

February 12, 1999

0466  
Dr. Jack Zaun  
Advanced Toxicology Network  
15201 E. I-10 Freeway  
Suite 125  
Channelview, TX 77530

Dear Dr. Zaun:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues described above. Once the issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed at the next inspection.



Dr. Zaun  
Page 2 of 2  
02/12/99

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M15



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 466  
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Channelview, TX

Document Reviewed:     Application Form  
                               Inspection Report #M15                      Date: 14 January 1999  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

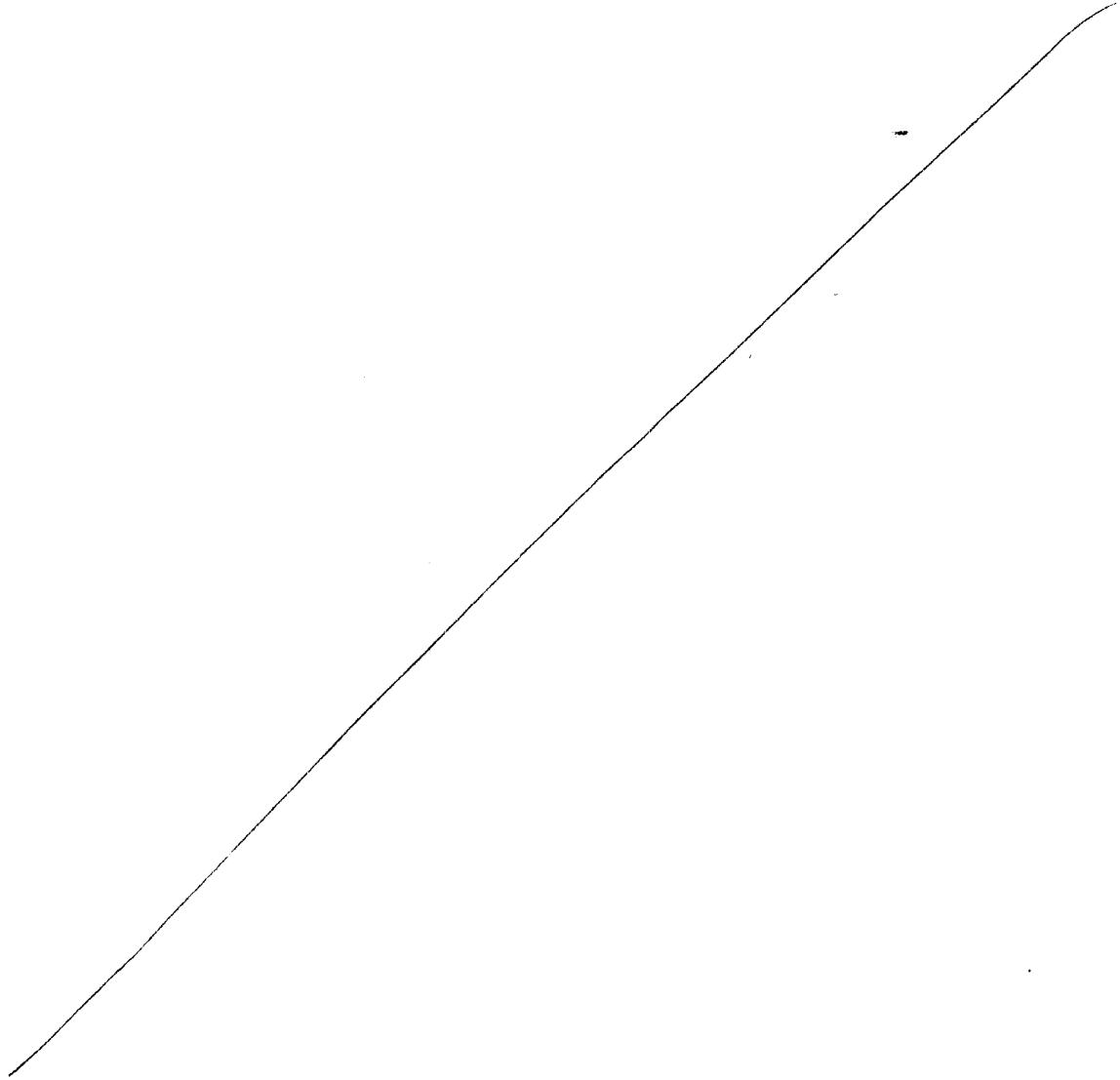
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Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

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Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received  
Sinc 3/11/99

March 10, 1999

Susan Crumpton  
NLCP Inspection Analyst  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Rd.  
Research Triangle Park, NC 27709


Dear Ms. Crumpton:

The following documentation is submitted to satisfy the requirement for corrective actions following the fifteenth maintenance inspection of the laboratory.

I have specifically addressed the items listed under section E, parts 5 and 8g.

If you have any other questions, please call me for clarification.,

Respectfully,

  
Jack W. Zaun, Ph.D.  
Responsible Person  
Advanced Toxicology Network-Channelview

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 17, 1999

0466  
Dr. Jack Zaun  
Advanced Toxicology Network  
15201 E. I-10 Freeway  
Suite 125  
Channelview, TX 77530

Dear Dr. Zaun:

We have reviewed the material provided in your correspondence of March 10, 1999, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of February 12, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program (NLCP). The laboratory must take steps to correct the issue cited above. All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

cc: Project Files/M15

