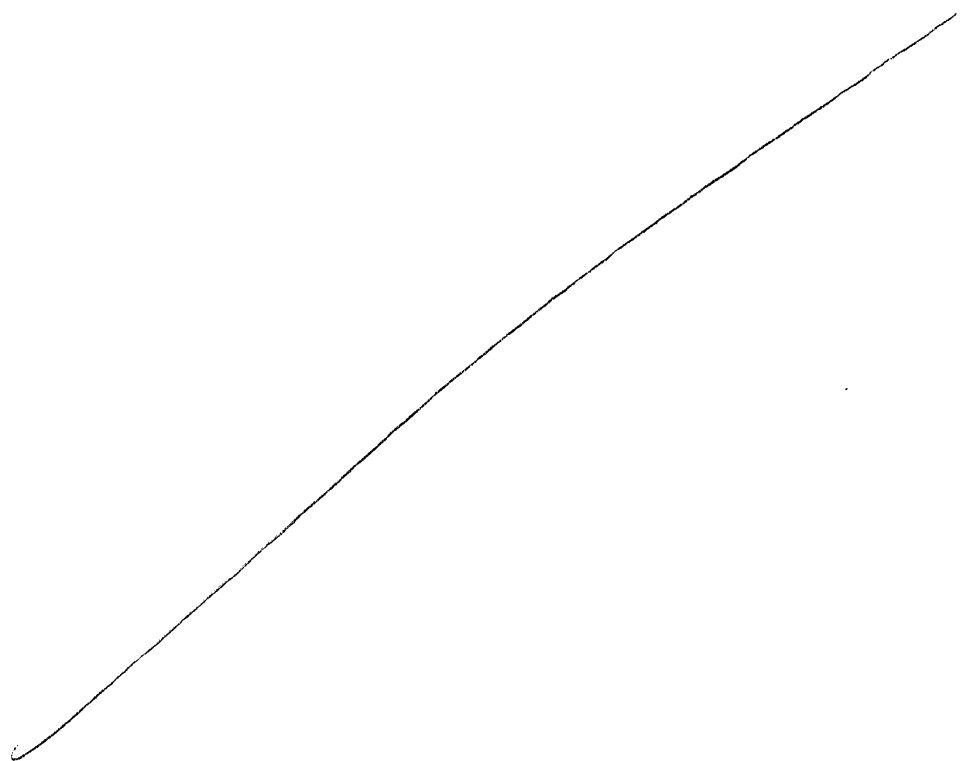




0447  
Dr. Derek Baker  
Pacific Toxicology Laboratories  
1519 Pontius Avenue  
Los Angeles, CA 90025

Dear Dr. Baker:

The enclosed critique was developed from the inspection reports of the two inspectors who conducted the eleventh 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 highly acceptable. However, the laboratory must correct/clarify the following issues raised:



Dr. Baker  
Page 2 of 2  
10/28/98

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions 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

Enclosure

cc: Project Files/M11

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

---

Laboratory I.D. Number: 0447  
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Los Angeles, CA

Document Reviewed:  Application Form  
 Inspection Report #M11  
 Other \_\_\_\_\_

Date: 24 September 1998

Status:  Highly Acceptable       Acceptable  
 Unacceptable                       Failure

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A review of the two independent National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

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

Section G. Records Audit

Section H. Personnel

Section I. Reagents

Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



# RESEARCH TRIANGLE INSTITUTE

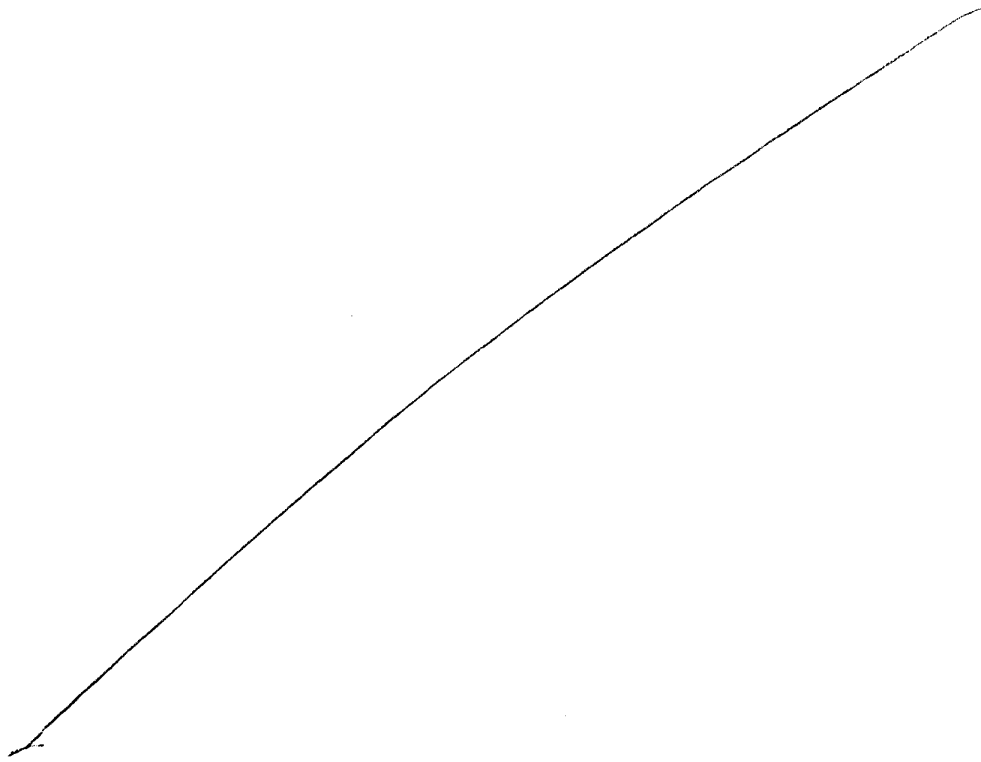
National Laboratory Certification Program

