



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 29, 1999

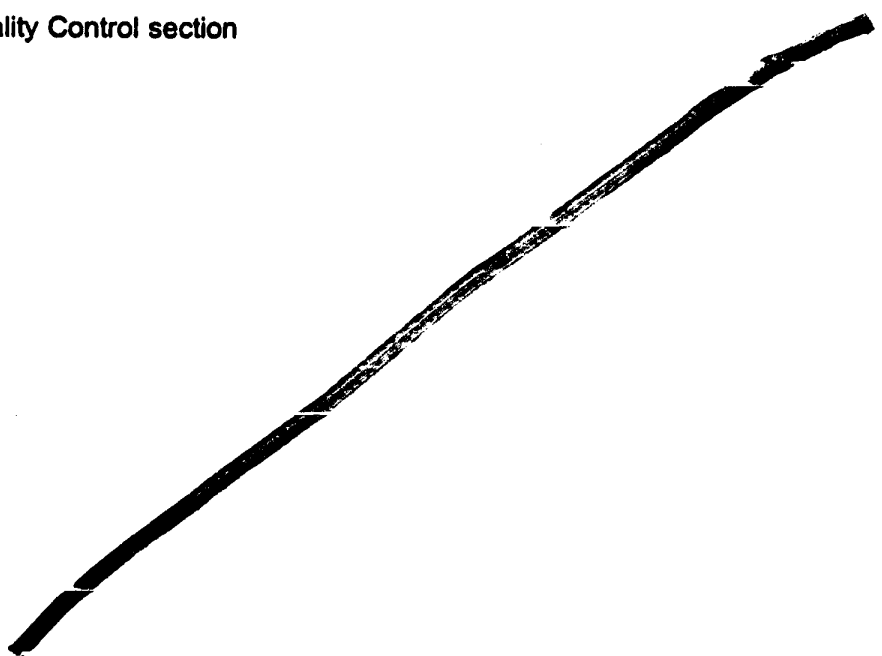
0554

Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourteenth 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 following issue was raised:

**G. The Quality Control section**



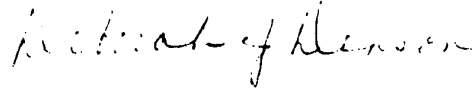
The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item 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.



Dr. Robert  
March 29, 1999  
Page 2 of 2

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/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: 0554  
Document No. Final

Laboratory: Aegis Analytical Laboratories, Inc.

Location: Nashville, TN

Document Reviewed:     Application Form  
                               Inspection Report #M14                      Date: 25 February 1999  
                               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

[Redacted]

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

[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[REDACTED]

Section N. Personnel

[REDACTED]



received  
5/5/99

345 HILL AVENUE, NASHVILLE, TENNESSEE 37210  
Telephone: (615) 255-2400 ■ Facsimile: (615) 255-3030

May 4, 1999

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

Dear Ms. Denson:

Enclosed please find the items which you have requested from this laboratory in your letter of March 29, 1999 as remedial actions arising from the 14<sup>th</sup> maintenance inspection of this laboratory.

I apologize for the delay in getting these materials to your office as well as the change in course of our remedial actions as initially presented to you on March 25, 1999. If any additional materials or clarification is required, please contact me immediately.

Sincerely,

A handwritten signature in cursive script that reads "Timothy A. Robert".

Timothy A. Robert, Ph.D.  
Assistant Director

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 24, 1999

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

We have reviewed the material provided in your correspondence of May 04, 1999, submitted in response to issues raised during the fourteenth inspection of your laboratory as outlined in our correspondence of March 29, 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:



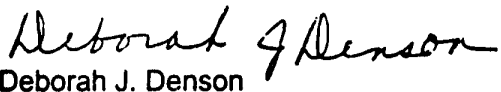
Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this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



Dr. Robert  
May 24, 1999  
Page 2 of 2

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/M14

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# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 1, 1999

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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 this critique and cover letter:

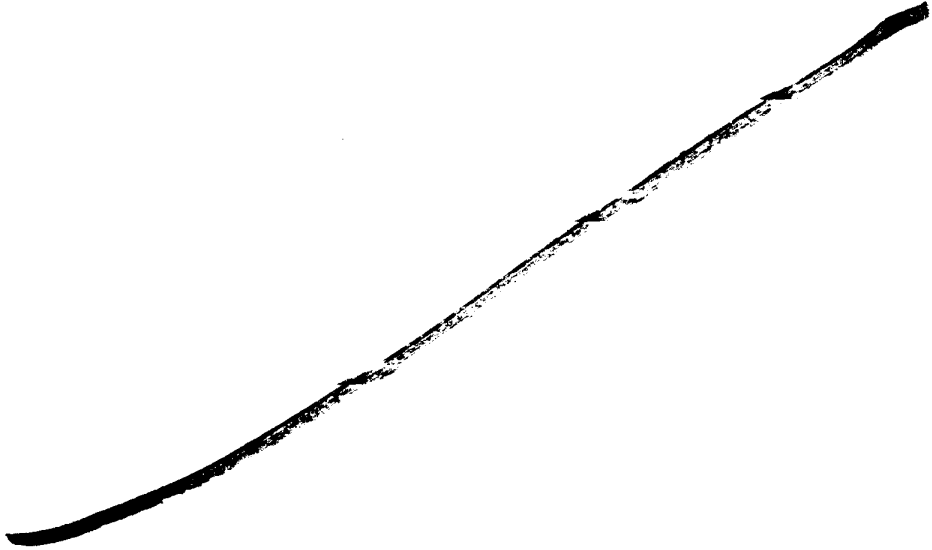
E. The Standard Operating Procedures (SOP)



F. The Chain of Custody, Accessioning, and Security section



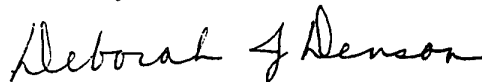
Dr. Robert  
October 1, 1999  
Page 2 of 2



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

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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: 0554  
Document No. Final

Laboratory: Aegis Analytical Laboratories, Inc.

Location: Nashville, TN

Document Reviewed:     Application Form  
                                  Inspection Report #M13                      Date: 26 August 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.

