the recommended actions had been crossed out on the draft QAIR. The inspectors identified another (second) draft QAIR

Attachment 1, also dated July 15, 1999. The second draft QAIR attachment contains different recommendations from the first draft QAIR attachment. The final QAIR was not issued until February 25, 2000, due to disagreements within Lambda as to the recommended corrective actions. Lambda procedures state that a QAIR is not final until it has been signed by the Director of Research. The inspectors discussed the reason for the delay in issuing the final QAIR. The Director of Research stated that there was a disagreement as to the required corrective actions which took a long time to resolve. Since one individual did not agree with the final resolution both QAIRs were kept in the records. Although it took an excessive time to finalize the QAIR, the inspectors were satisfied that the client had been notified in a timely manner and Lambda was actively discussing necessary internal corrective actions.

The inspectors noted that the two QAIR attachments, both labeled Attachment 1 and dated the same were confusing and suggested Lambda improve the identification of such documents in future similar cases.

Based upon the documents reviewed, the inspectors were unable to identify precisely when the client was informed of the Lambda sample mounting error. The original report was issued on June 10, 1999, and the QAIR records indicate that Lambda began to prepare for the re-analysis on June 18, 1999. Since Lambda would need a new sample from the client in order to re-analyze the material, it is apparent that the client was informed sometime in that time frame which encompassed six working days. As noted above, the QAIR does not relate to a nuclear safety-related order. However, Lambda's actions in response to this QAIR appeared to be indicative of Lambda's response and provided the inspectors a basis to judge how Lambda might respond to a similar safety-related episode.

Training Module: During the review of associated Part 21 records, the inspectors reviewed the training module for a recently performed Part 21 training class. The inspectors noted that one section of the training syllabus, regarding "when should you report" deviations or failures to comply, inadvertently created a high threshold for individuals to inform their supervision of deviations or failures to comply. Additionally, the syllabus did not clearly articulate the five working day time limit to report deviations to customers.

Discussions were conducted between the inspectors and Lambda staff to discuss the inconsistencies between the Part 21 regulation and the training syllabus. Prior to the exit meeting, Lambda had corrected its training module to reflect the appropriate Part 21 training narrative that would more accurately reflect the regulations and Lambda committed to reiterate those sections to Lambda personnel.

c. Conclusions

The NRC inspectors concluded that the Lambda Part 21 procedure available at the start of the inspection did not contain the timeliness requirements for reporting as specified in 10 CFR Part 21. This constitutes a minor violation of 10 CFR Part 21. The procedure was revised prior to the end of the inspection and a draft was provided to the inspectors for review. The draft was acceptable and Lambda committed to issuing the revised Part 21 procedure prior to October 19, 2004. No further action or response is necessary.

Based upon a review of Lambda's actions with regard to the texture analysis error QAIR, the inspectors believe it likely that Lambda would respond in a timely manner, in accordance with the requirements of 10 CFR Part 21. The inspectors did not identify any concerns in this area.

3.2 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on September 27, 2004, the NRC Inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with the Lambda office manager. In the exit meeting on September 28, 2004, the NRC Inspectors discussed their concerns and findings with the Lambda President and staff.

3.3 PERSONNEL CONTACTED

Paul S. Prev�y III	President	Lambda
Kimberly Bellamy	Office Manager	Lambda
Sandy Messerly	QA Administrator	Lambda
Chris Barger	Engineering Assistant	Lambda