May 20, 1999

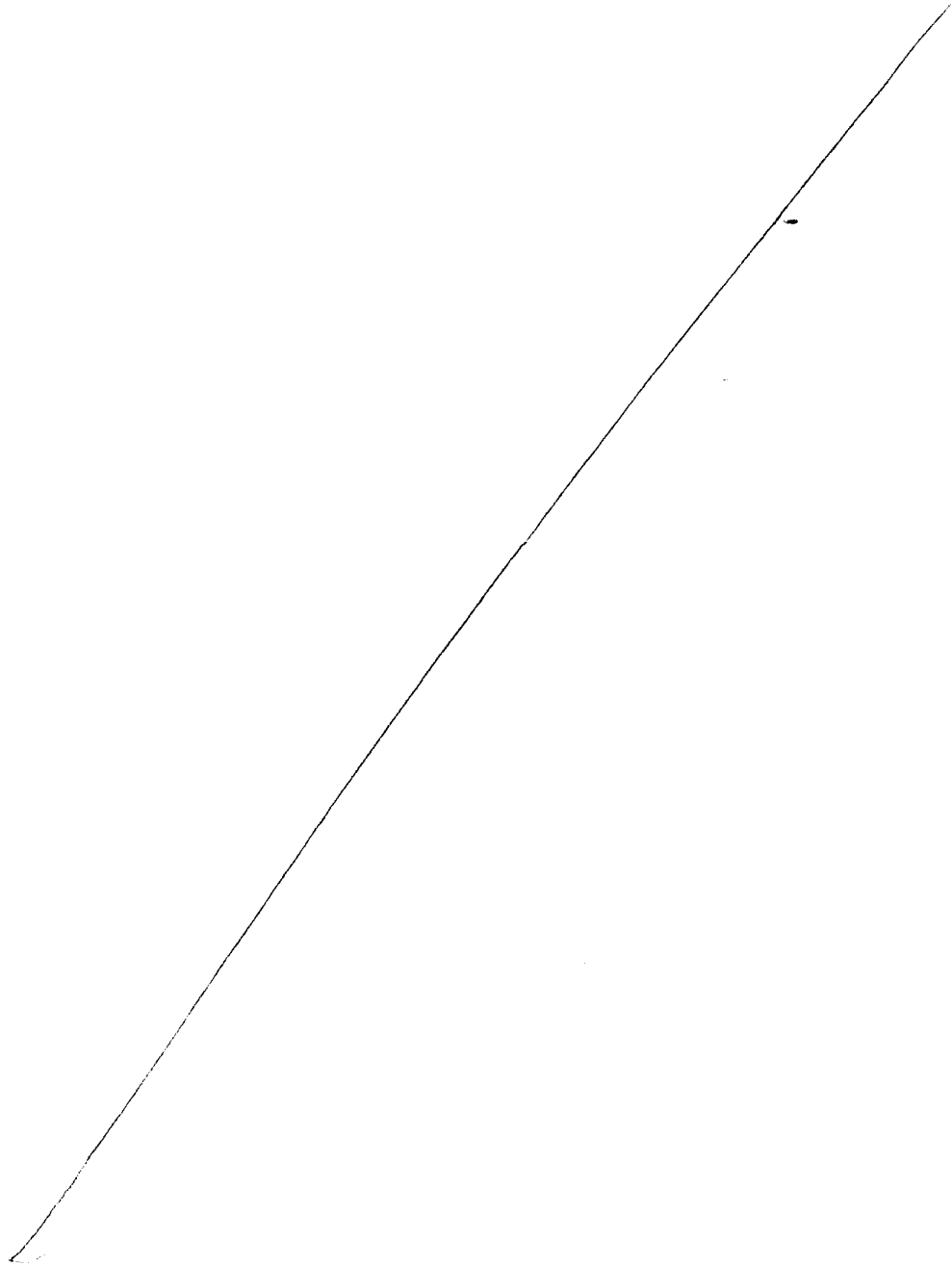
0447  
Dr. Derek Baker  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

Dear Dr. Baker:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twelfth 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 clarify/correct the following issues raised:



Dr. Baker  
Page 2 of 4  
05/20/99



v.

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 raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these



Dr. Baker  
Page 4 of 4  
05/20/99

issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the 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 receipt of this correspondence and will be reviewed at the next inspection.

If we can be of assistance or answer any questions, 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/M12

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0447  
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Woodland Hills, CA

Document Reviewed:     Application Form  
                               Inspection Report #M12            Date: 25 March 1999  
                               Other \_\_\_\_\_

Status:                 Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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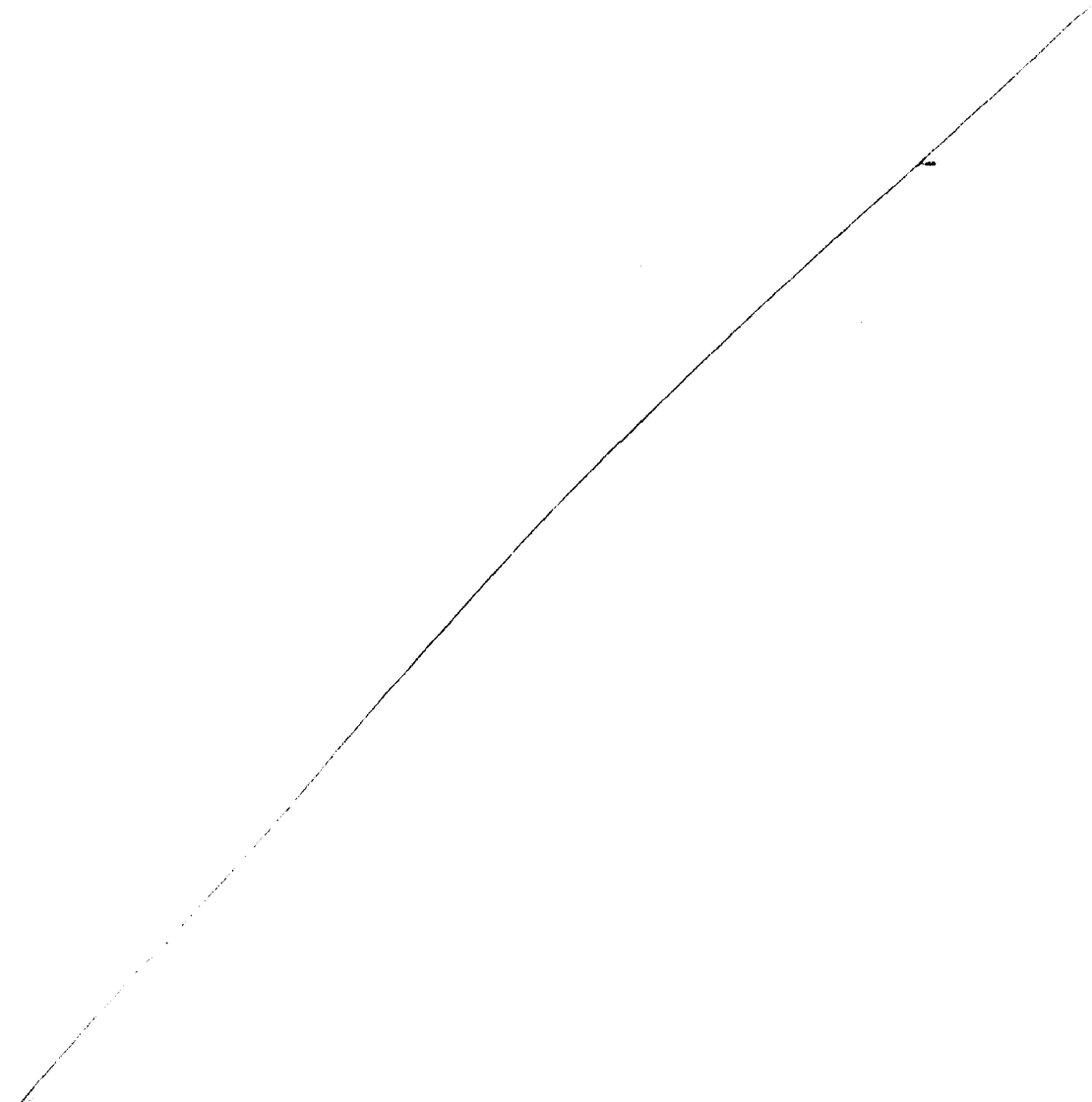
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Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required 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