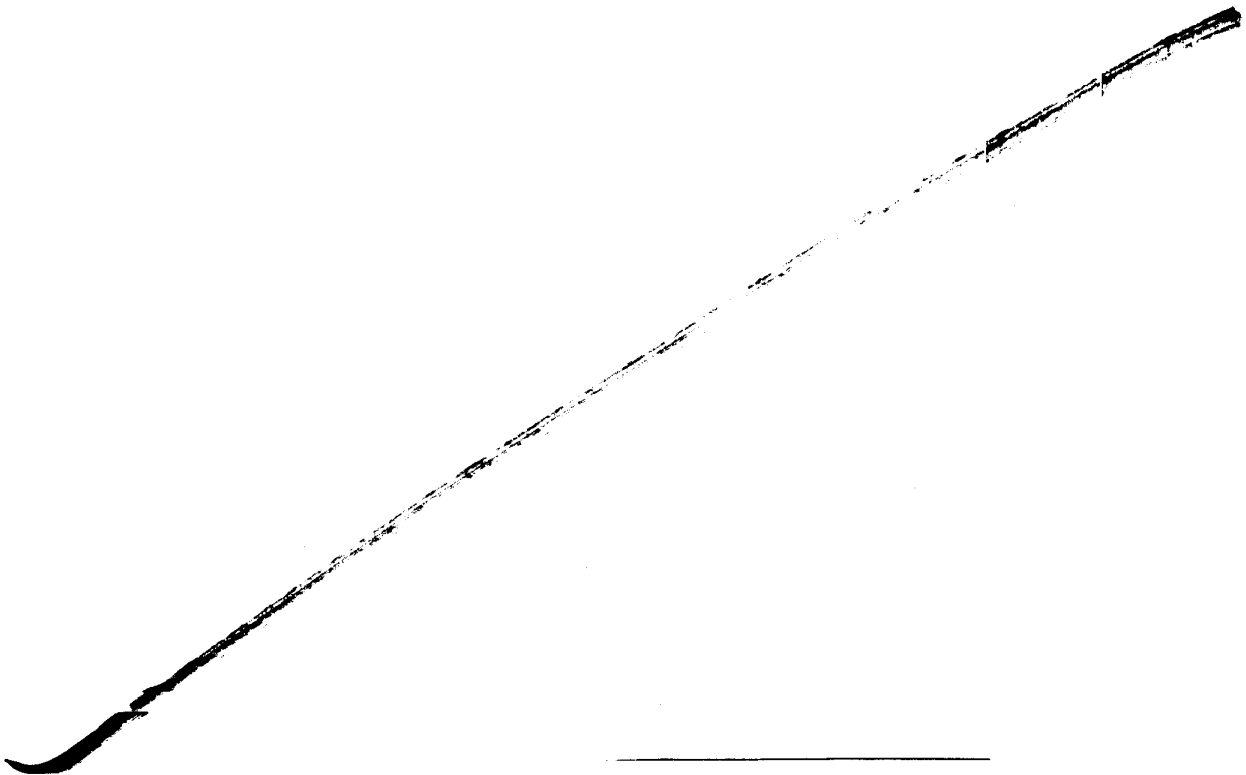
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



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



[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

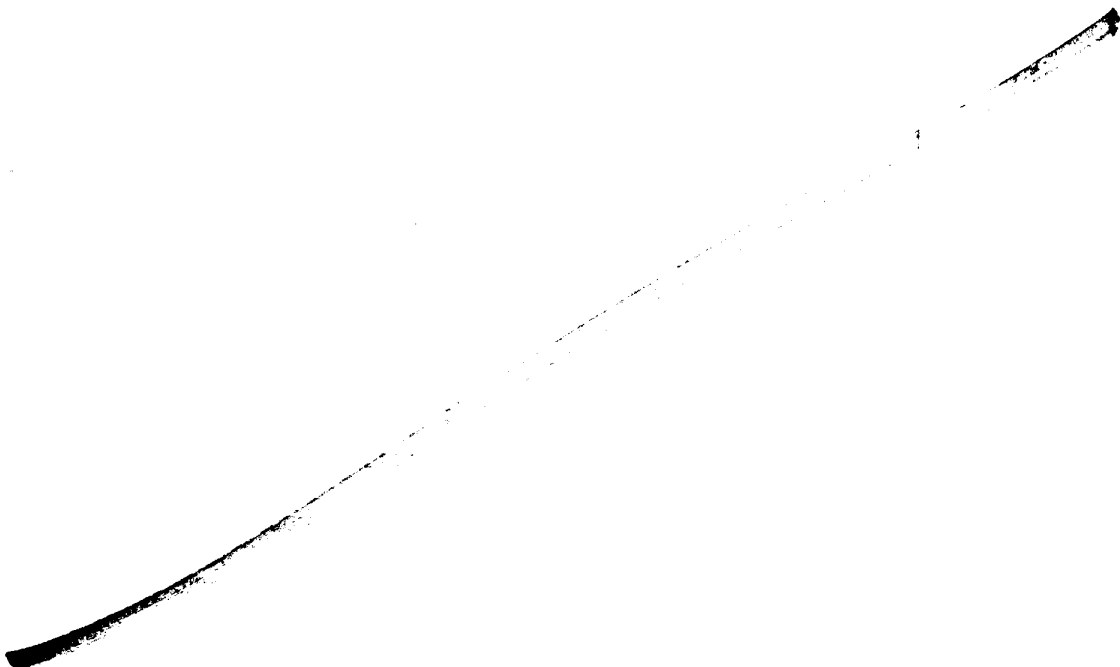
[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]



Section M. Equipment and Maintenance



Section N. Personnel







received  
11/15/99 DD

345 HILL AVENUE, NASHVILLE, TENNESSEE 37210  
Telephone: (615) 255-2400 ■ Facsimile: (615) 255-3030

November 11, 1999

Ms. Deborah J. Denson  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Rd.  
Research Triangle Park, NC 27709-2194