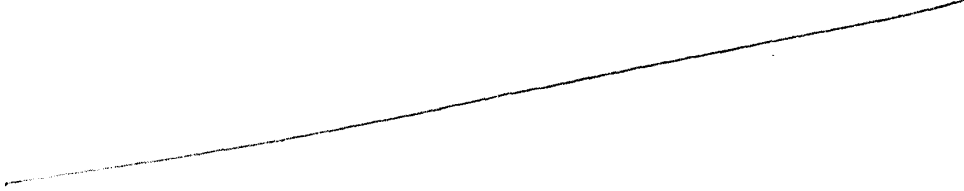
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

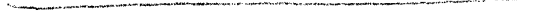
Section H. Initial Tests



Section I. Confirmatory Tests



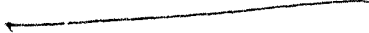
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel

July 1, 1999

4167 3910 1020

Susan Crumpton  
NLCP Inspection Analyst  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, North Carolina 27709

Re: Inspection Report #M12 Response  
Pacific Toxicology Laboratories  
Laboratory I.D. Number: 0447  
March 25, 1999

Dear Susan:

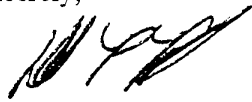
Enclosed please find the response to the above described Maintenance Inspection of our laboratory und the NLCP.

Again, I apologize for the delay in responding.

Please contact me directly at (310) 312-0056 with any questions.

Thank you for your consideration.

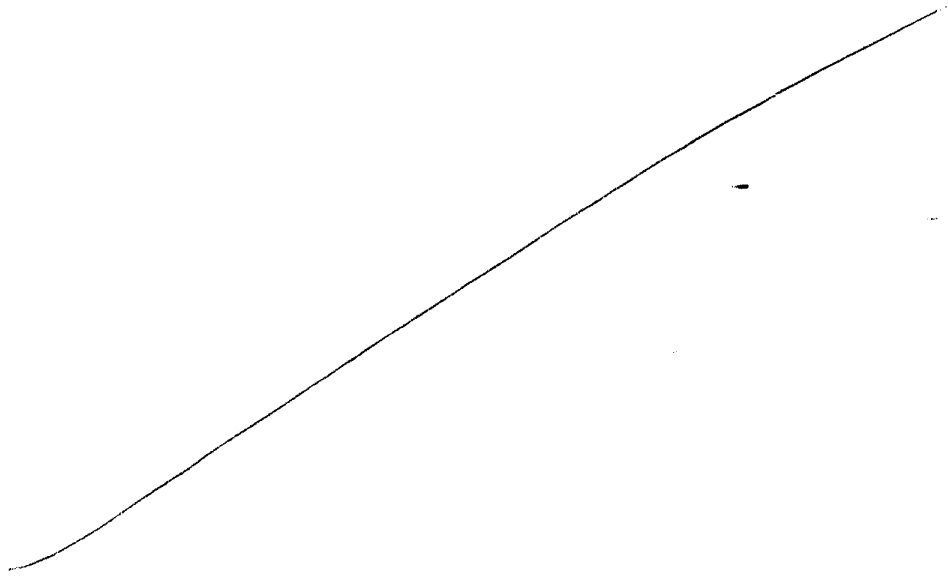
Sincerely,



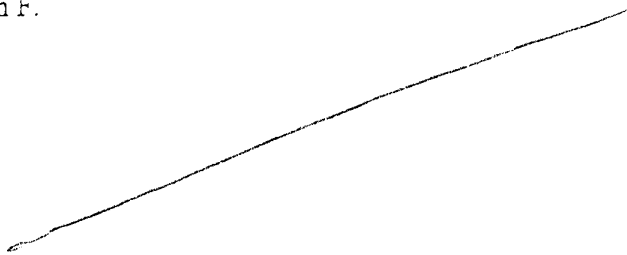
Derek P. Baker, Ph.D.  
Responsible Person

Enclosure

Section E.

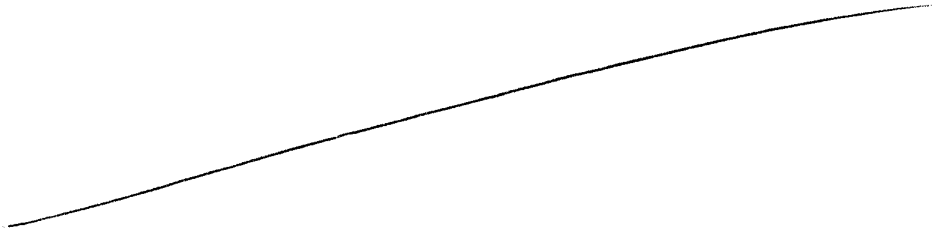


Section F.

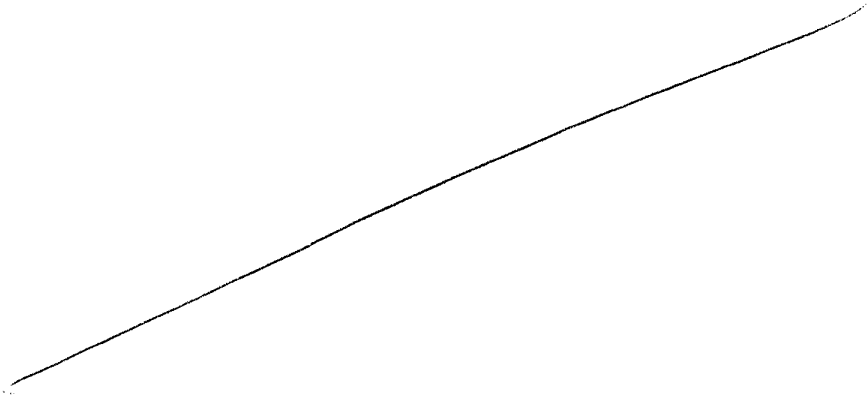




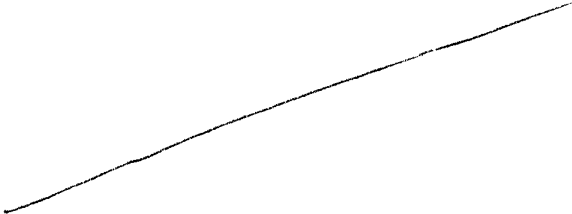
Section G.