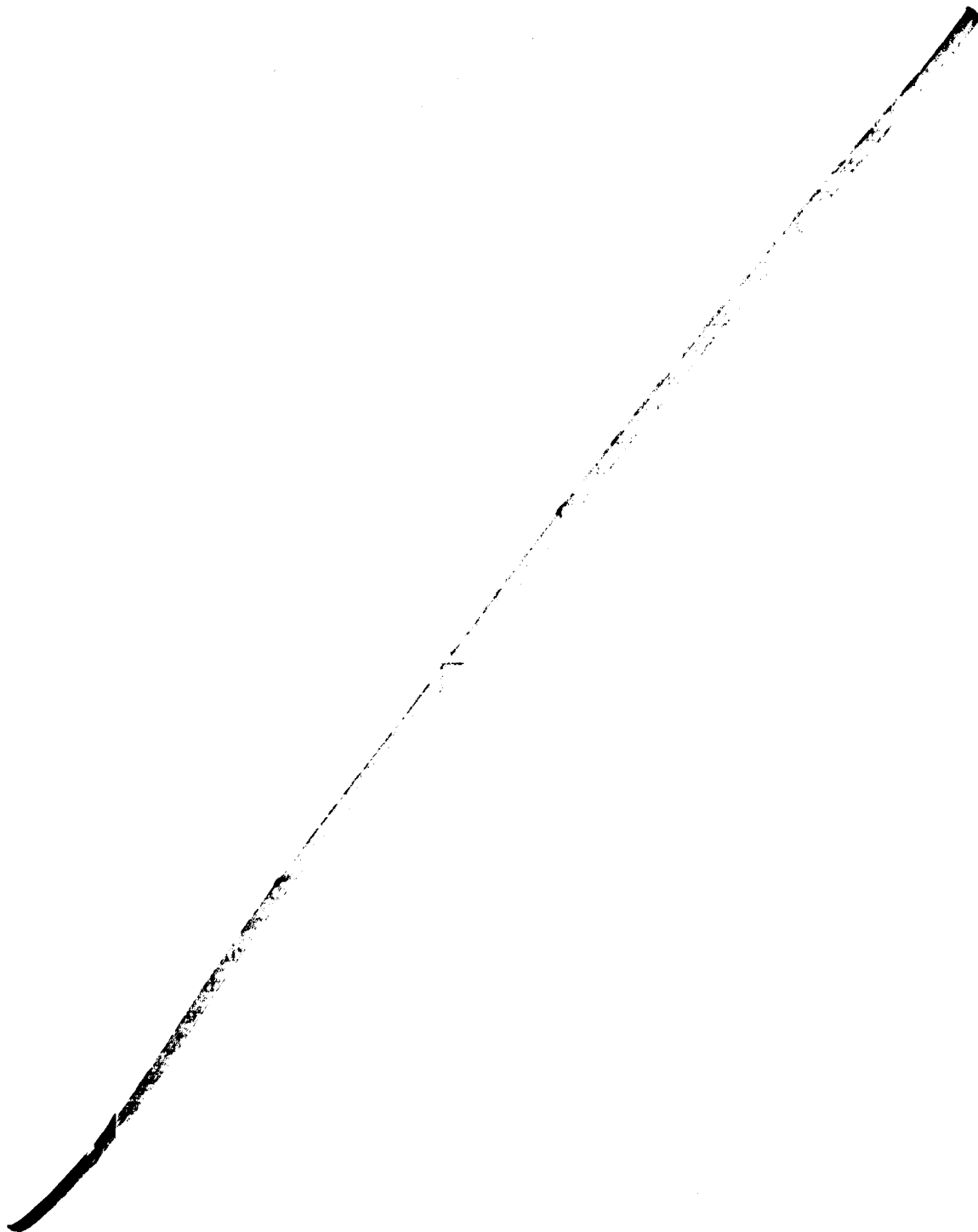
Dear Ms. Denson:

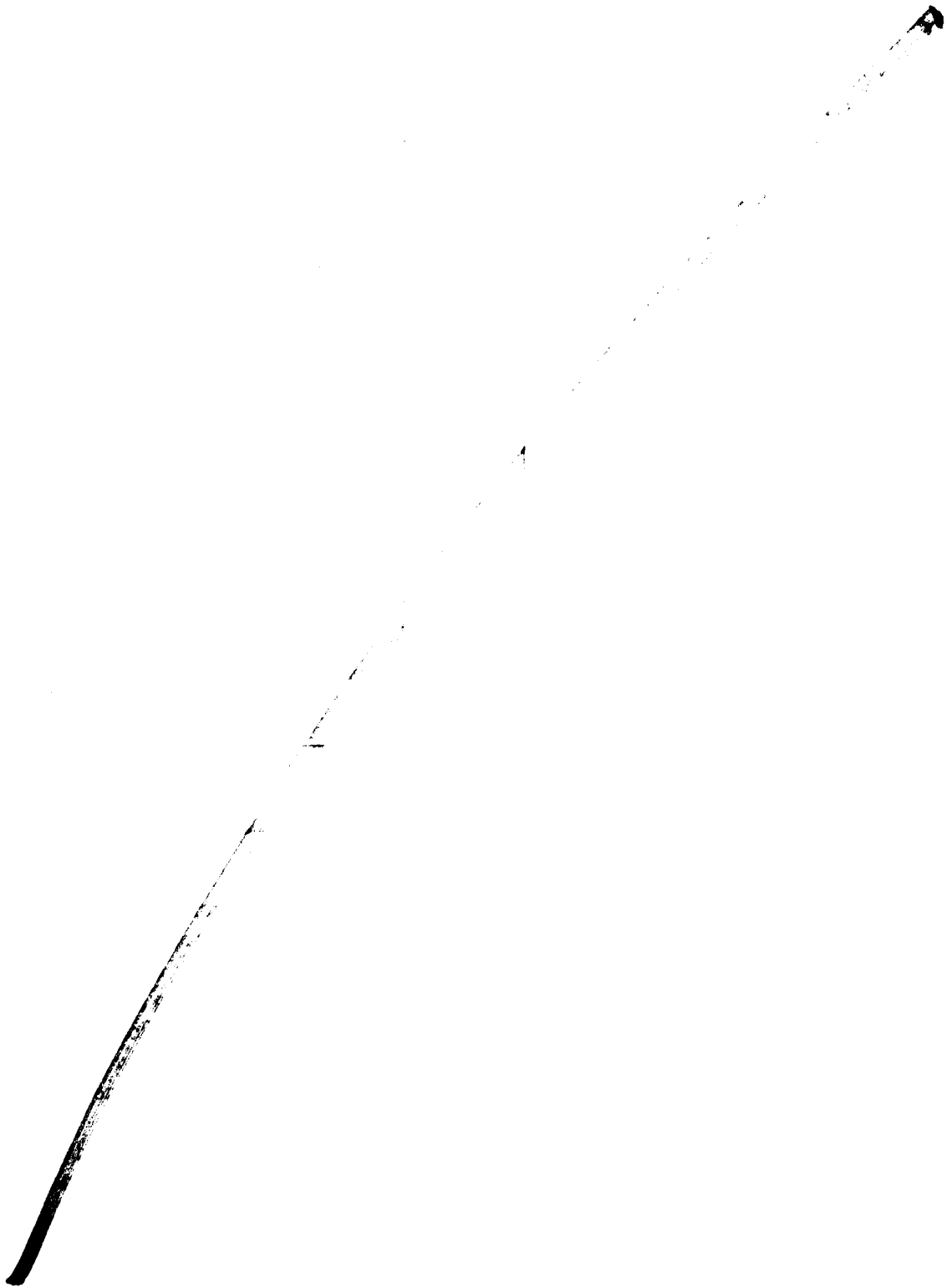
Sincerely,

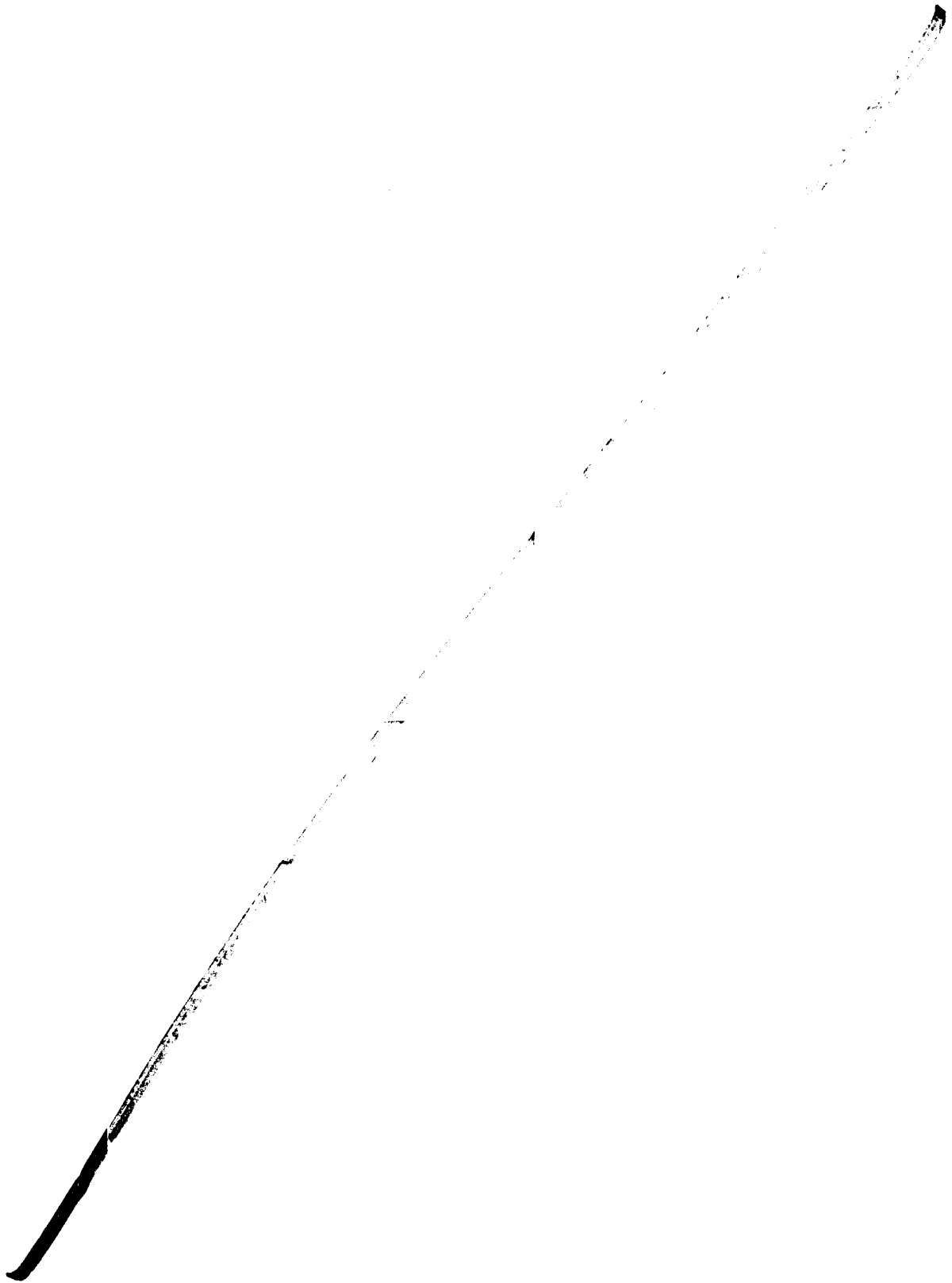
Timothy A. Robert, Ph.D.  
Assistant Director  
Responsible Person

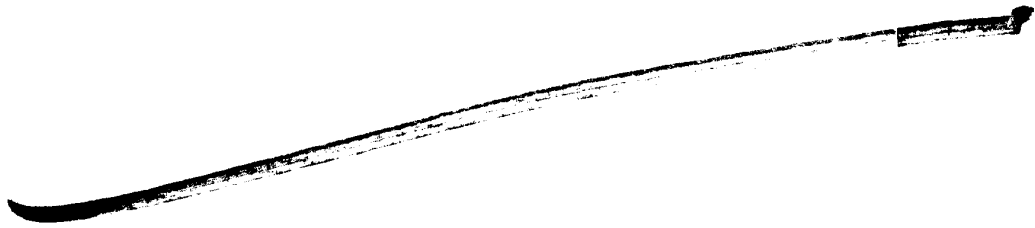


Remedial Actions for Maintenance Inspection  
August 1999









RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 18, 1999

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

We have reviewed the material provided in your correspondence of November 11, 1999, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of October 01, 1999 (this correspondence incorrectly listed the inspection as the thirteenth maintenance inspection). The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

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. (919) 541-7043.