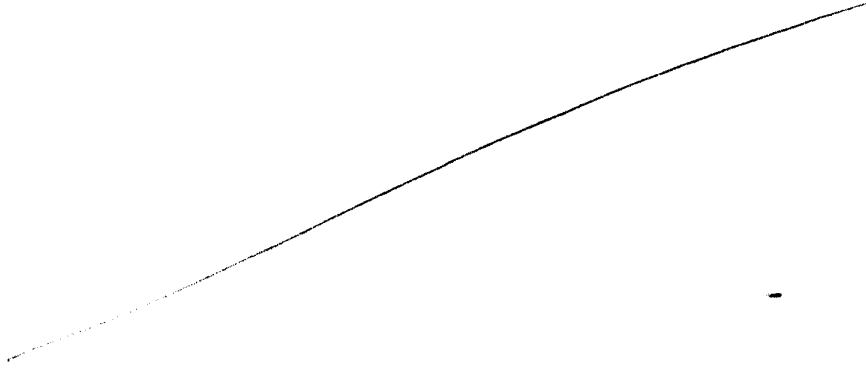
Section H.



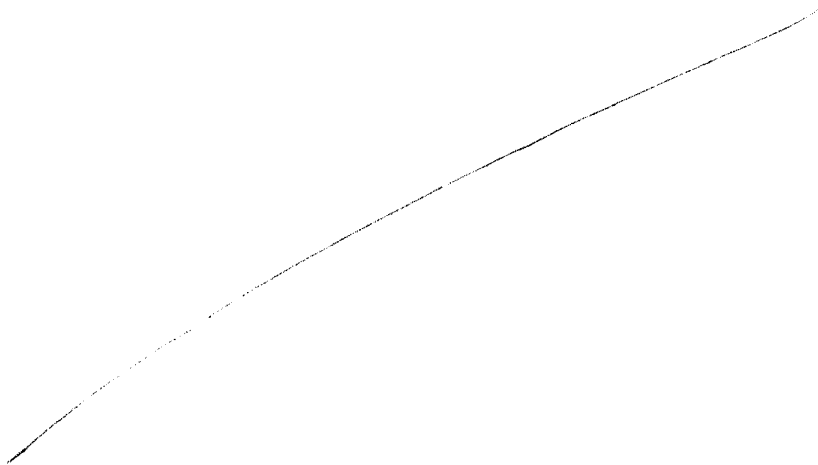
Section I.



Section K.



Section N.



RESEARCH TRIANGLE INSTITUTE



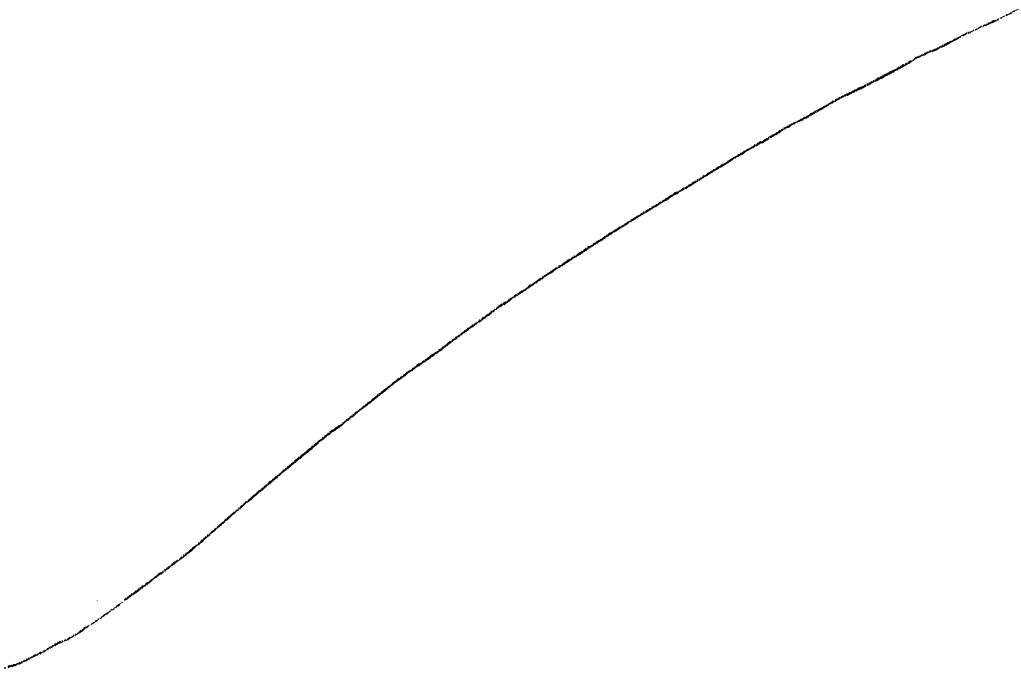
National Laboratory Certification Program

July 19, 1999

0447  
Dr. Derek Baker  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

Dear Dr. Baker:

We have reviewed the material provided in your correspondence received July 13, 1999 (dated July 1, 1999), submitted in response to issues raised during the twelfth maintenance inspection of your laboratory as outlined in our correspondence of May 20, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. The following is a review of the material submitted:



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. All corrective actions must be implemented within 30 days of the 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 Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M12



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 10, 1999

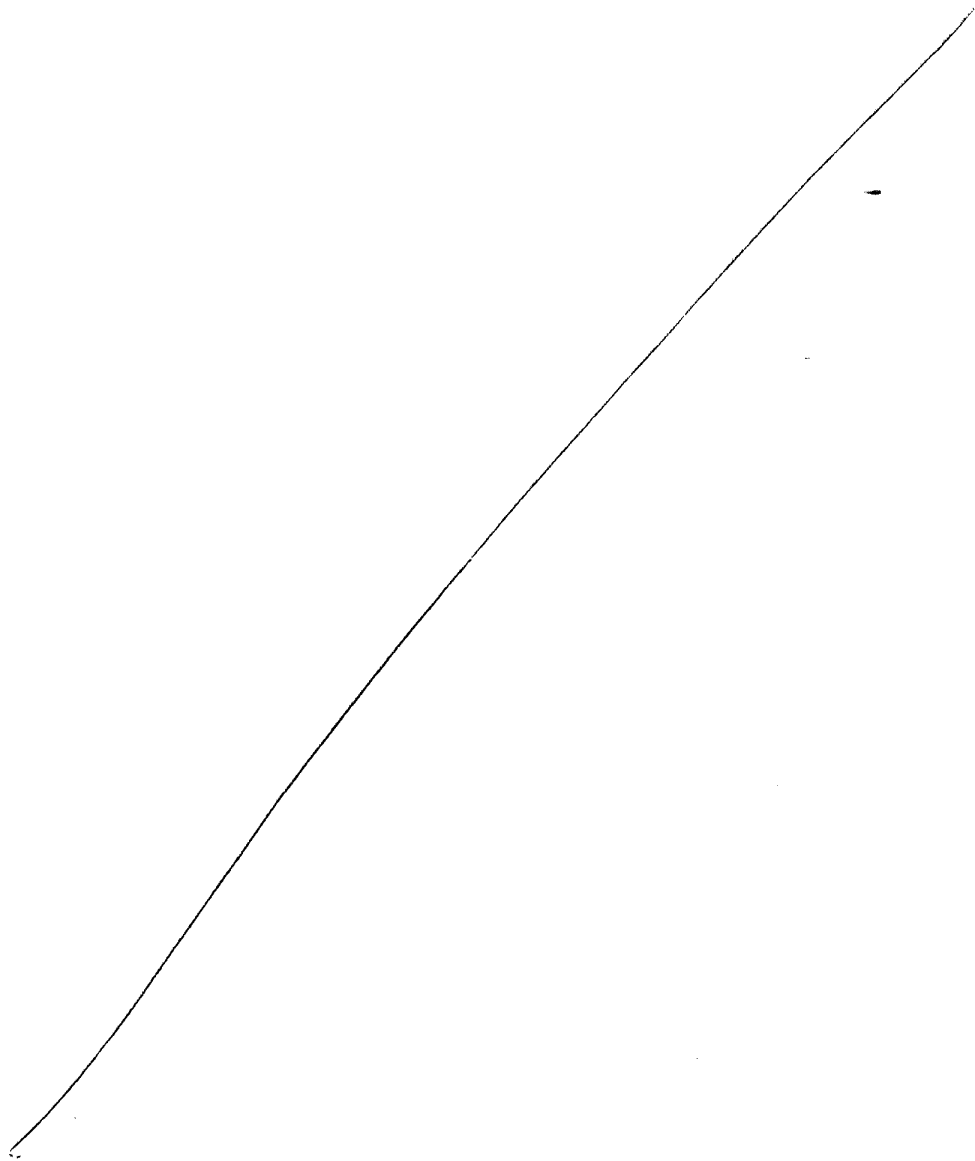
0447  
Dr. Derek Baker  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

Dear Dr. Baker:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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 all corrective actions described in the critique and/or cover letter:



Dr. Baker  
November 10, 1999  
Page 2 of 3

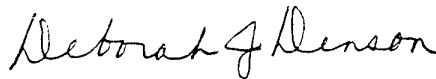


Dr. Baker  
November 10, 1999  
Page 3 of 3

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 raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the 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 receipt of this correspondence and will be reviewed at the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M13

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0447  
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Woodland Hills, CA

Document Reviewed:     Application Form  
                               Inspection Report #M13                      Date: 30 September 1999  
                               Other \_\_\_\_\_

Status:                 Highly Acceptable                 Acceptable  
                               Unacceptable                       Failure

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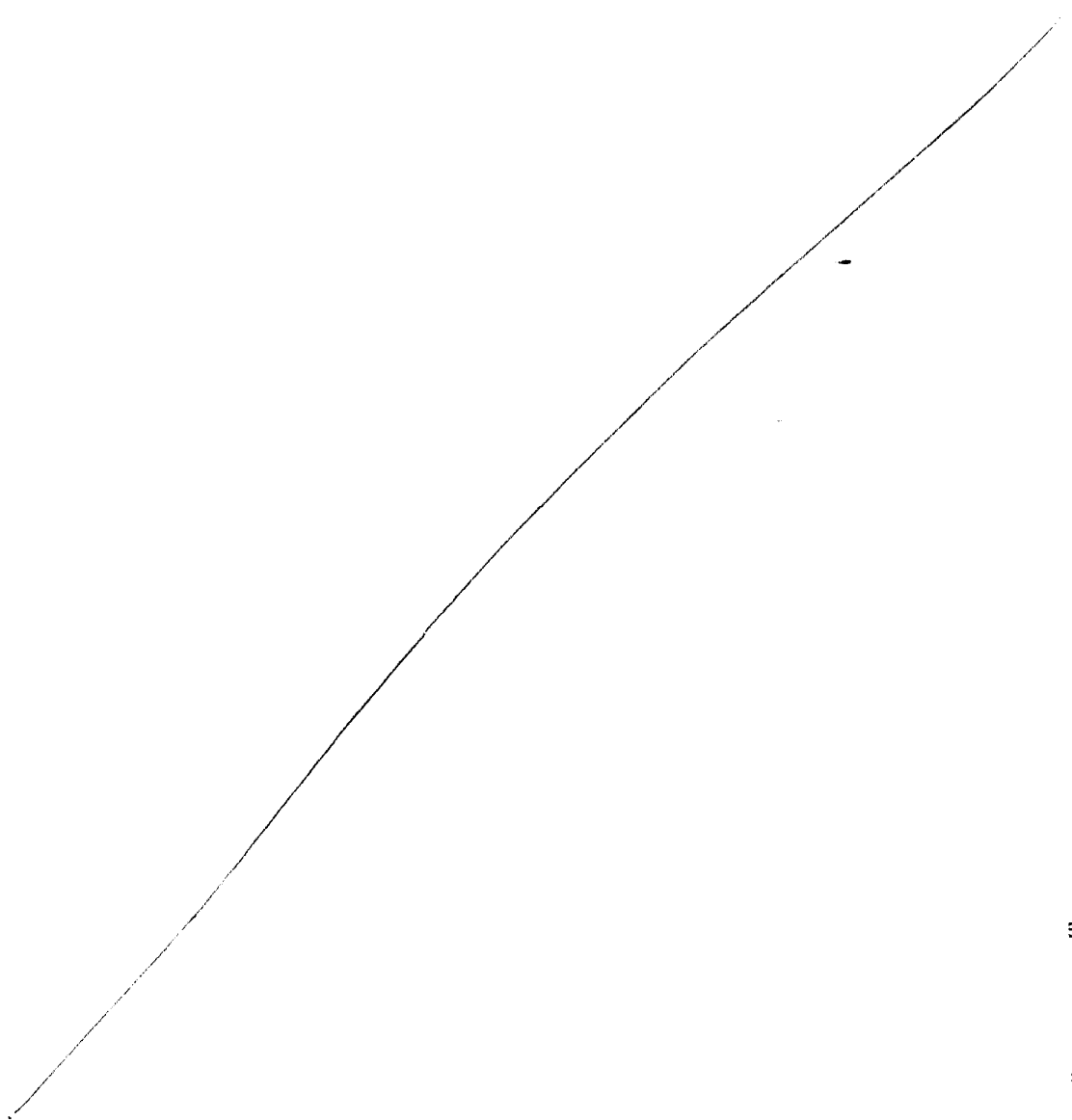
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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



3  
3  
3

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

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

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Section J. Records Audit

Section K. Reporting


Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received  
01/13/2000 DJ

PACIFIC  
TOXICOLOGY  
LABORATORIES  616C Variel Ave. Woodland Hills, Ca 91367  
(818) 598-3110 • FAX (818) 598-3116 • (800) 326-6942

January 11, 2000

Deborah J. Denson  
NLCP Inspection Analyst  
Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Research Triangle Park, North Carolina 27709-2194

RE: Pacific Toxicology Laboratories  
Laboratory I.D. Number 0447  
Response To Inspection Report #M13  
September 30, 1999

Dear Ms. Denson:

Enclosed please find our response to the critique and inspection report prepared from our eleventh maintenance inspection under the National Laboratory Certification Program (NLCP) for review.