Sincerely,

A handwritten signature in cursive script that reads "Deborah J. Denson".

Deborah J. Denson  
NLCP Inspection Analyst

cc: Project Files/M13





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 4, 2000

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth 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:

E. The Standard Operating Procedures section

A large, thick, black diagonal scribble redacting the content of item E.

F. The Chain of Custody, Accessioning, and Security section

A large, thick, black diagonal scribble redacting the content of item F.

[Redacted]

G. The Quality Control section

[Redacted]

H. The Initial Tests section

[Redacted]

I. The Confirmatory Tests section

[Redacted]

Dr. Robert  
April 4, 2000  
Page 3 of 4

J. The Records Audit section

N. The Personnel section

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,

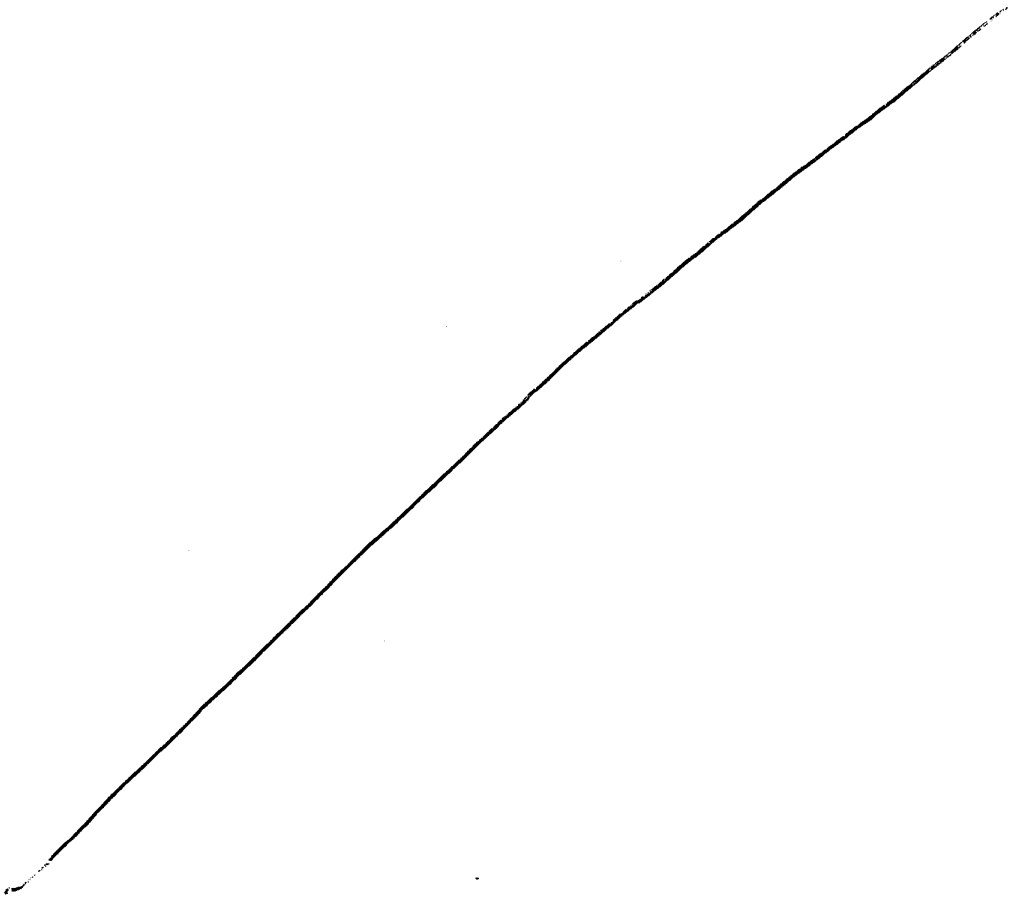


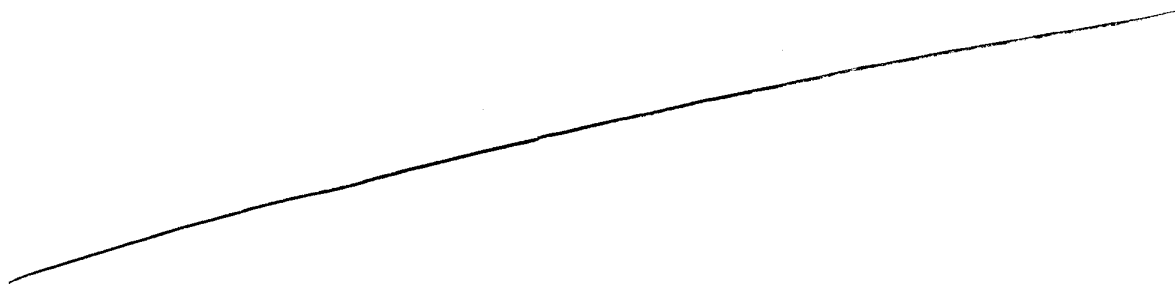
Deborah J. Denson  
NLCP Technical Analyst