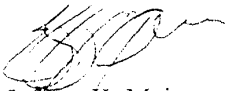
Please contact me directly at (818) 598-3110 with any questions.

Thank you for your consideration.

Sincerely,



Derek P. Baker, Ph.D.

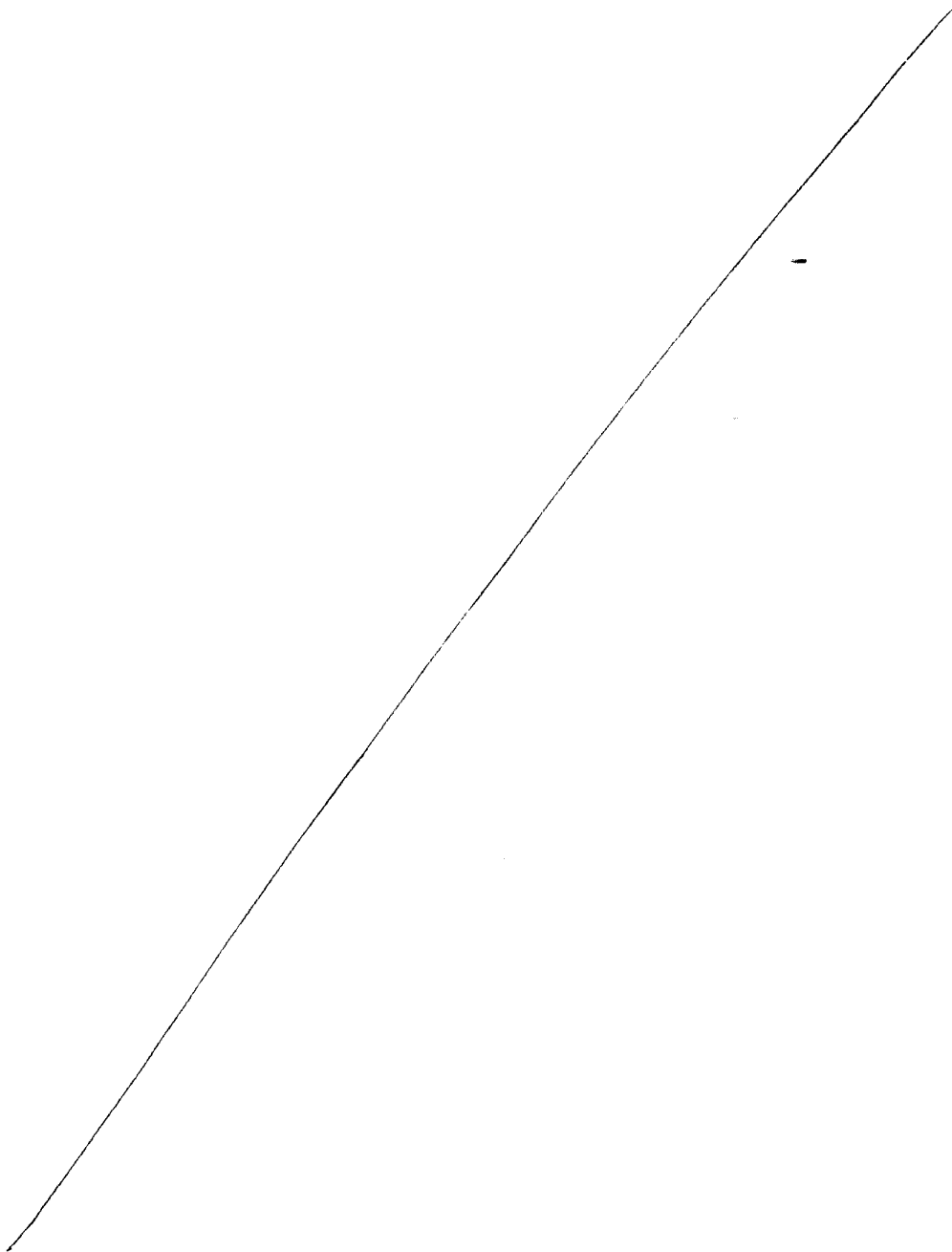


Jeffrey K. Maier

Attachment

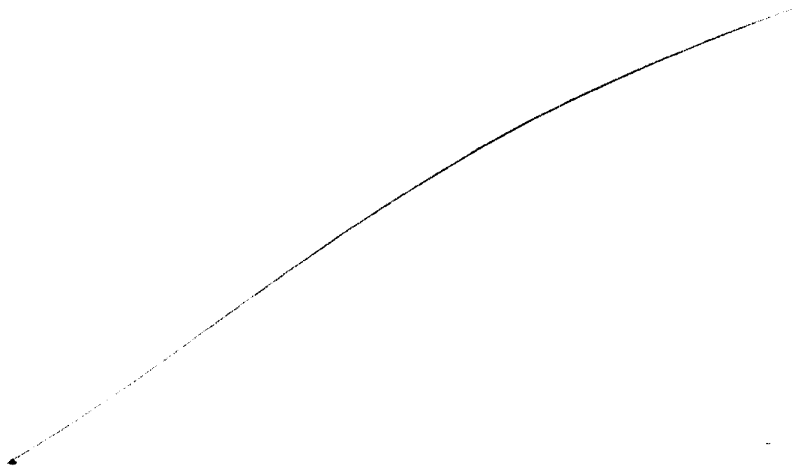
Response To Inspection Report M13

Section E

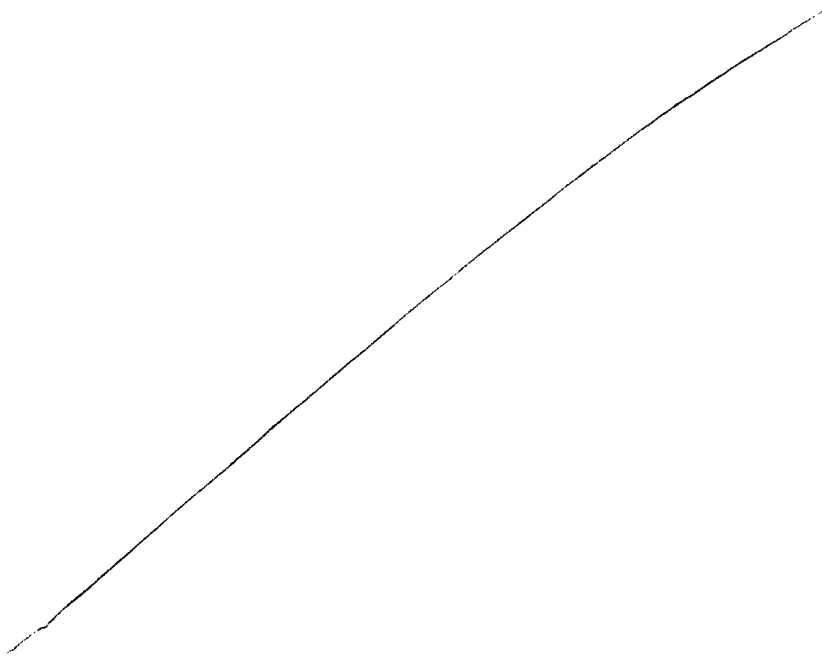



*FB*






Section F






Section G



Section H



Section I



Section J



Section K



Section N



*Handwritten initials or mark.*



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 19, 2000

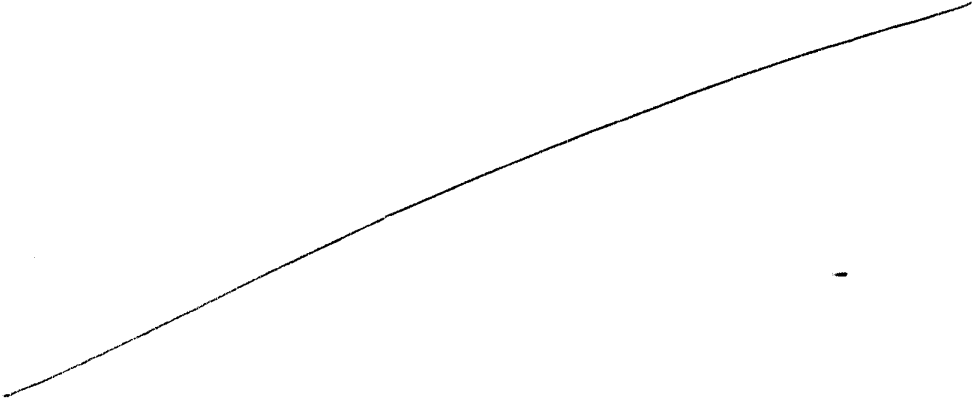
0447  
Dr. Derek Baker  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

Dear Dr. Baker:

We have reviewed the material provided in your correspondence of January 11, 2000, submitted in response to issues raised during the thirteenth maintenance inspection of your laboratory as outlined in our correspondence of November 10, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:



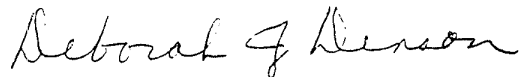
Dr. Baker  
January 19, 2000  
Page 2 of 2



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. All corrective actions must be implemented within 30 days of the 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) 541-7265 or Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

cc: Project Files/M13



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 12, 2000

0447  
Mr. Jeffrey Maier  
Mr. Michael Henson  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

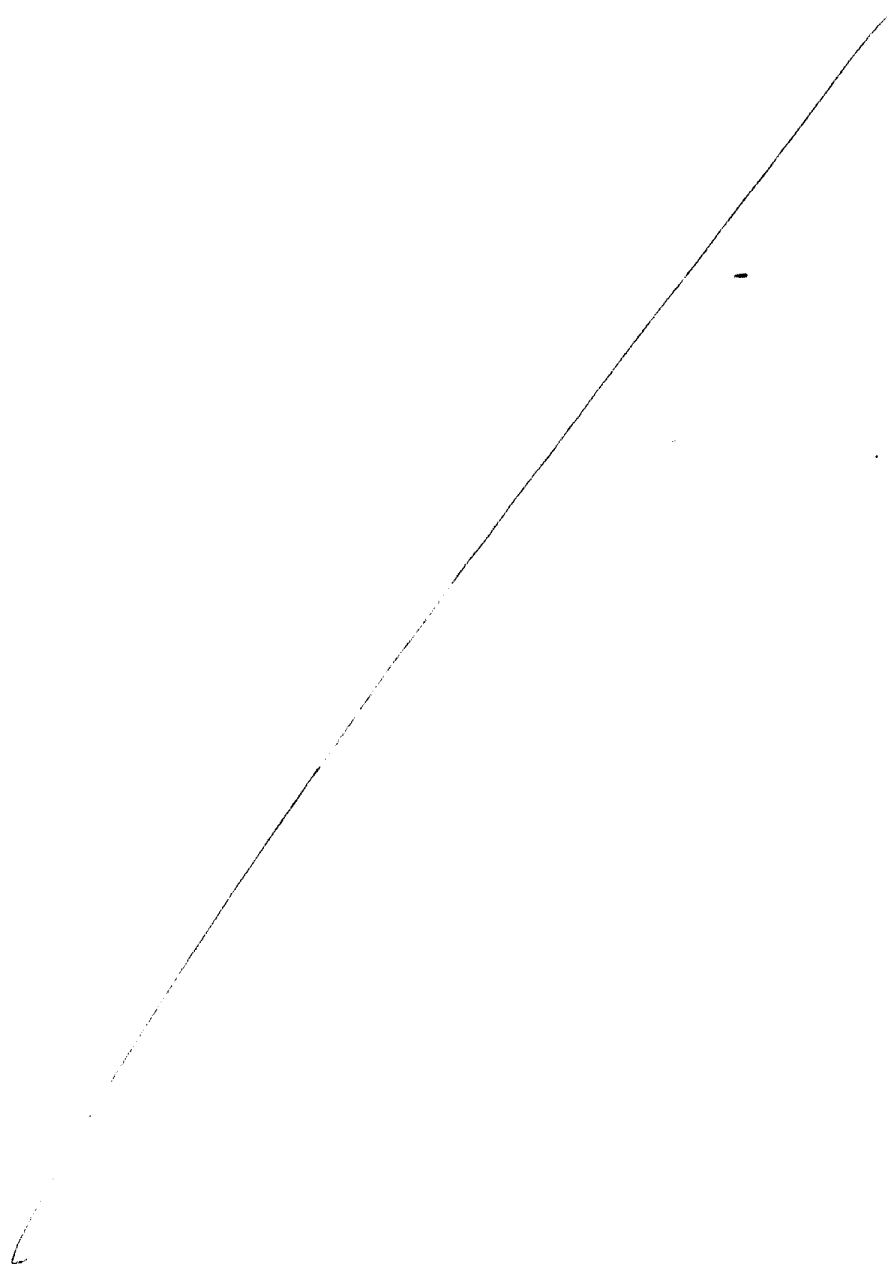
Dear Mr. Maier and Mr. Henson:

The National Laboratory Certification Program (NLCP) staff at RTI have reviewed the the inspection reports of the inspectors who conducted the fourteenth maintenance inspection of your laboratory and the report of the inspector who conducted the April 13, 2000, performance testing (PT) inspection of your laboratory under the NLCP.