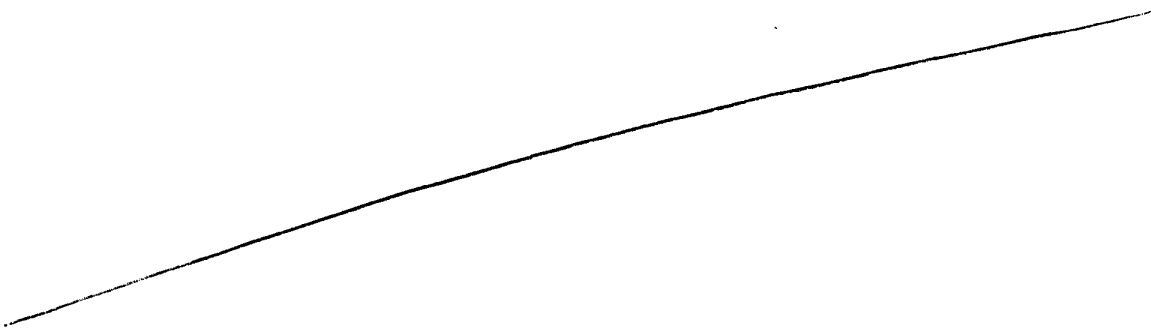


Section F. Chain-of-Custody, Accessioning, and Security

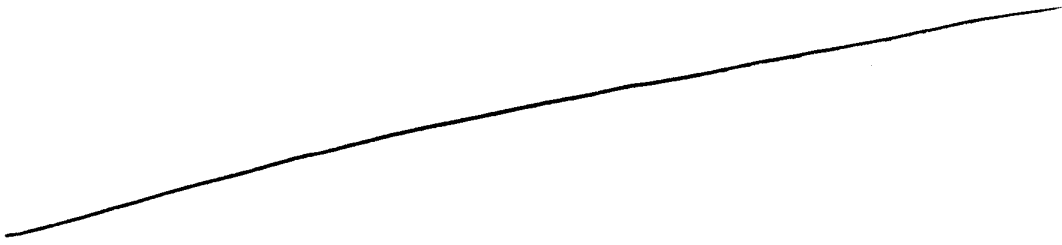




Section G. Quality Control



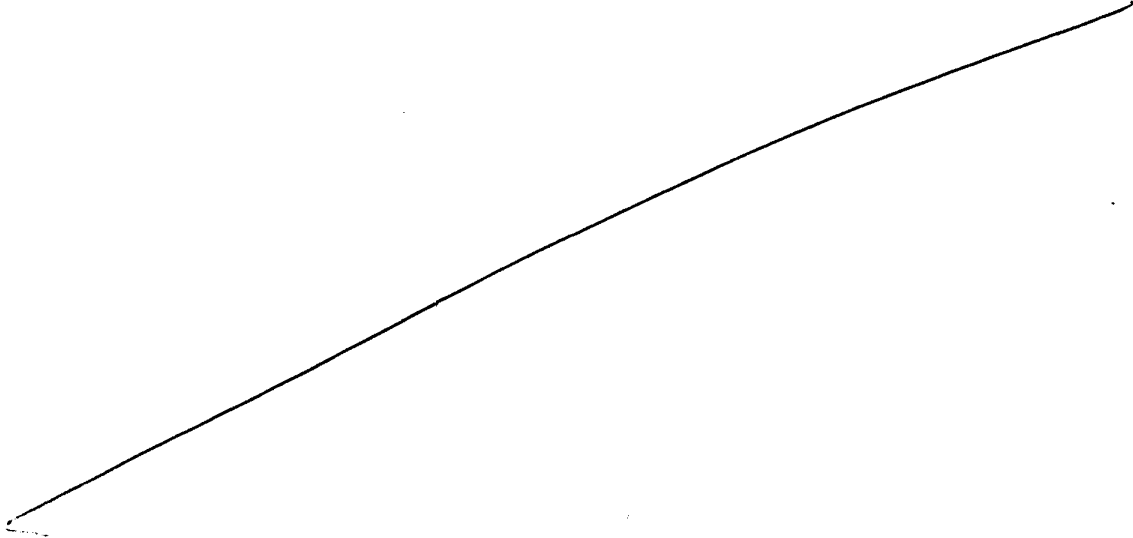
Section H. Initial Tests



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Section I. Confirmatory Tests

Section J. Records Audit

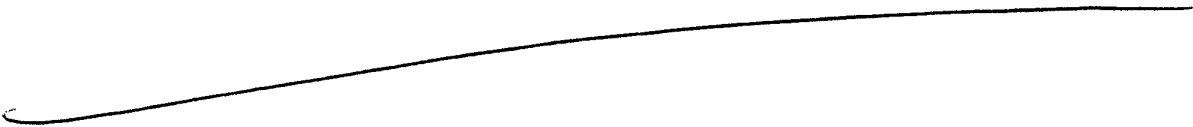


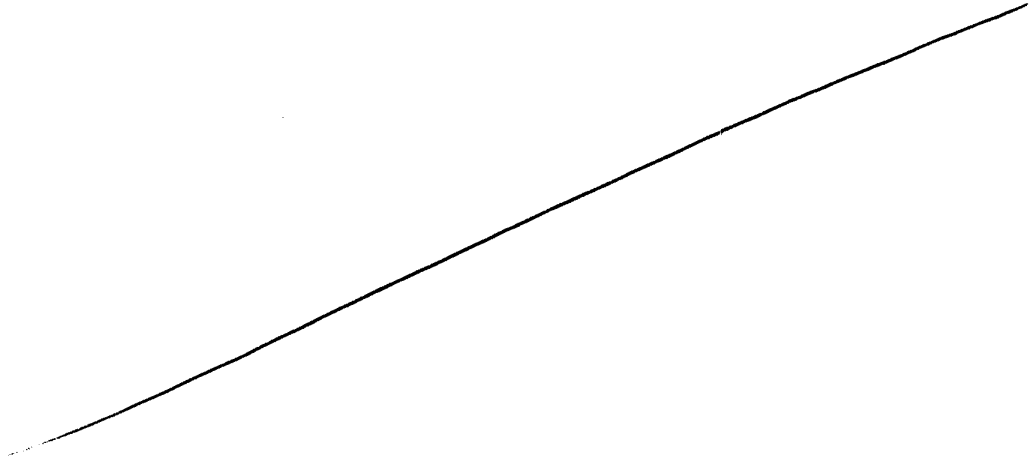
Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel







received  
5/5/00 JN

345 HILL AVENUE, NASHVILLE, TENNESSEE 37210  
Telephone: (615) 255-2400 ■ Facsimile: (615) 255-3030

May 4, 2000

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

Dear Ms. Denson:

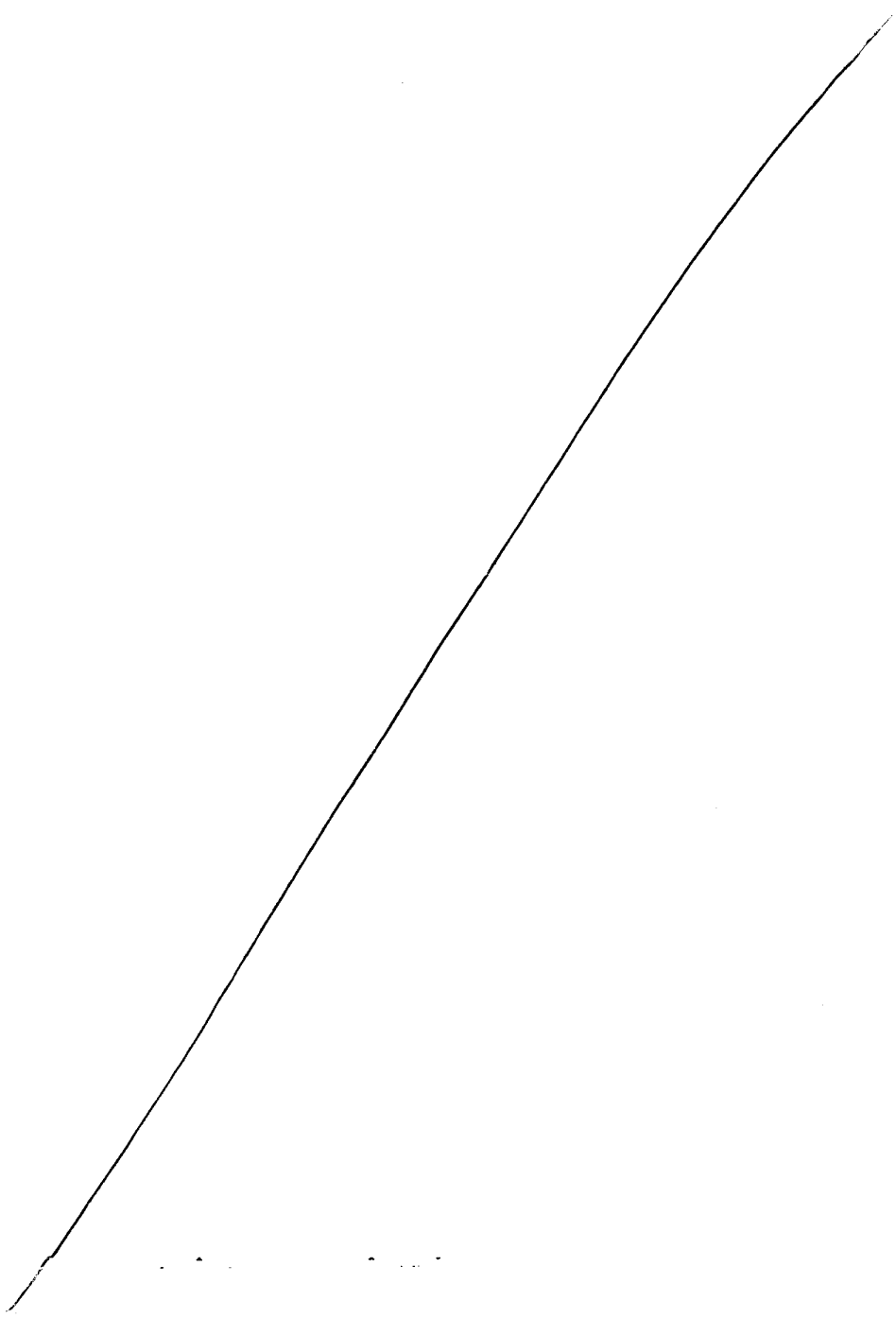
Enclosed please find my commentary and a number of items which you have requested from this laboratory in your letter of April 4, 2000 as remedial actions arising from the 15<sup>th</sup> maintenance inspection of this laboratory. If any additional materials or clarification is required, please contact me immediately.

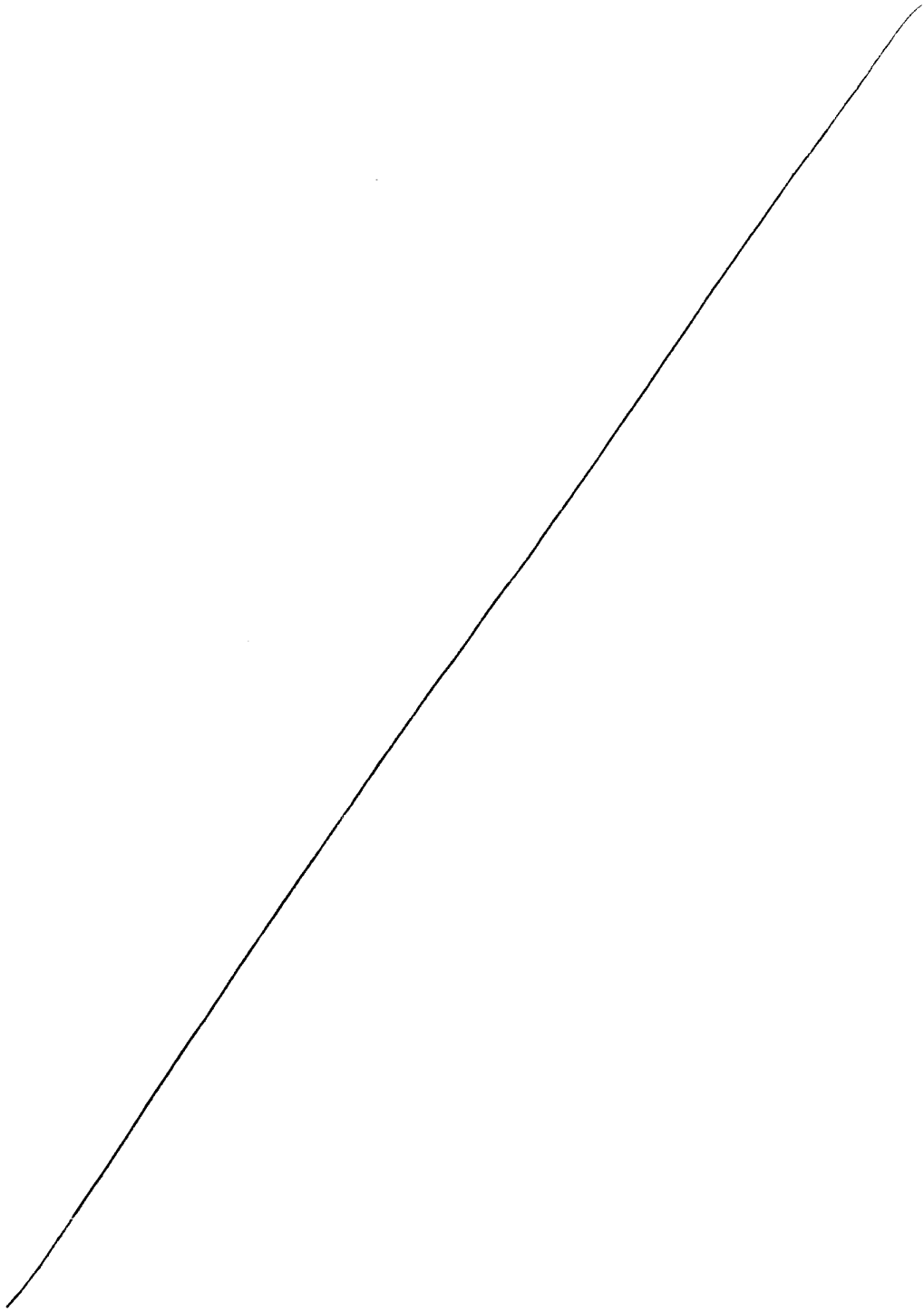
Sincerely,

A handwritten signature in black ink, appearing to read "Timothy A. Robert", is written over a faint, circular stamp or watermark.

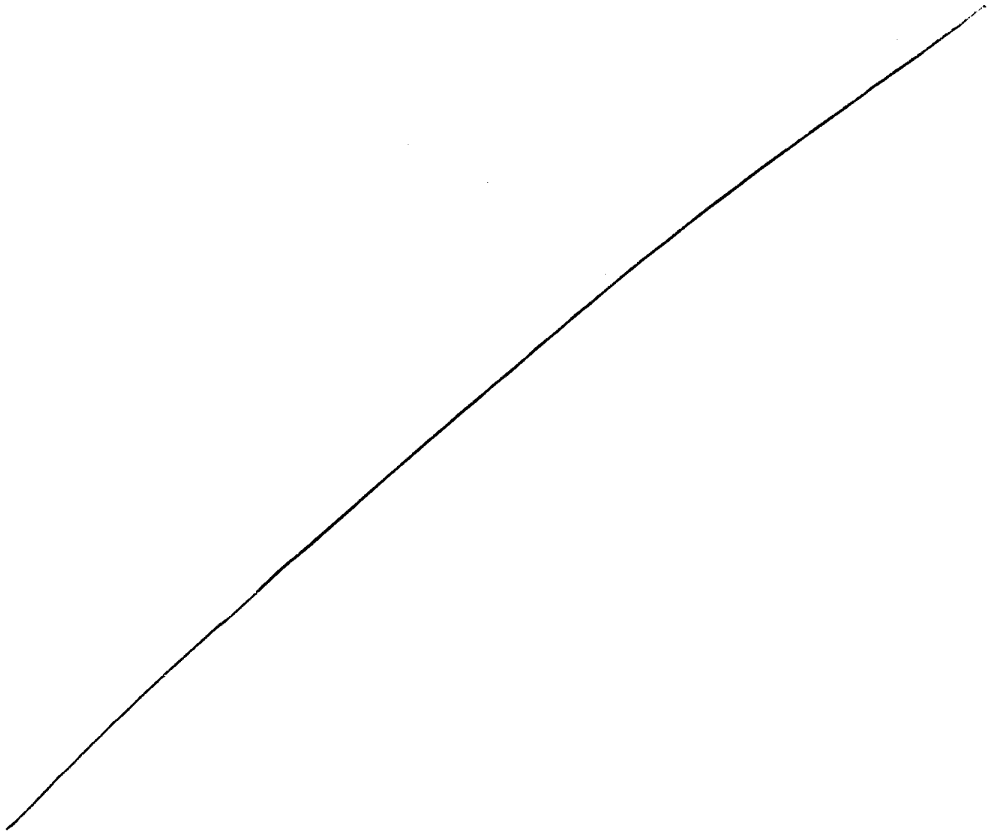
Timothy A. Robert, Ph.D.  
Assistant Director

MAINTENANCE INSPECTION 16 REMEDIAL ACTIONS











RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 12, 2000

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

We have reviewed the material provided in your correspondence of May 4, 2000, submitted in response to issues raised during the sixteenth inspection of your laboratory as outlined in our correspondence of April 4, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. However, the following issue requires additional clarification:

The laboratory must submit, within 10 calendar days of receipt of this letter, information to clarify the issue raised above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continues to be certified under the National Laboratory Certification Program pending successful resolution of this item. The implementation of all remedial actions will be subject to review by 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 Technical Analyst

cc: Project Files/M16





**received**  
5/26/00 AD

345 HILL AVENUE, NASHVILLE, TENNESSEE 37210  
Telephone: (615) 255-2400 ■ Facsimile: (615) 255-3030

May 25, 2000

Ms. Deborah J. Denson  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

This correspondence is in response to your letter of May 12, 2000 requesting further details of the remedial actions undertaken by this laboratory regarding Maintenance Inspection M16 item F19. I have enclosed a copy of the SOP Manual Chapter 3 that pertains to personnel.

It is my belief that the current collection procedures in place at this facility are consistent with program requirements. If there are additional questions or concerns, please contact me.

Sincerely,

A handwritten signature in cursive script, appearing to read "Timothy A. Robert".

Timothy A. Robert, Ph.D.  
Assistant Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 1, 2000

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

We have reviewed the material provided in your correspondence of May 25, 2000, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of April 04, 2000. 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:

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 R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,

A handwritten signature in cursive script that reads "Deborah J. Denson".

Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M16



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 17, 2000

0554  
Dr. Timothy Robert  
Aegis Analytical Lab  
345 Hill Avenue  
Nashville, TN 37210

Dear Dr. Robert:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth 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.

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.



Dr. Robert  
October 17, 2000  
Page 2 of 2

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

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

Enclosure

cc: Project Files/M17  
Mr. Eric J. Mueller  
Ms. Lisa D. Tarnai

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0554  
Document No. Final

Laboratory: Aegis Analytical Lab

Location: Nashville, TN

Document Reviewed:     Application Form  
                               Inspection Report # M17            Date: 17 August 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