The enclosed critique was developed from the fourteenth maintenance inspection reports. Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Mr. Maier  
Mr. Henson  
Page 2 of 3  
05/12/00



Mr. Maier  
Mr. Henson  
Page 3 of 3  
05/12/00

RTI is recommending to HHS that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions 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 Technical Analyst

Enclosure

cc: Project Files/M14



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0447  
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Woodland Hills, CA

Document Reviewed:     Application Form  
                               Inspection Report #M14                      Date: 30 March 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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:

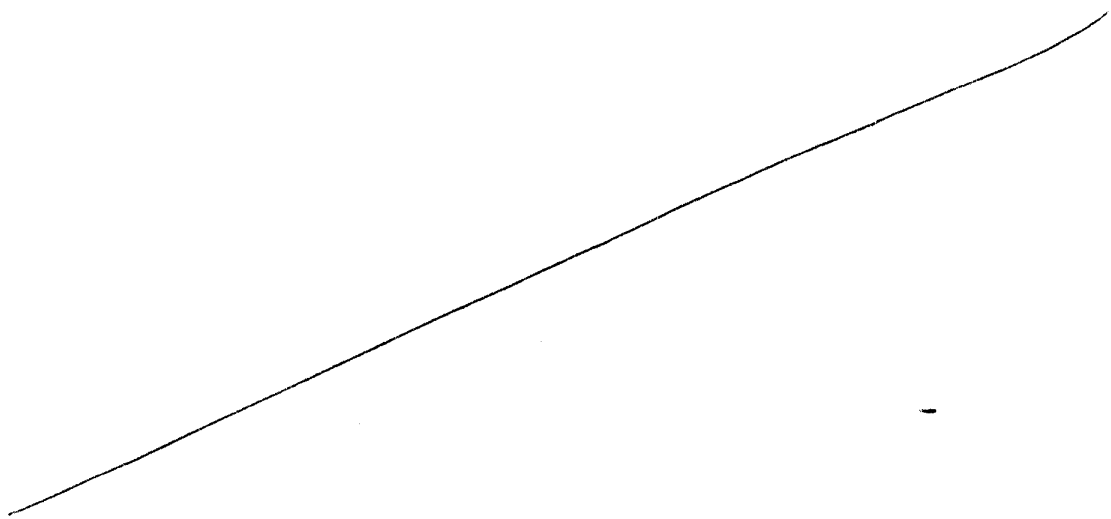
Section E. Standard Operating Procedures - Procedures Manual

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

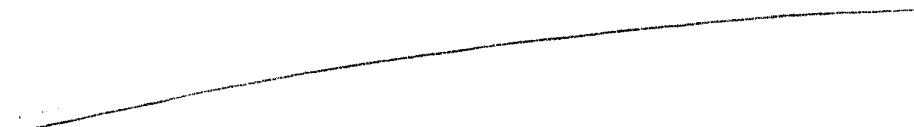
Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests



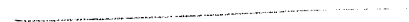
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 1, 2000

0447  
Mr. Jeffrey Maier  
Mr. Michael Henson  
Pacific Toxicology Laboratories  
6160 Variel Avenue  
Woodland Hills, CA 91367

Dear Mr. Maier and Mr. Henson:

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 highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

Mr. Maier  
Mr. Henson  
Page 2 of 2  
11/01/00

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions 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 Technical 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: 0447  
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Woodland Hills, CA

Document Reviewed:     Application Form  
                               Inspection Report #M15                      Date: 28 September 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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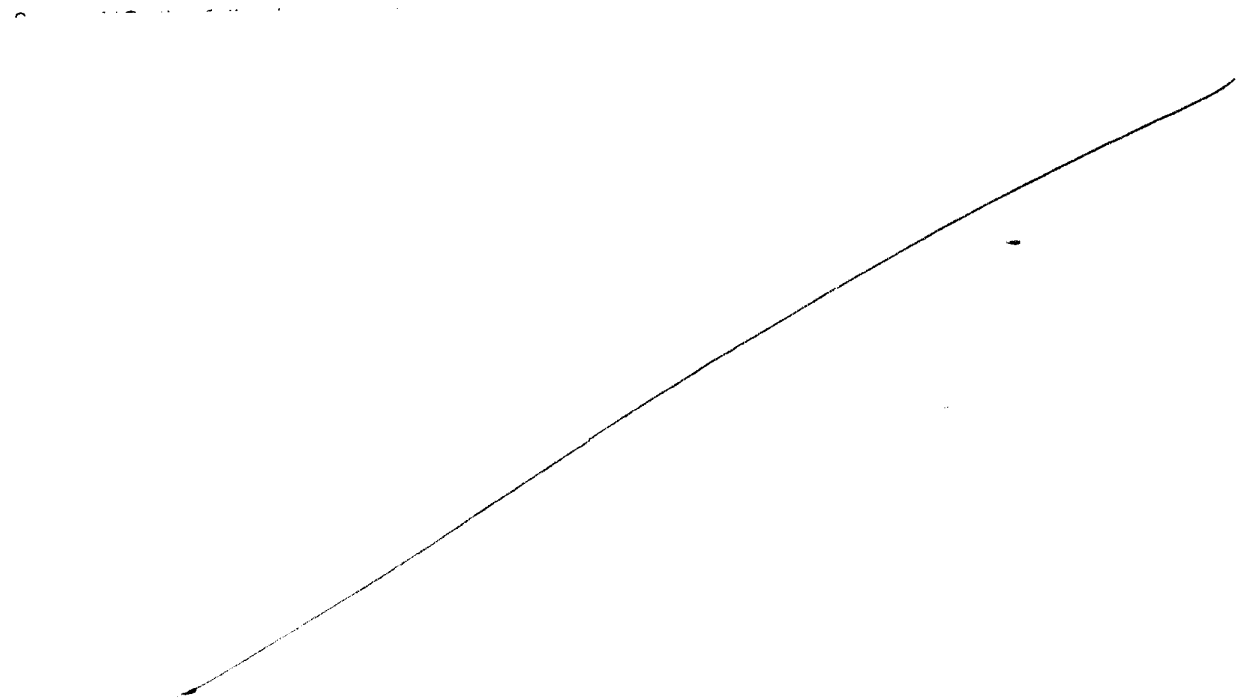
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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



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



Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel