

RESEARCH TRIANGLE INSTITUTE



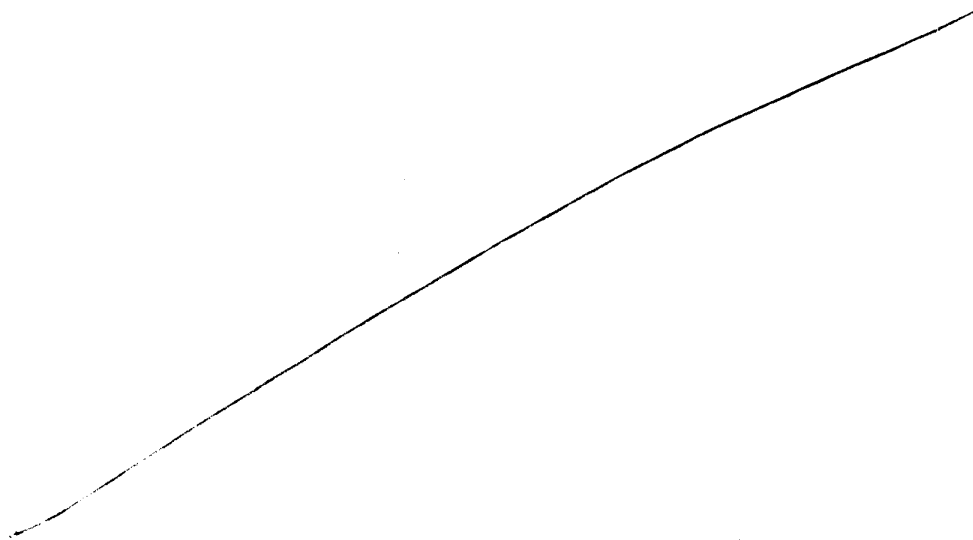
National Laboratory Certification Program

February 26, 1999

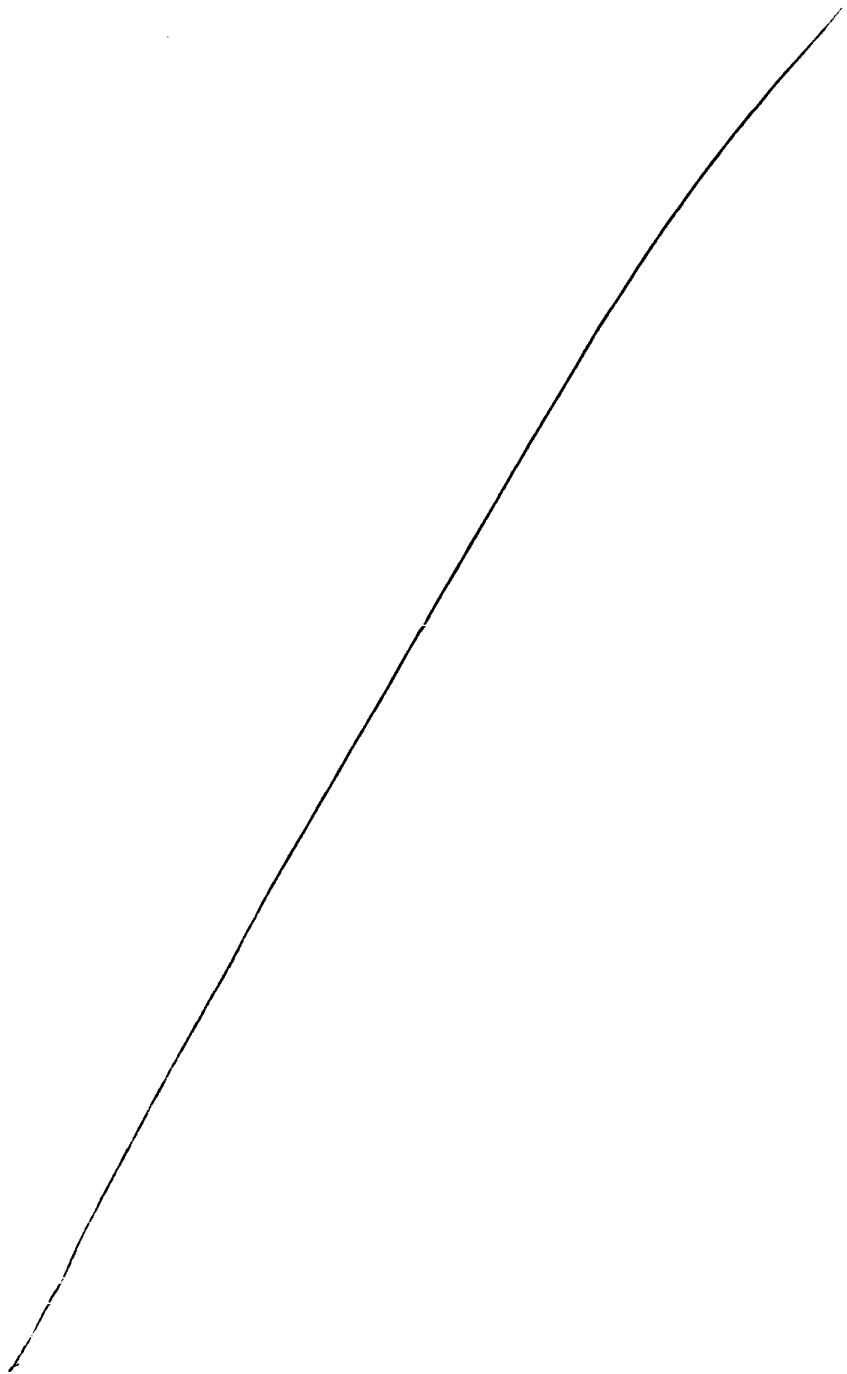
0215
Dr. Robert F. Foery
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118


Dear Dr. Foery:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the initial inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the outcome of the laboratory's performance in this inspection is acceptable; however, the laboratory must clarify and/or correct the following issues before a recommendation for certification can be made:



Dr. Foery
Page 2 of 3
02/26/99





Dr. Foery
Page 3 of 3
02/26/99

The laboratory must submit documentation to clarify and/or correct the items cited above. Once the laboratory has successfully completed these actions, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory be certified under the NLCP. The laboratory must also review the enclosed critique and take all necessary corrective actions.

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/1

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #11
 Other _____

Date: 28 January 1999

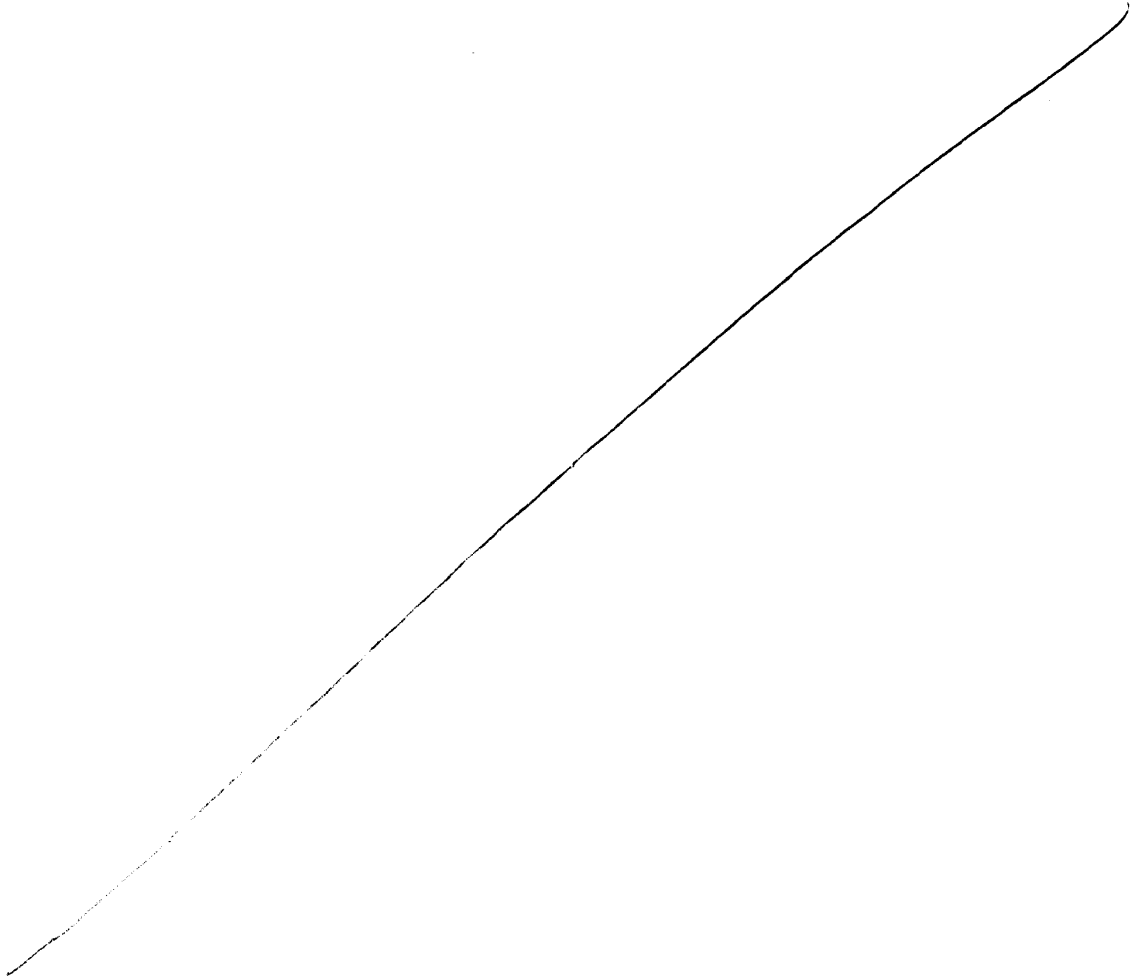
Status: Acceptable Failure

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.

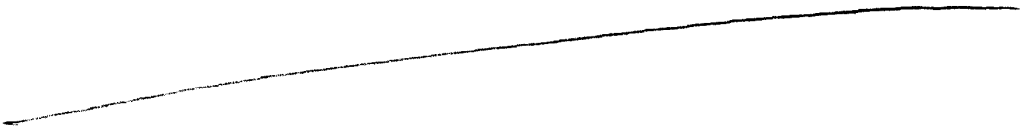
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



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



Section G. Quality Control

[Redacted content]

Section H. Initial Tests

[Redacted content]

Section I. Confirmatory Tests

[Redacted content]

Section J. Records Audit

[Redacted content]

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

ATN

MEMPHIS, TN 38125

3/05/99

3/05/99

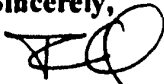
**Ms. Susan Crumpton, Analyst
National Laboratory Certification Program
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194**

Dear Ms. Crumpton,

Enclosed is ATN-Memphis response to the inspection report of 26 February 1999.

We appreciate the thoroughness of the Inspectors' report and look forward to the mutually successful conclusion of what has become an arduous inspection process.

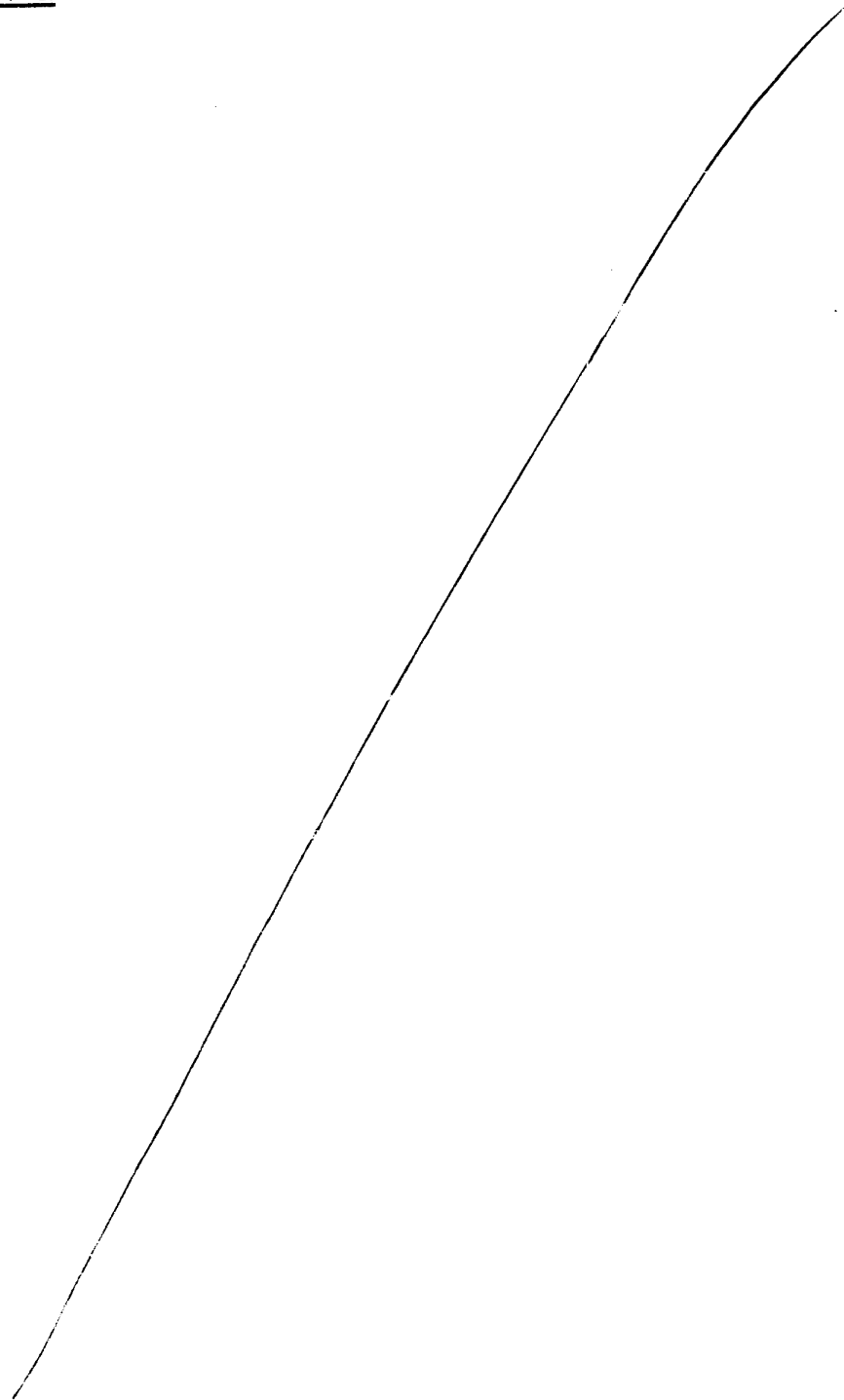
Sincerely,



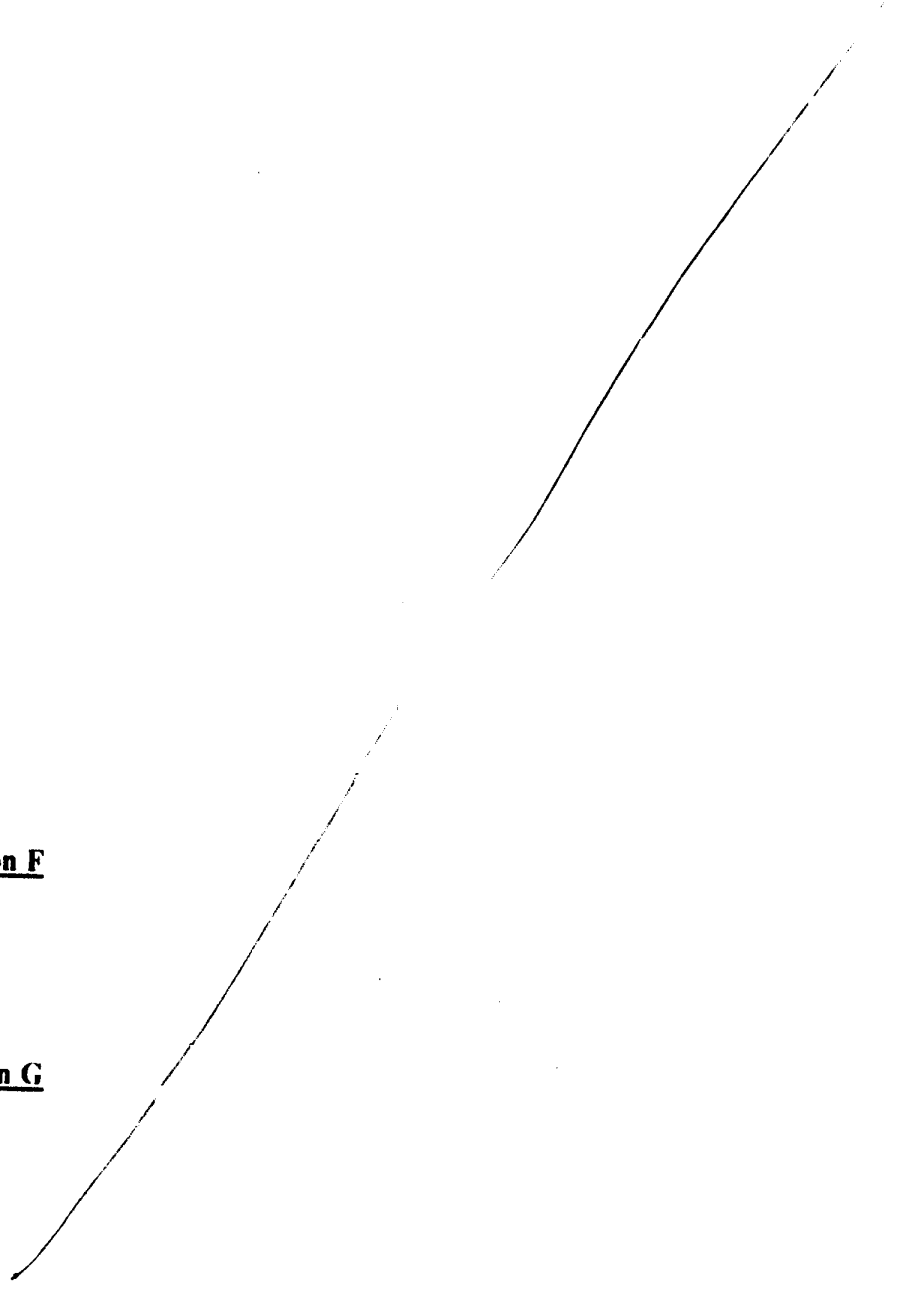
**Robert F. Foery, Ph.D.
Chief Operating Officer**

Document Review and Critique

SECTION E



1000



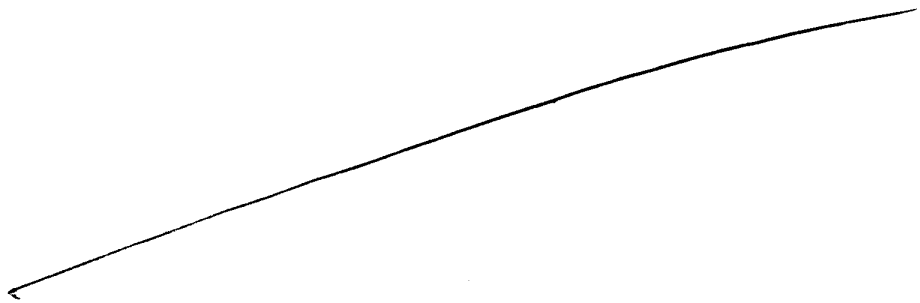
Section F

Section G

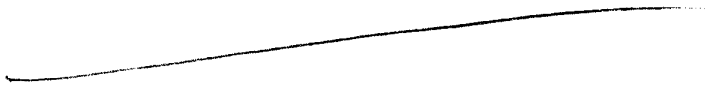
Section H



Section I



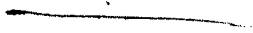
SECTION J



SECTION L



SECTION M



SECTION N

RESEARCH TRIANGLE INSTITUTE



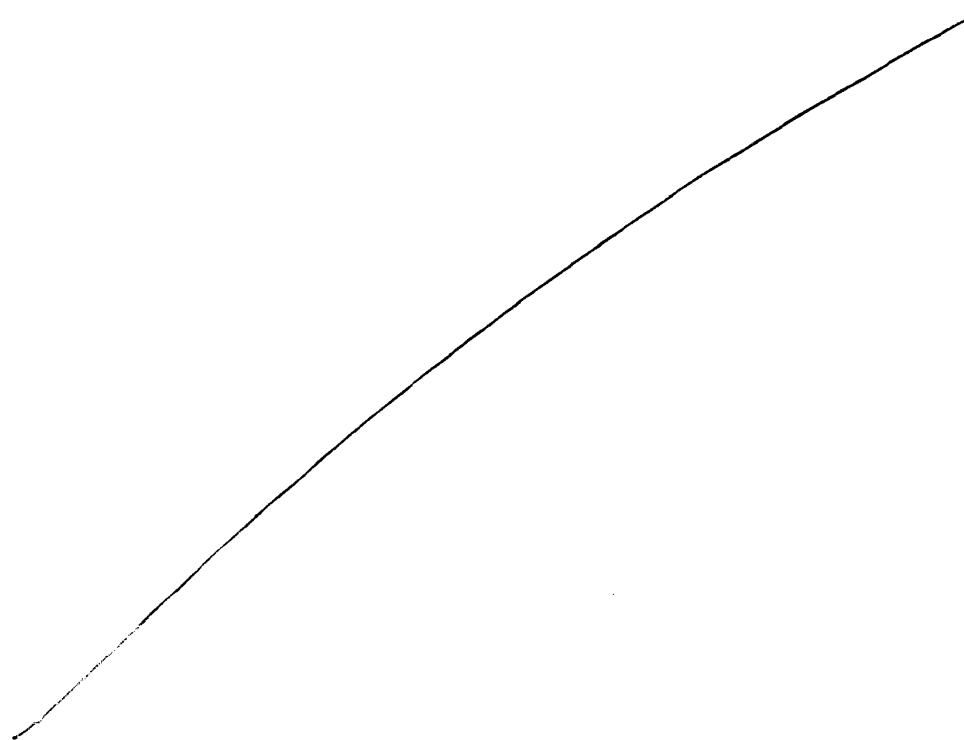
National Laboratory Certification Program

August 18, 1999

0215
Dr. Robert Foery
Mr. Roger Rutter
Advanced Toxicology Network
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Dr. Foery and Mr. Rutter:

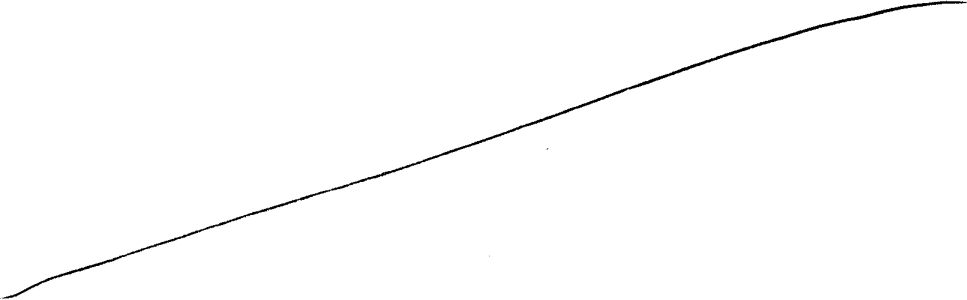
The enclosed critique was developed from the inspection reports of the inspectors who conducted the second inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:



- 
- G. The Quality Control section was not found fully acceptable. The following issues were raised:

- 
- H. The Initial Test section was found overall acceptable. However, the following issue was raised:
- 

- 
- J. The Records Audit section was found overall acceptable. However, the following issues were raised:


- 
- L. The Computers, Software, and LIMS section was found overall acceptable. However, the following issue was raised:

Dr. Foery
Mr. Rutter
Page 4 of 4
08/18/99

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/2



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #2
 Other _____

Date: 24 June 1999

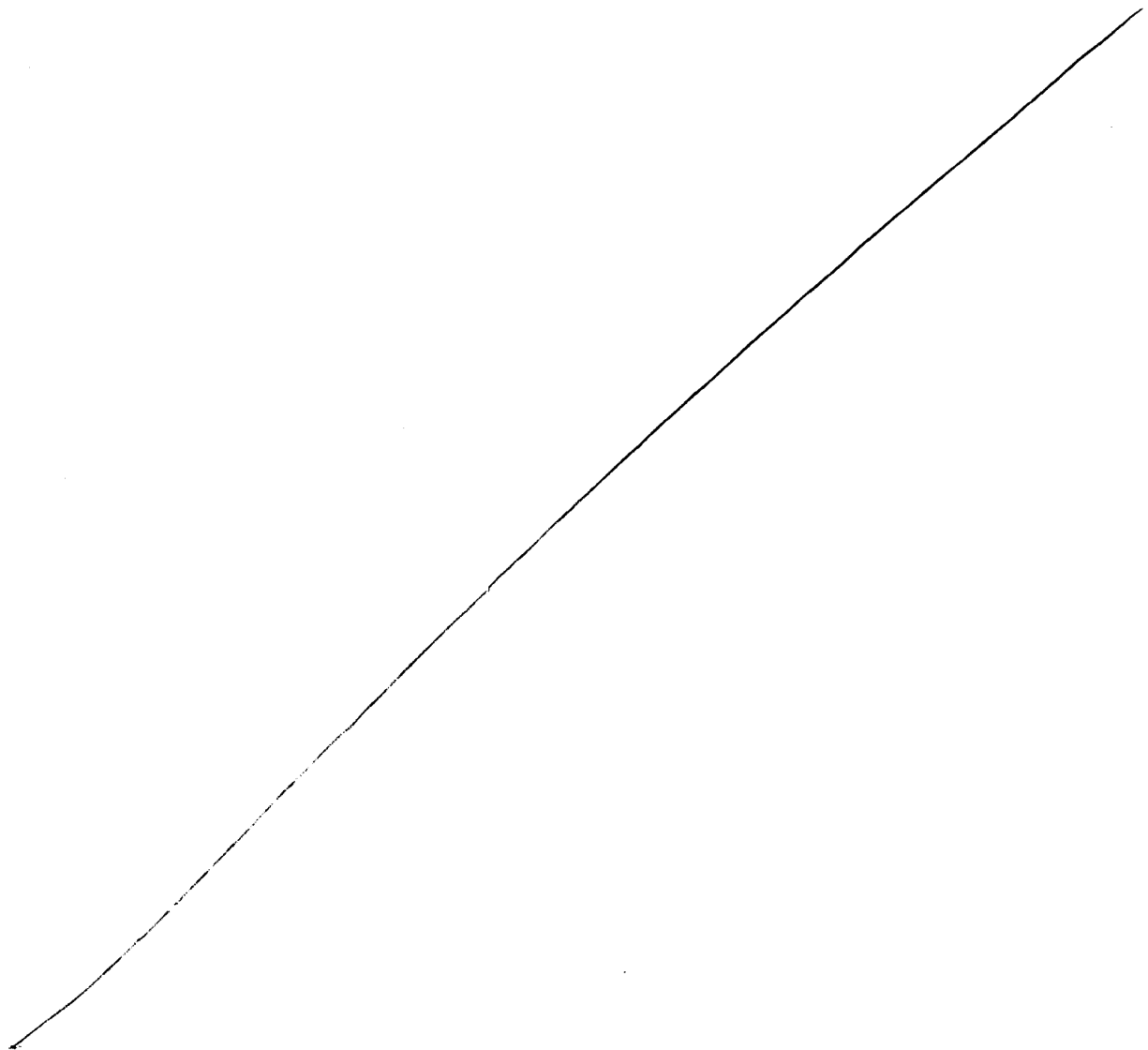
Status: Highly Acceptable Acceptable
 Unacceptable Failure

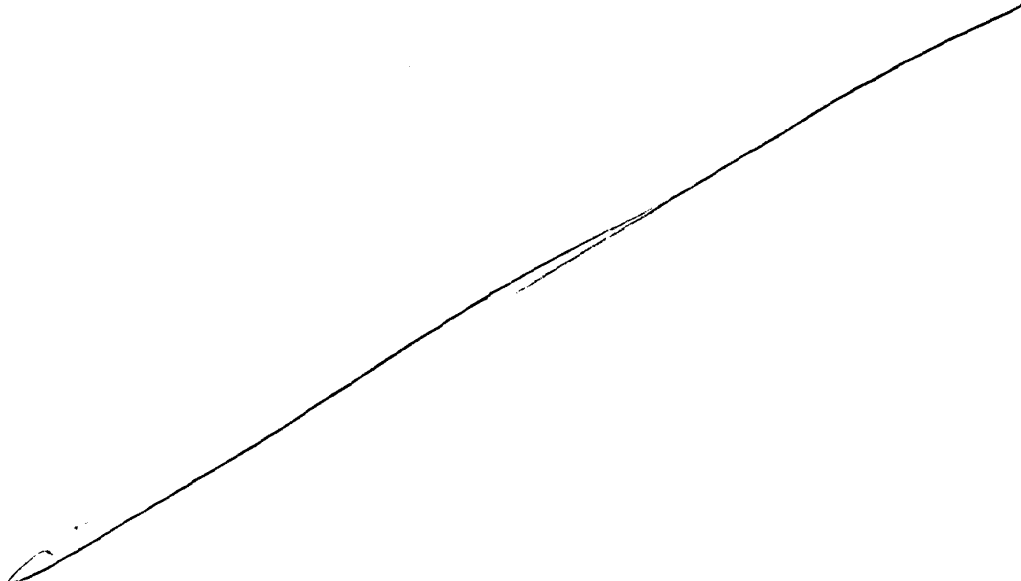
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

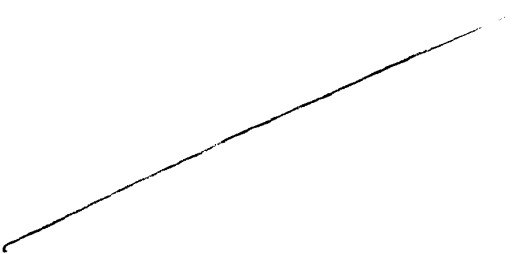
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

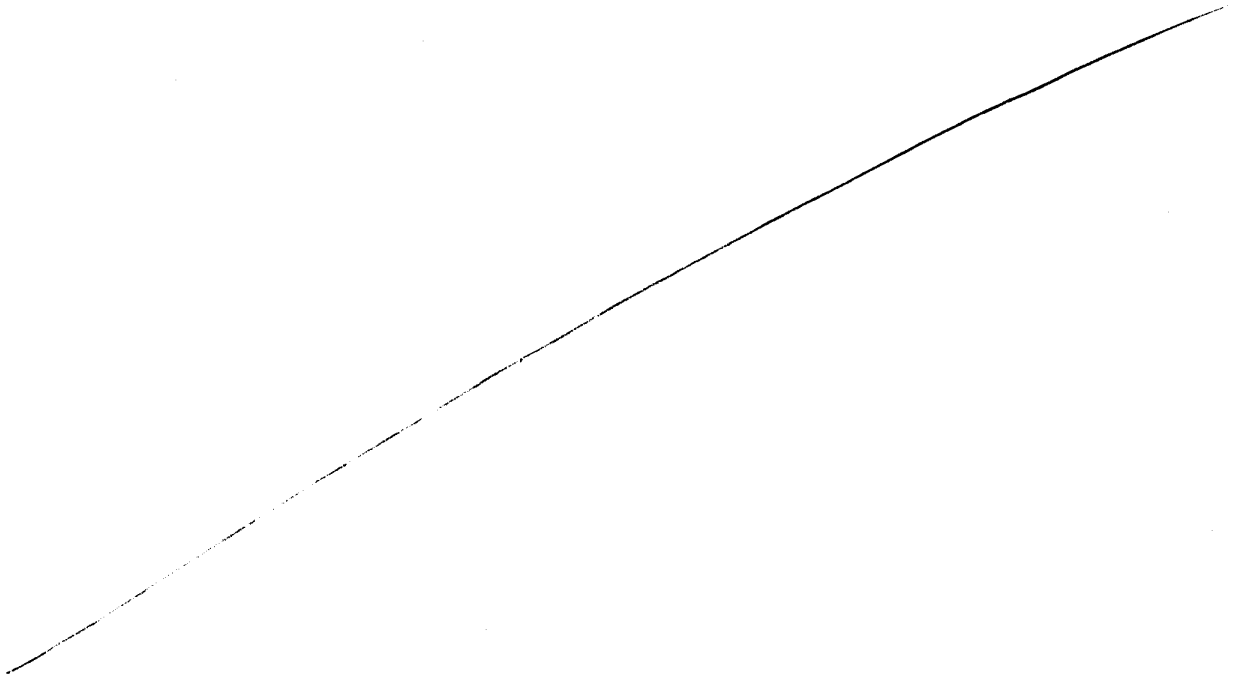




Section F. Chain-of-Custody, Accessioning, and Security



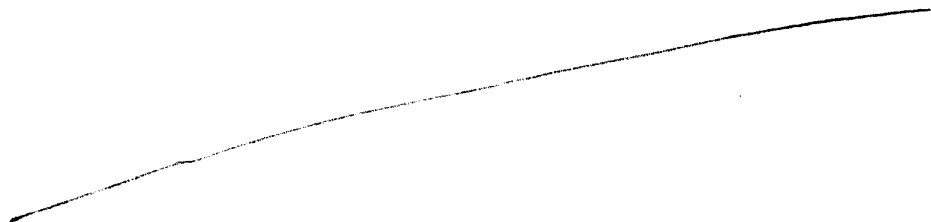
Section G. Quality Control

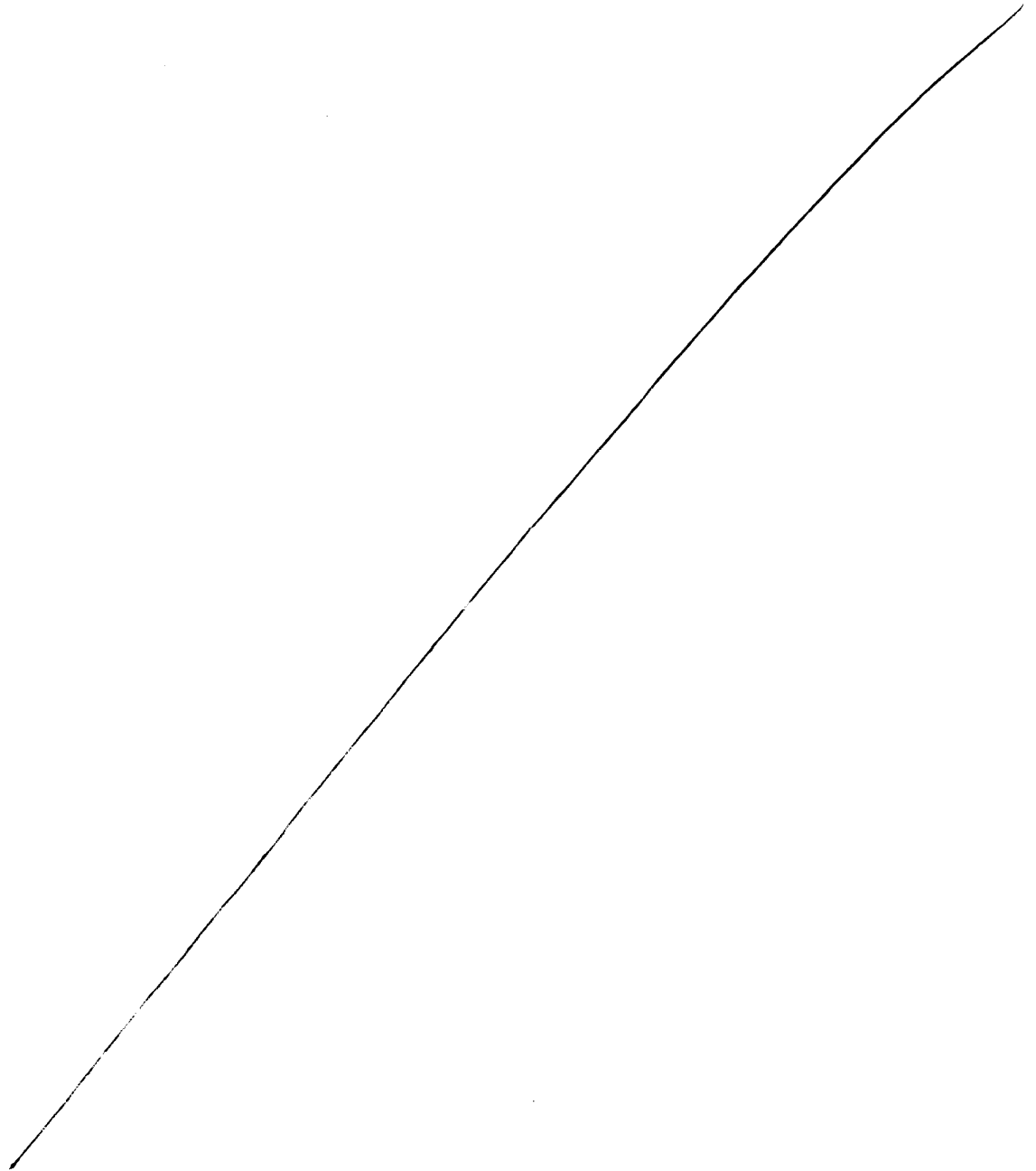


Section H. Initial Tests



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



received
9/17/99

15 September 1999

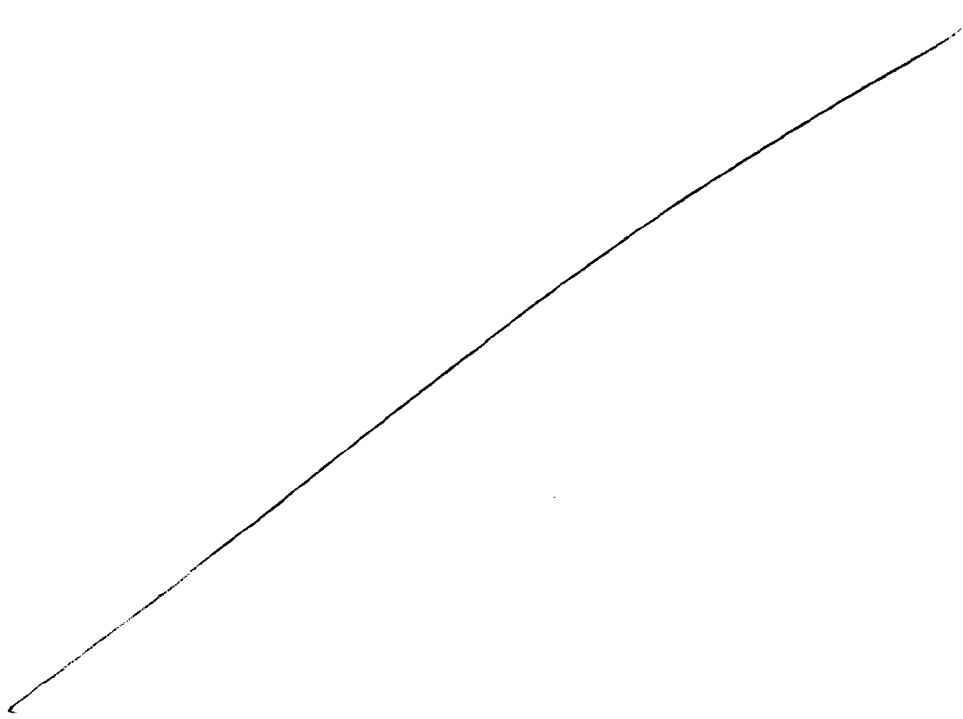
Ms. Deborah J. Denson, Inspection Analyst
National Laboratory Certification Program R.T.I.
3040 Cornwallis Road / Box 12194
Research Triangle Park, NC 27709-2194

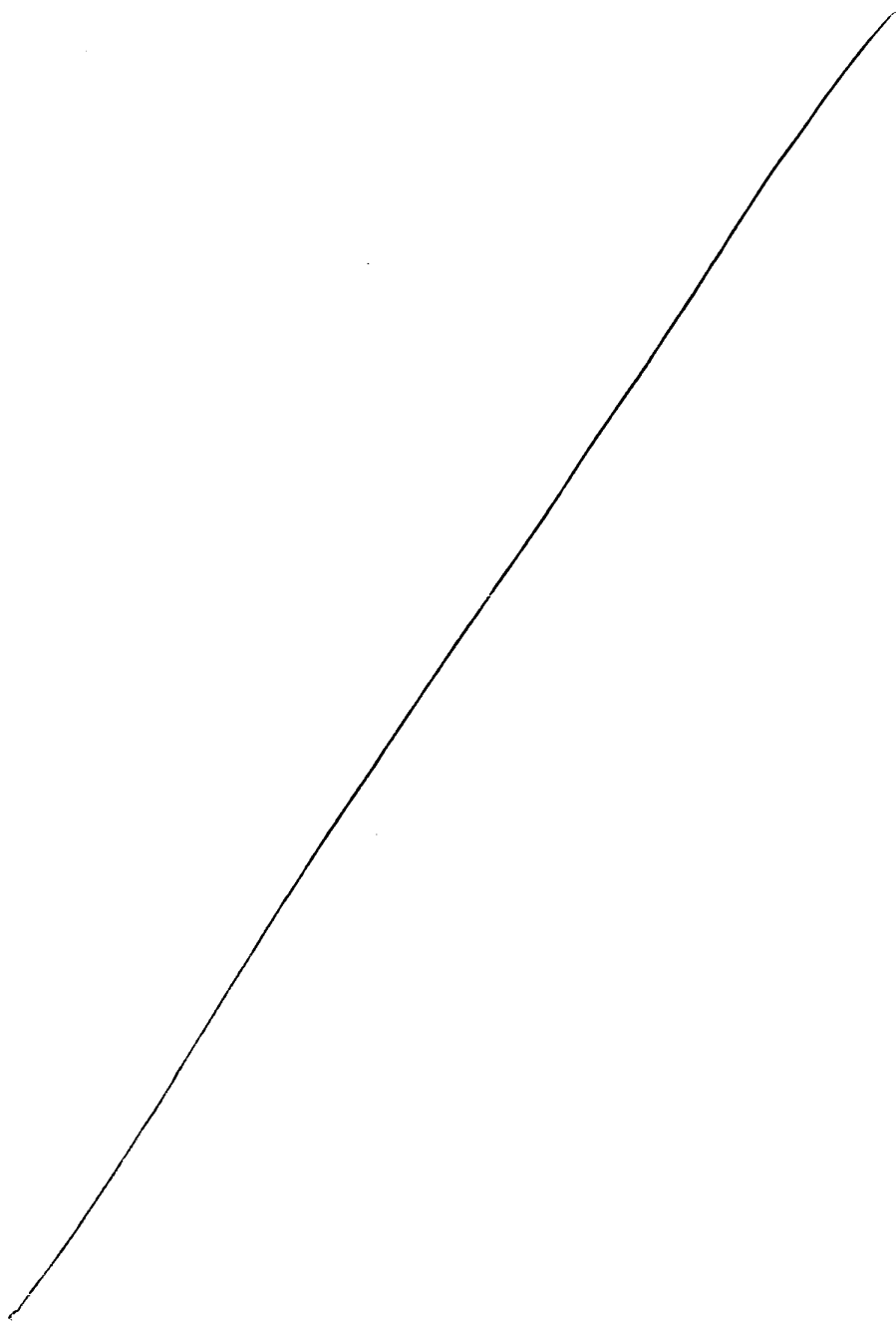
Dear Ms. Denson,

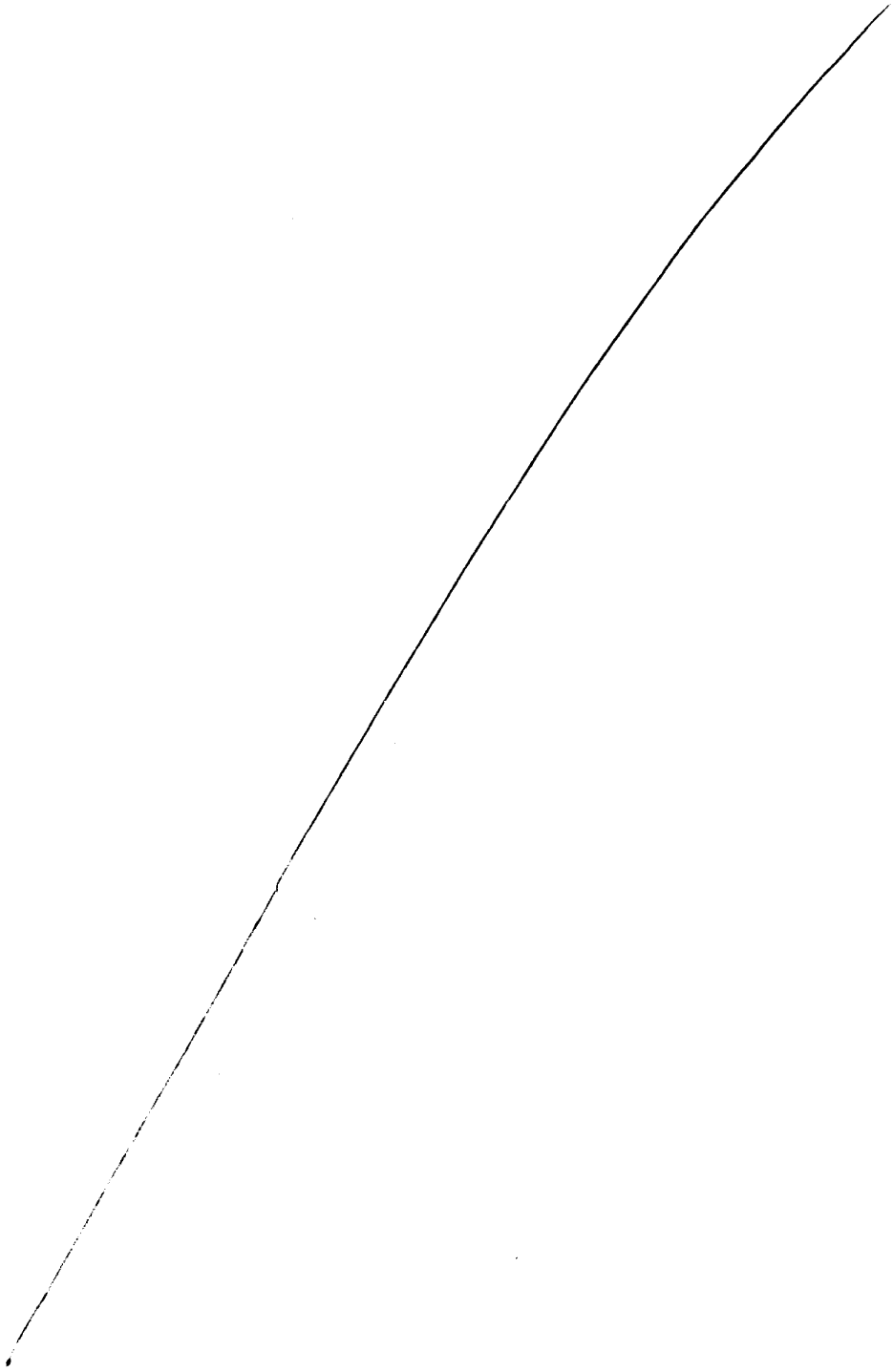
Following is ATN's response to your letter of 18 August 1999 and to the Document Review and Critique for Inspection Report #2 (24 June 1999) contained therein.

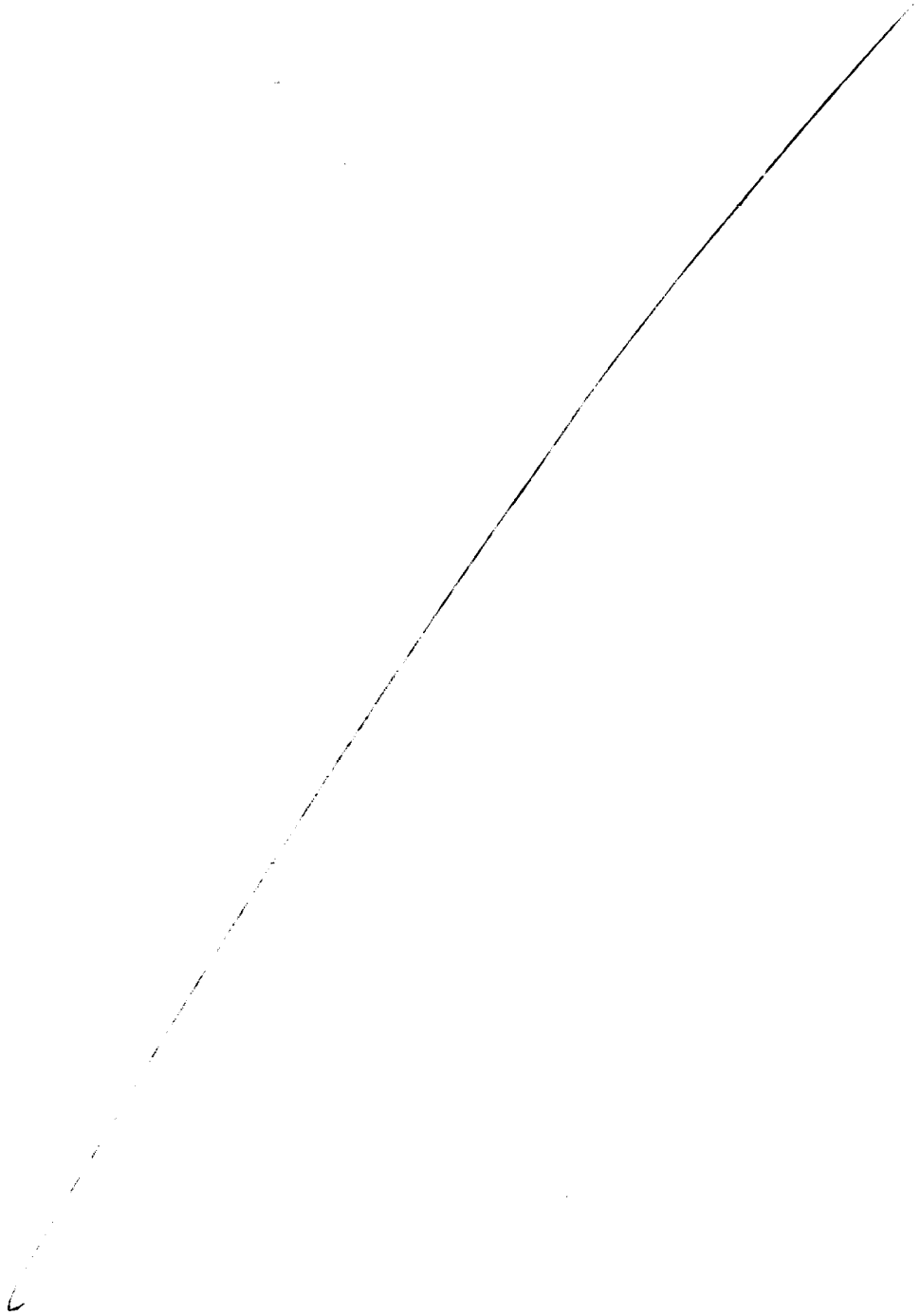
Part I Document Review and Critique

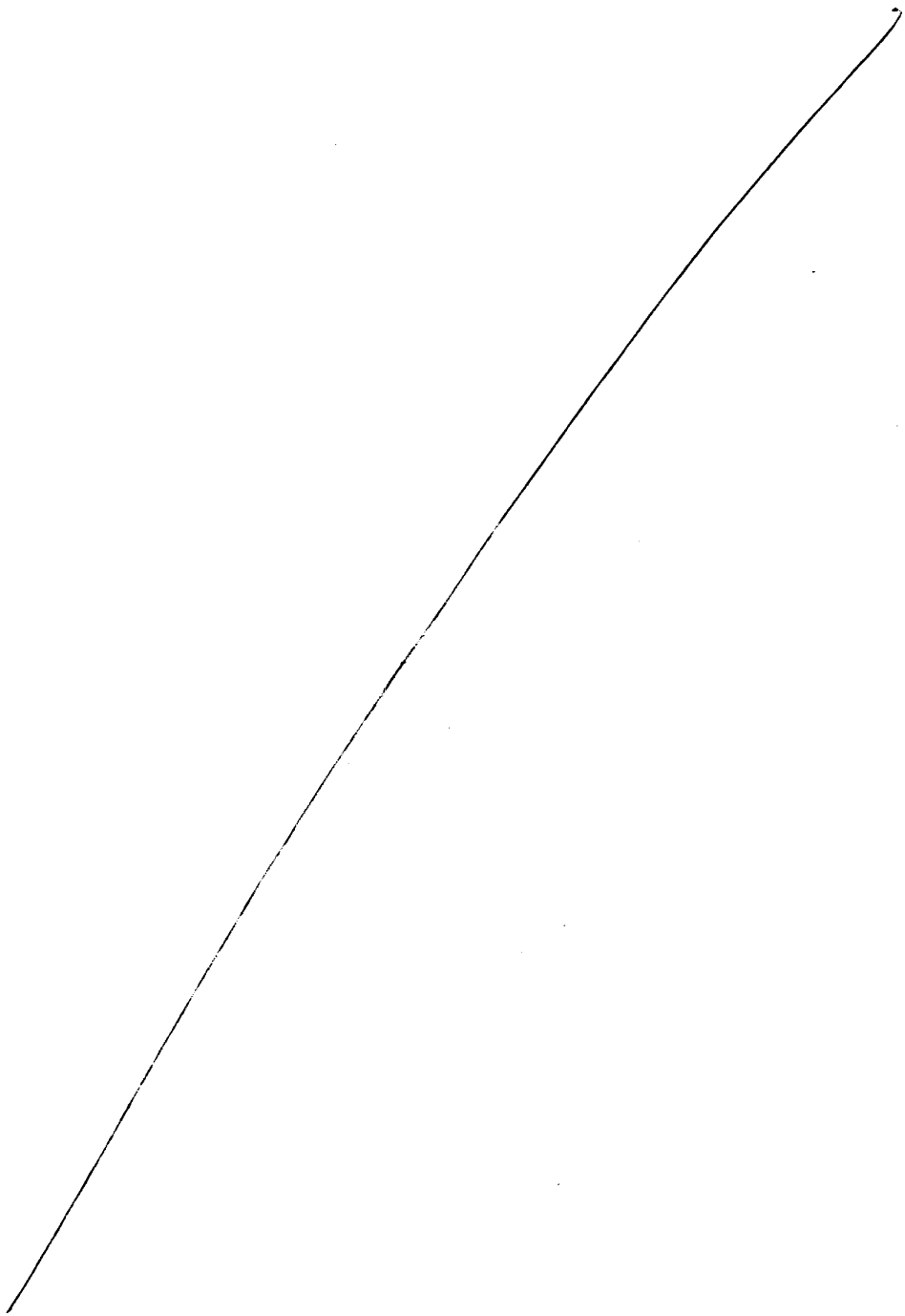
Section E: Item 2:





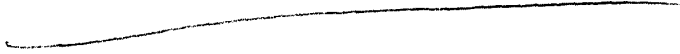




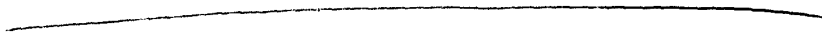


2

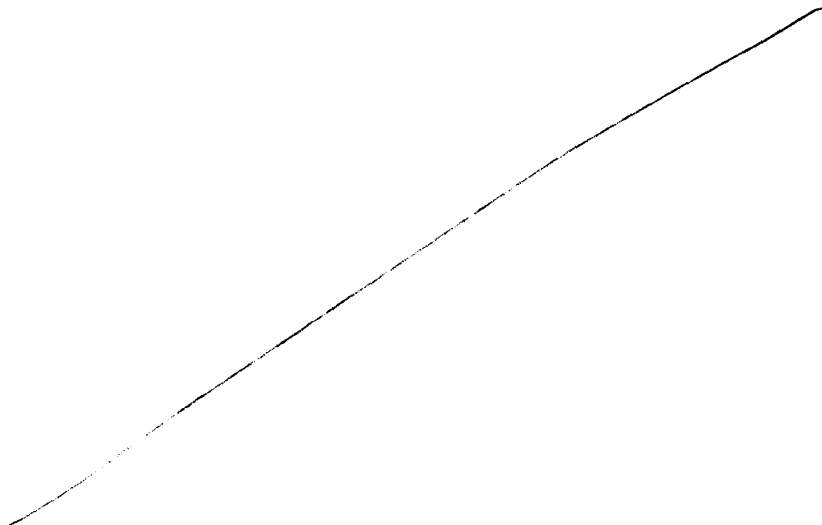
Section N:



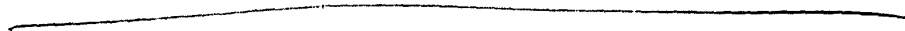
Section E:



Section F:



Section H:



Section I:



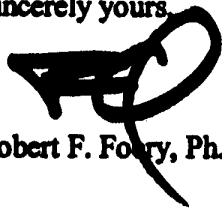
Section J:

Section L:

Section N:

Please contact me at 1-888-290-1150 if further information is required.

Sincerely yours,



Robert F. Foery, Ph.D.



RESEARCH TRIANGLE INSTITUTE

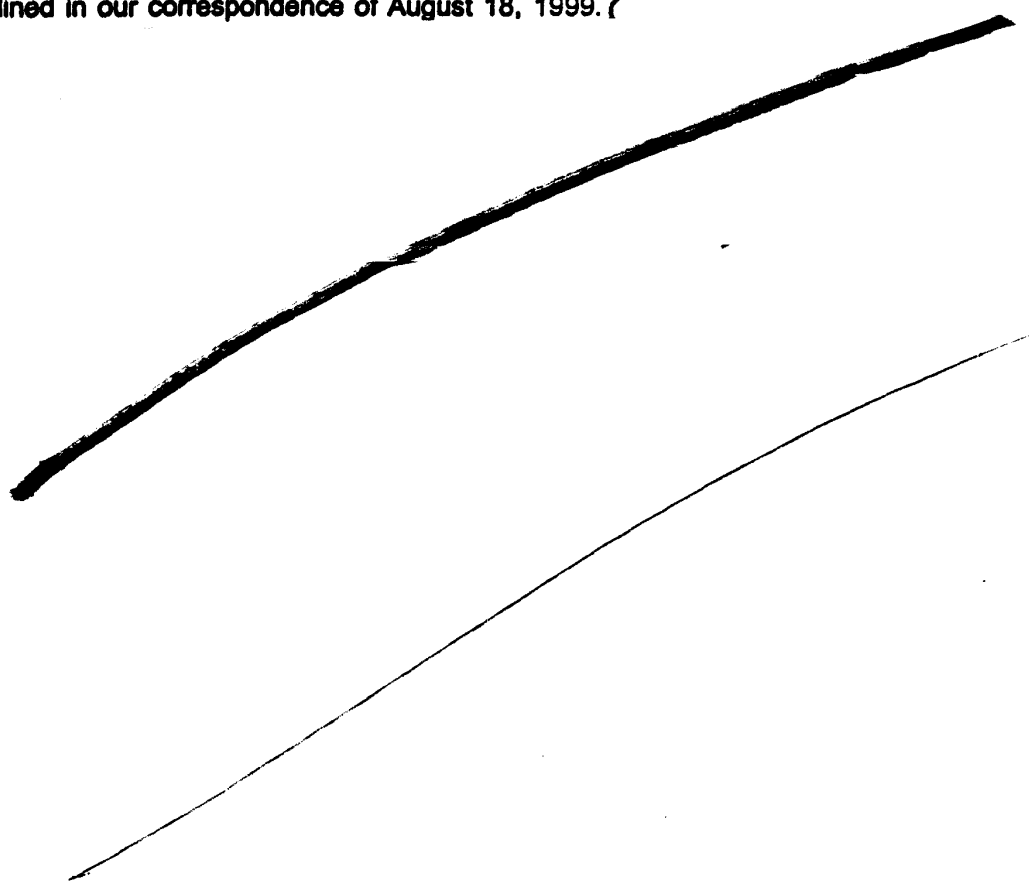
National Laboratory Certification Program

October 5, 1999

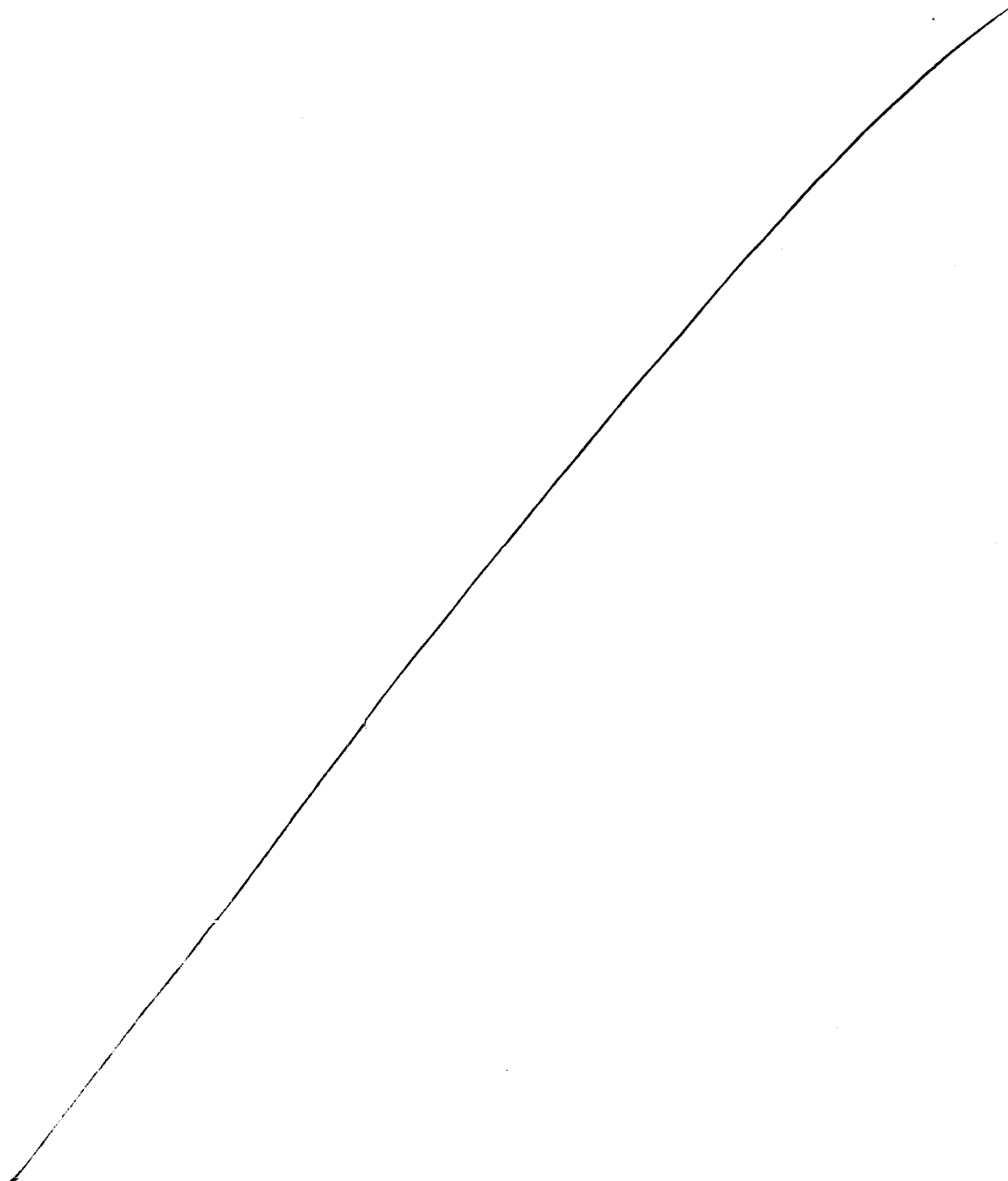
0215
Dr. Robert F. Foery
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Dr. Foery and Mr. Rutter:

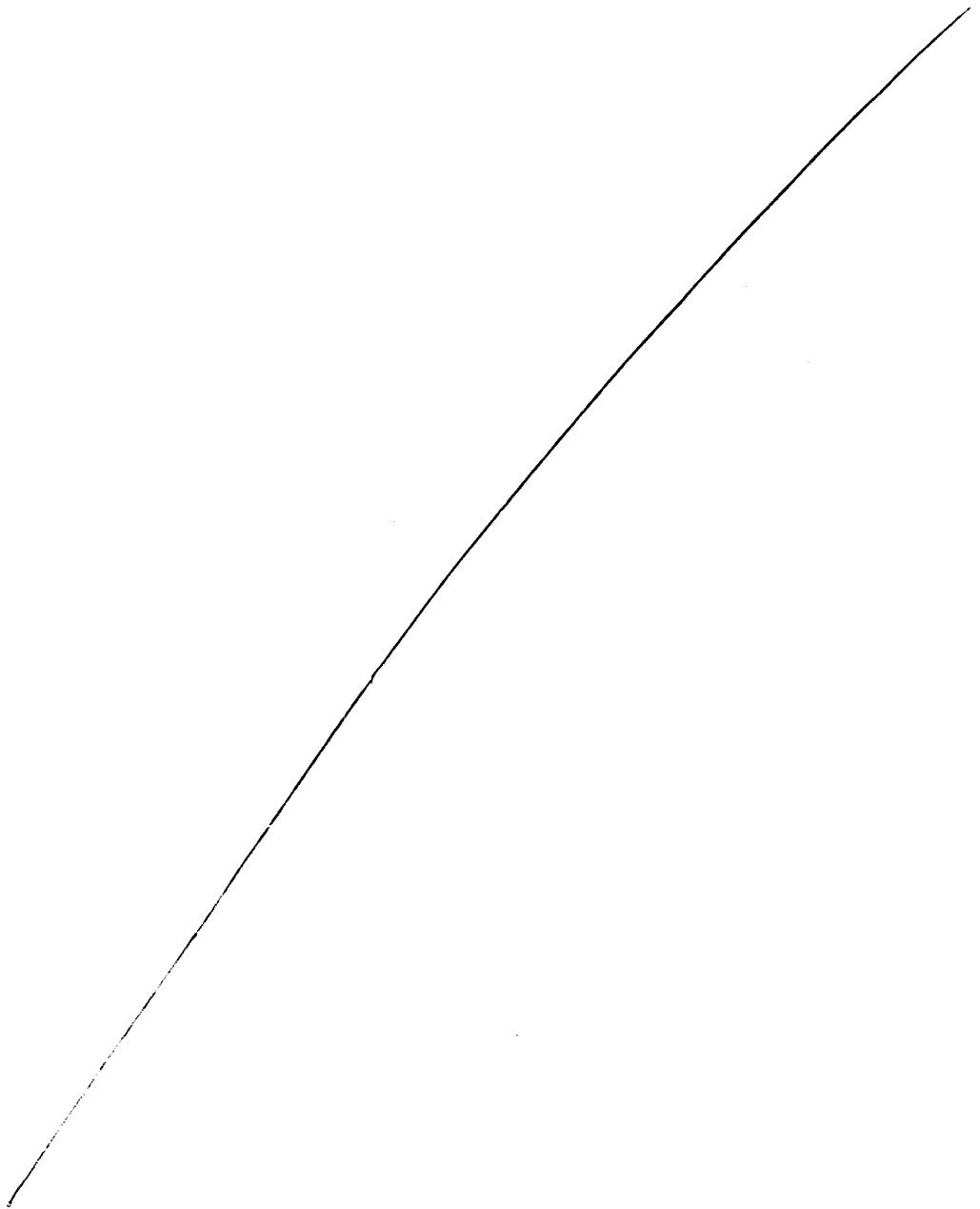
We have reviewed the material provided in your correspondence of September 15, 1999, submitted in response to issues raised during the second inspection of your laboratory as outlined in our correspondence of August 18, 1999. (



Dr. Robert Foery
Mr. Roger Rutter
October 5, 1999
Page 2 of 4



**Dr. Robert Foery
Mr. Roger Rutter
October 5, 1999
Page 3 of 4**

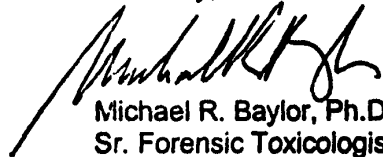


Dr. Robert Foery
Mr. Roger Rutter
October 5, 1999
Page 4 of 4

The laboratory must submit, within 10 working days of receipt of this letter, information to finalize the remedial actions addressed above. RTI will *not* recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program *until* there is successful resolution of these items. 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) 541-7043 or Deborah Denson. at (919) 541-7265.

Sincerely,



Michael R. Baylor, Ph.D
Sr. Forensic Toxicologist

cc: Project Files/2



Rec'd 10/20/99
SDC

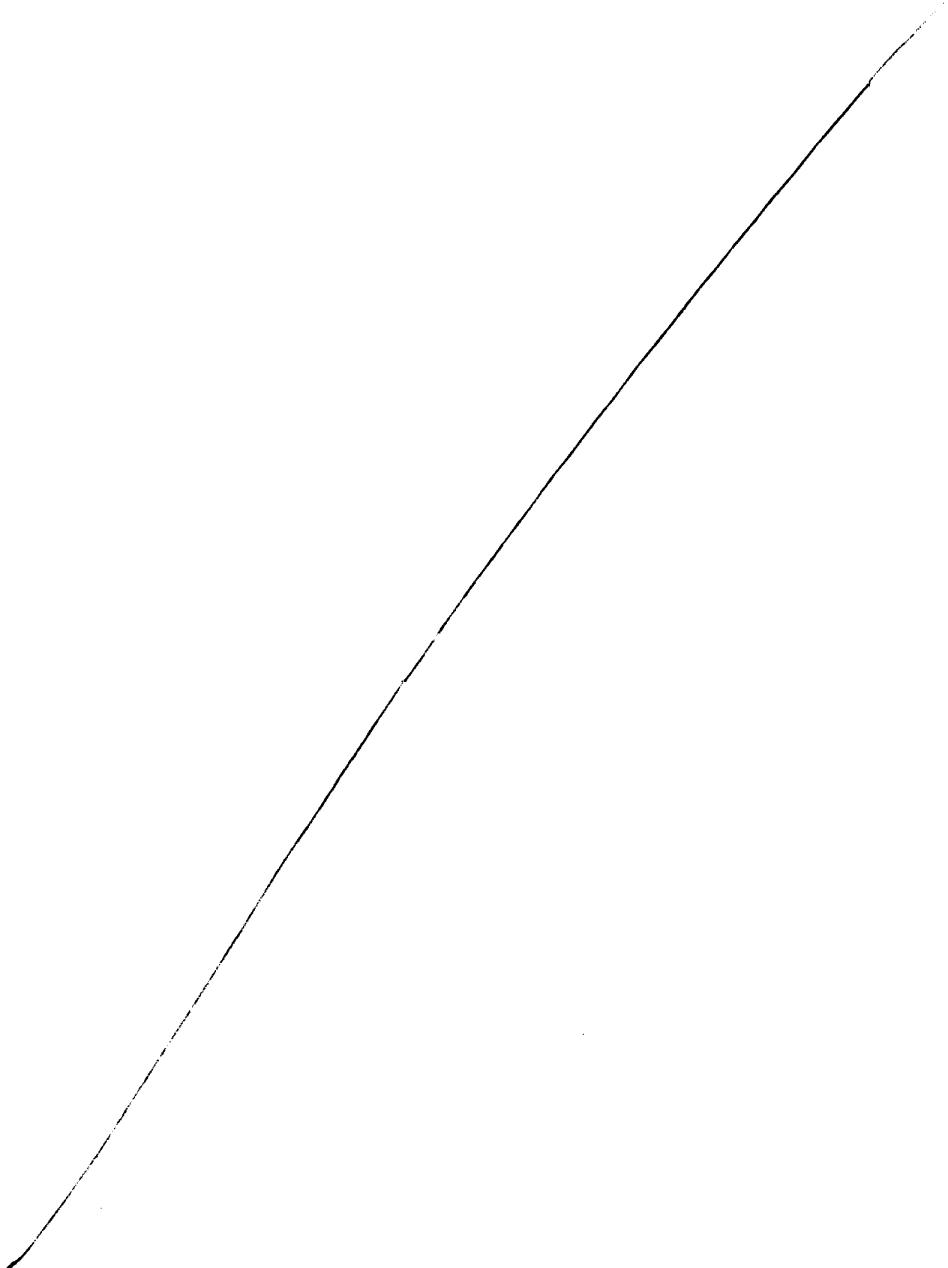
October 19 1999

**Michael Baylor, Ph.D./Senior Forensic Toxicologist
National Laboratory Certification Program / R.T.I.
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194**

Dear Dr. Baylor,

Thank you for your letter of 5 October 1999 (rec'd at ATN on 10/6/99).





Please contact me at 1-888-290-1150 ext. 190 if further information is required.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'R. Foery', with a large circular flourish at the end.

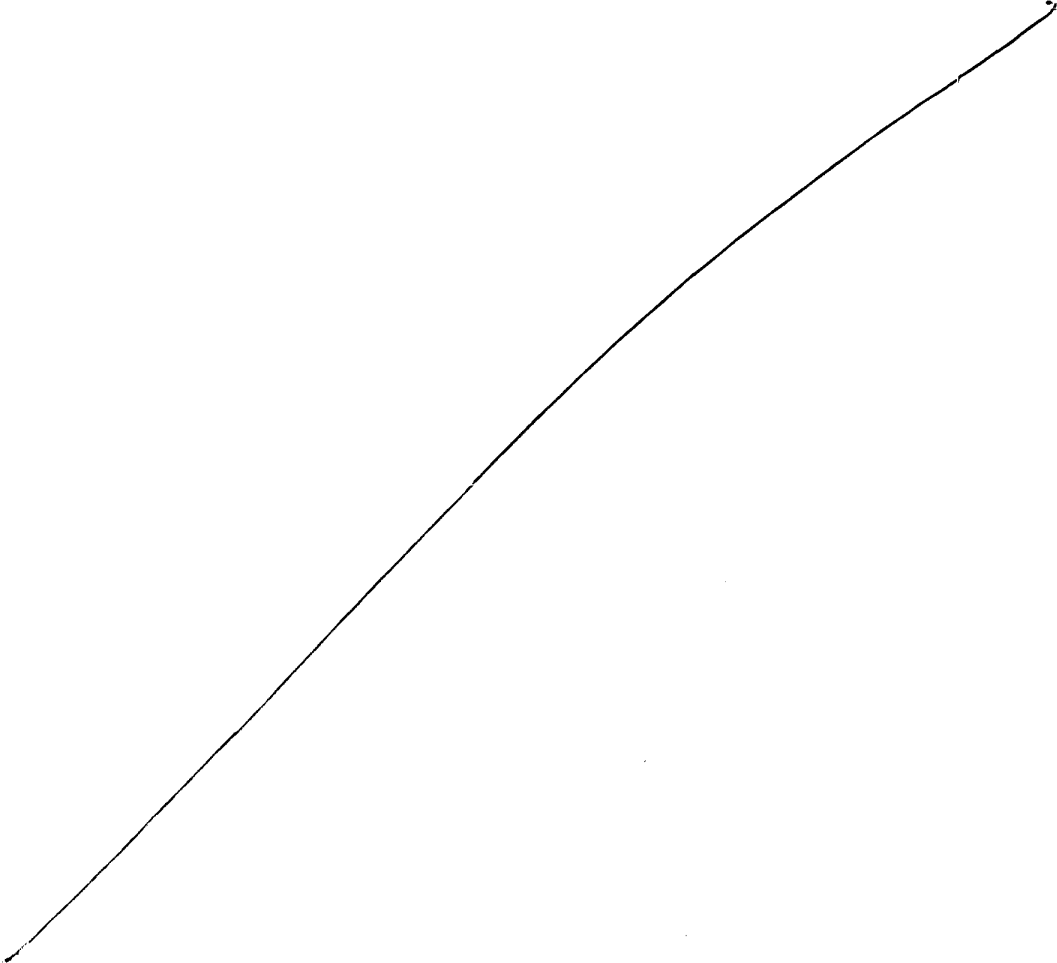
Robert F. Foery, Ph.D.
Chief Operating Officer/Responsible Person

October 29, 1999

0215
Dr. Robert F. Foery
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Dr. Foery and Mr. Rutter:

We have reviewed the material provided in your correspondence of October 19, 1999, submitted in response to issues raised during the second inspection of your laboratory as outlined in our correspondence of October 05, 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:

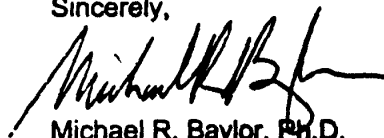


Dr. Robert Foery
Mr. Roger Rutter
October 29, 1999
Page 2 of 2

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues 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) 541-7043 or Deborah J. Denson at (919) 541-7265.

Sincerely,



Michael R. Baylor, Ph.D.
Sr. Forensic Toxicologist

cc: Project Files/2



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 10, 2000

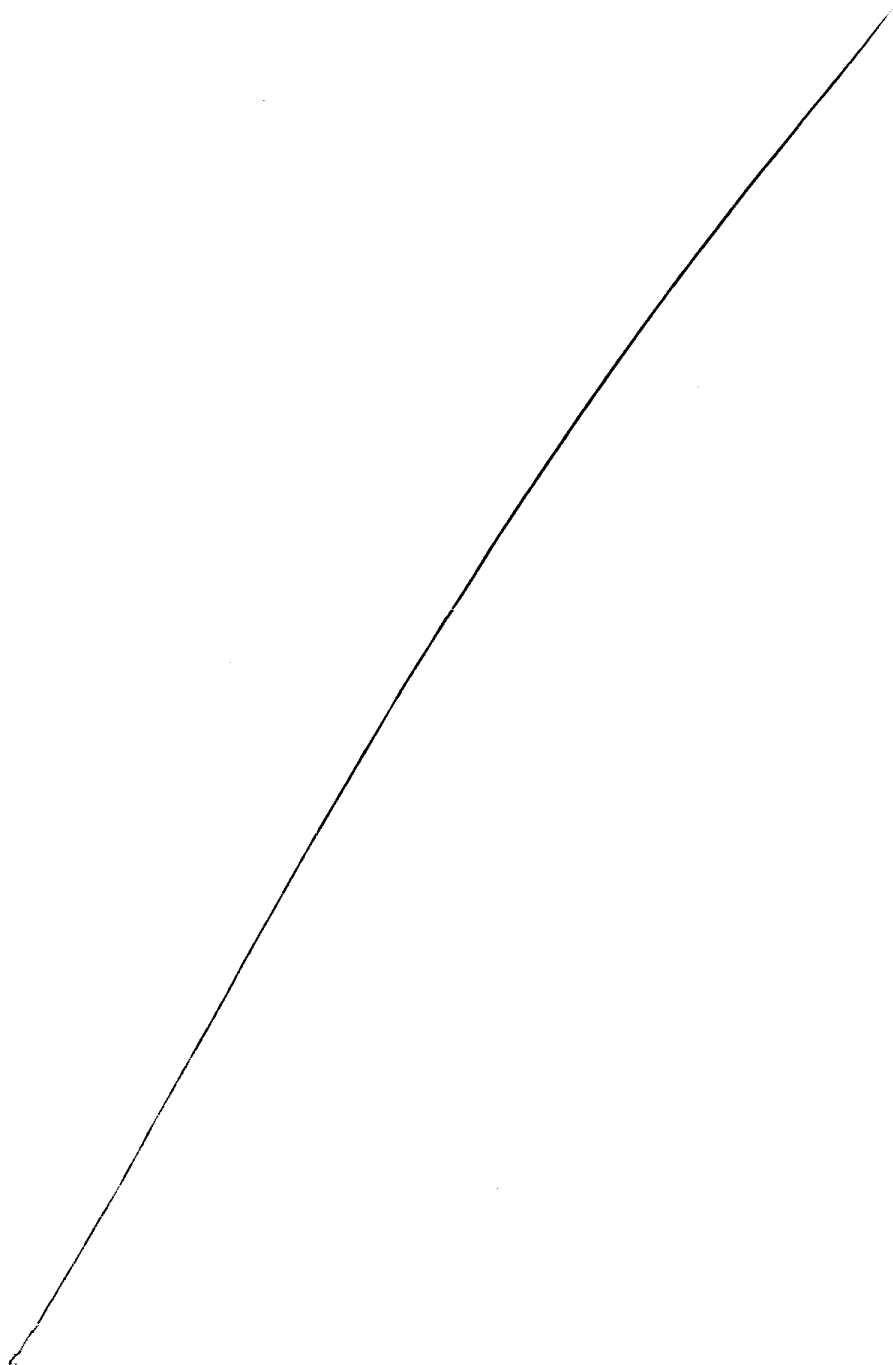
0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

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



Mr. Rutter
Page 2 of 4
02/10/00






K. The Reporting



N. The Personnel sectic



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

Mr. Rutter
Page 4 of 4
02/10/00

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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/215



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M1 Date: 16 December 1999
 Other _____

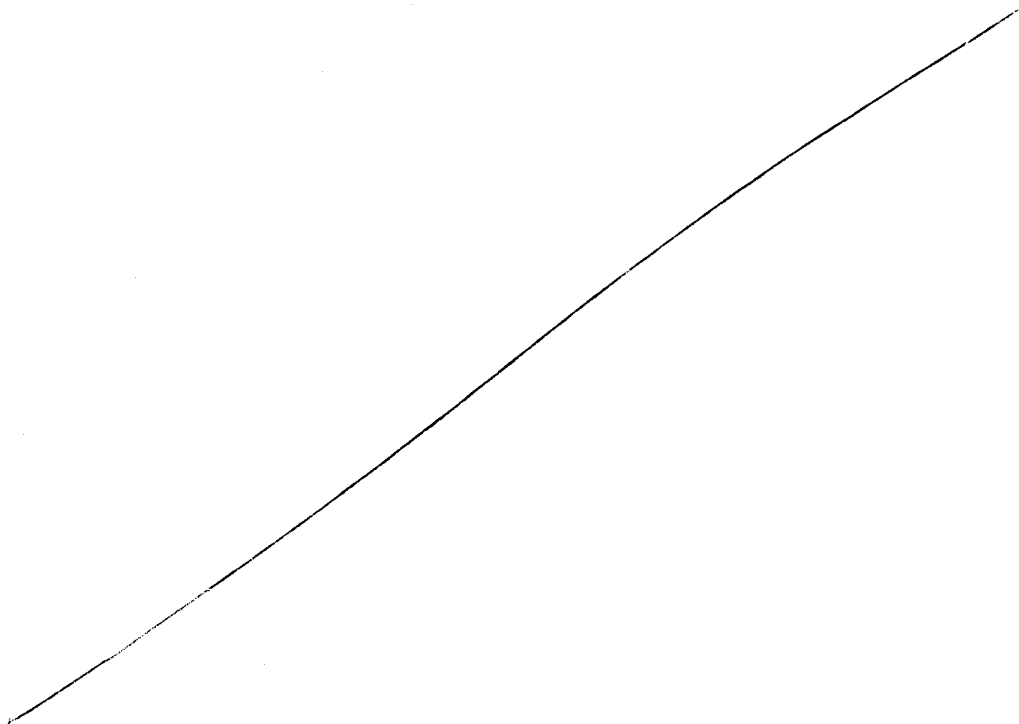
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

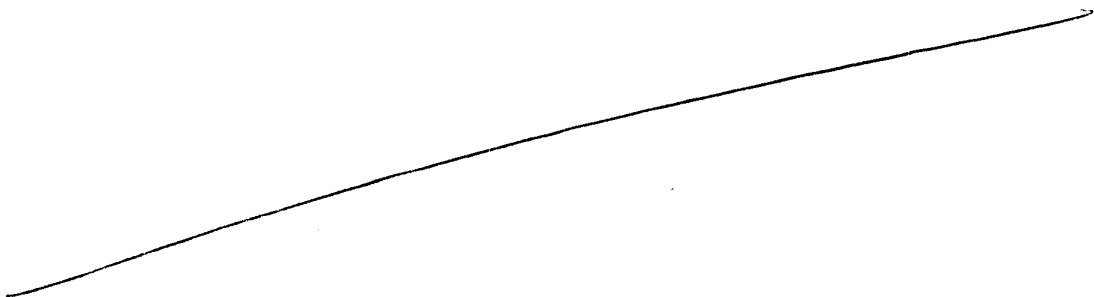
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

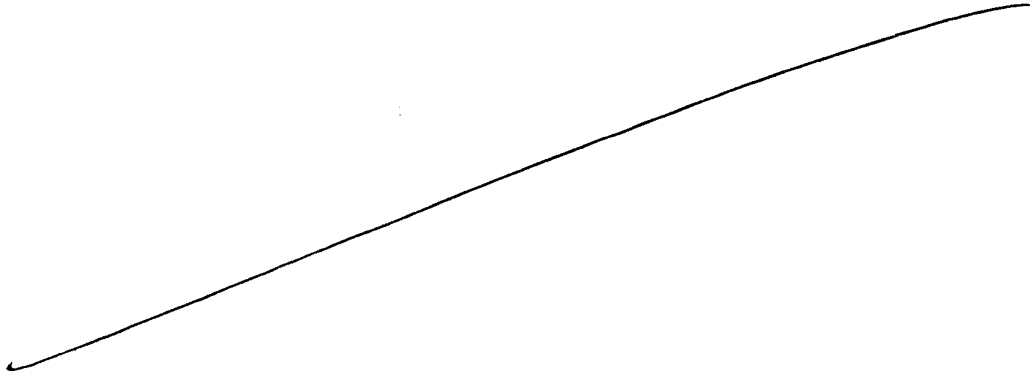
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

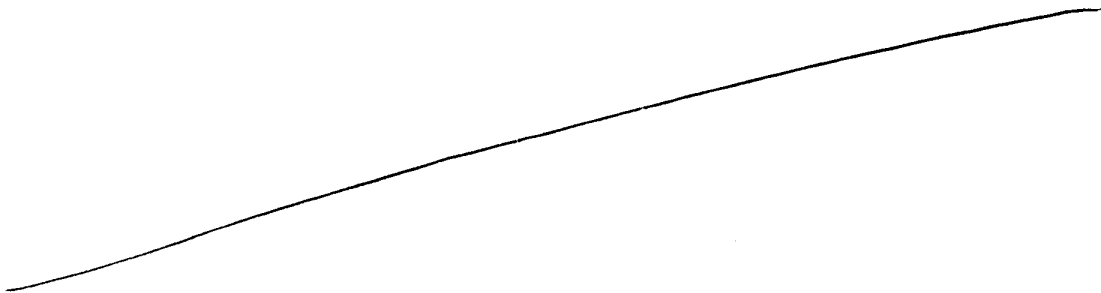


Section F. Chain-of-Custody, Accessioning, and Security

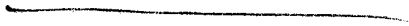




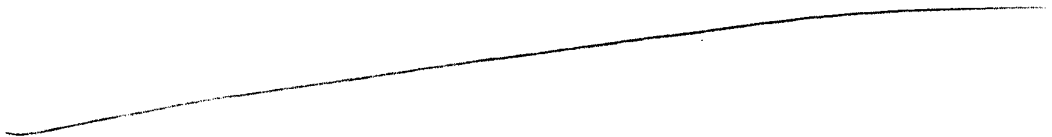
Section G. Quality Control



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



received
3/9/00 SDC

March 6, 2000

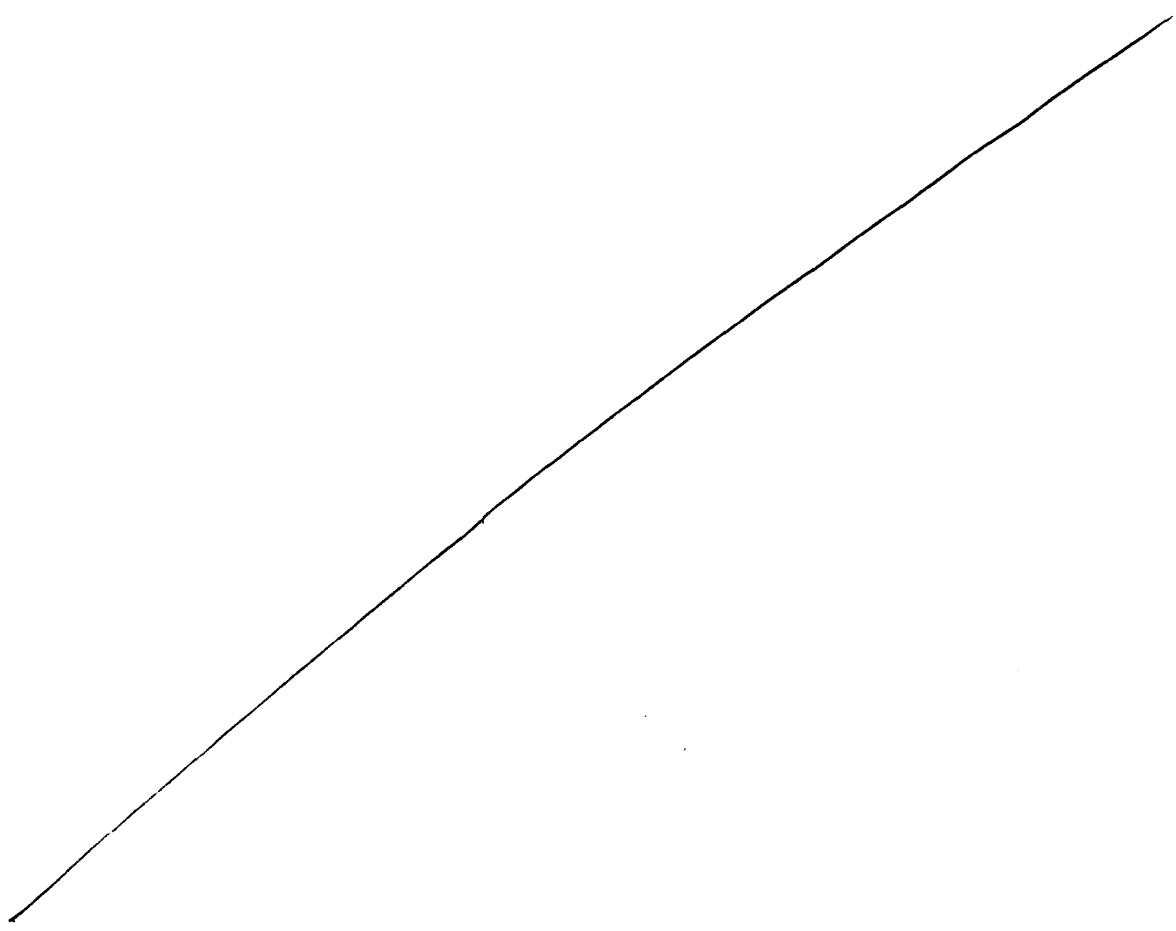
Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road, Box 12194
Research Triangle Park, NC 27709-2194

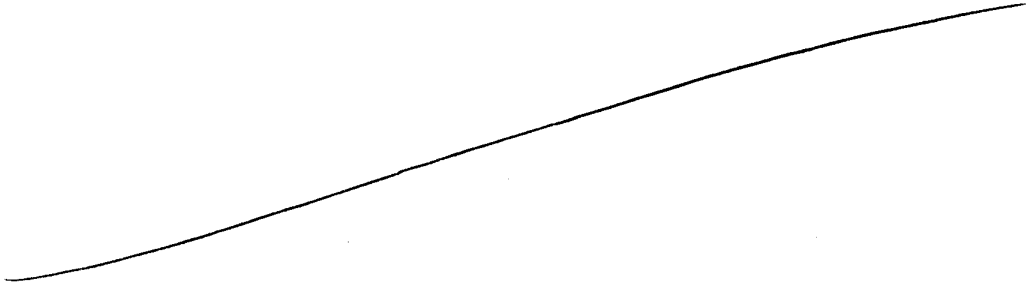
Dear Ms. Crumpton,

Thank you for your correspondence of 10 February 2000 and the critique contained therein. The following is ATN's response to the Document Review and Critique for our most recent maintenance inspection (16 December 1999).

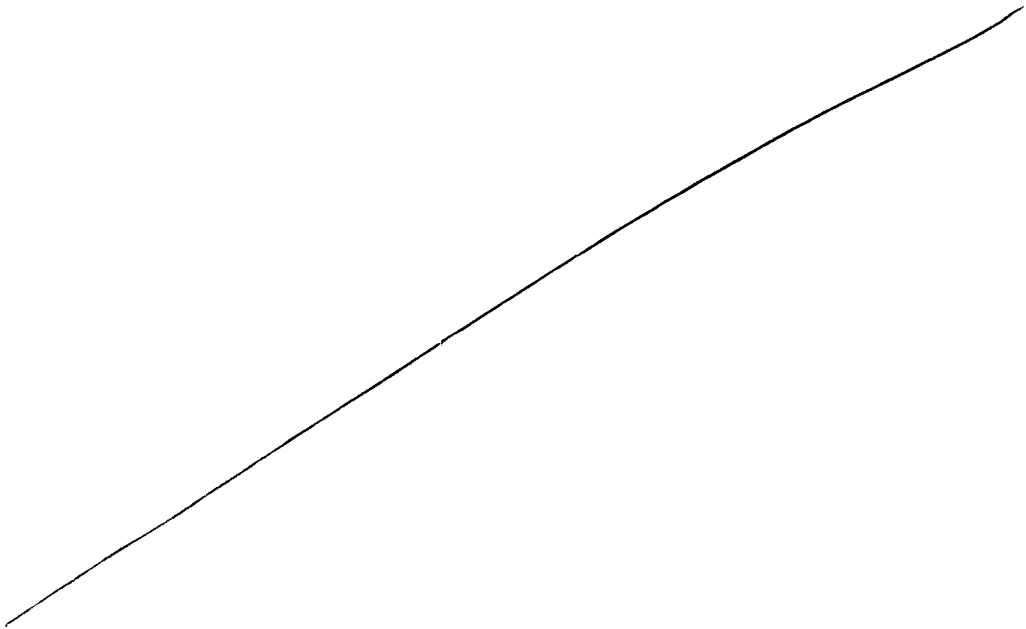
Section E

Item 2

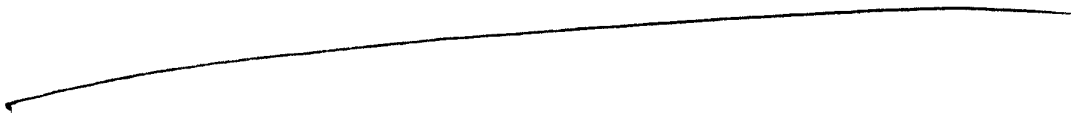


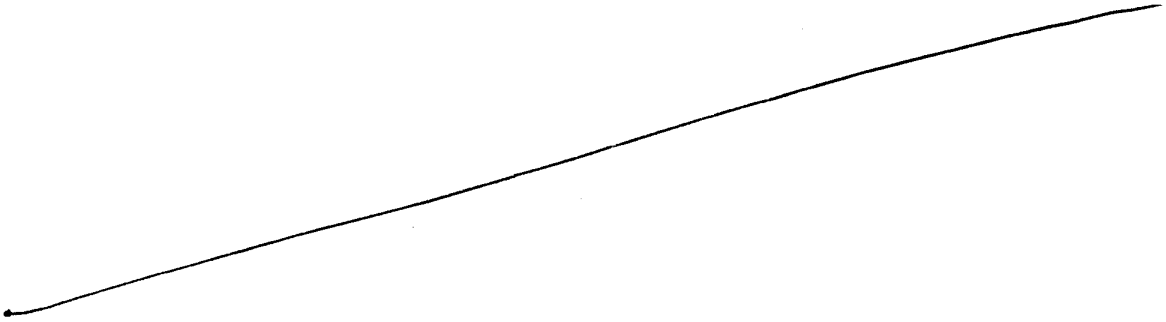


Section F

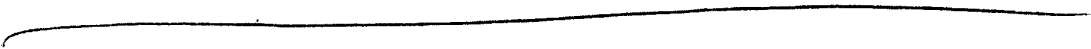


Section G

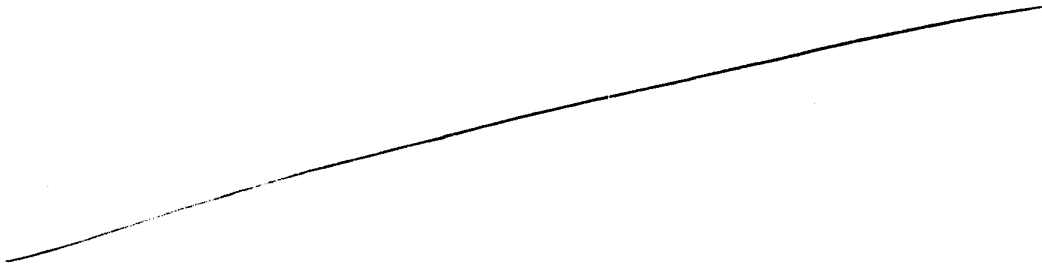




Section H



Section I



Section J



[Redacted]

[Redacted]

Section K

[Redacted]

Section N

[Redacted]

We look forward to your review of this response.

Sincerely,



Roger L. Rutter
Responsible Person
e-mail: Roger.Rutter@atnlabs.com

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 17, 2000

0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

We have reviewed the material provided in your correspondence of March 6, 2000, submitted in response to issues raised during the first maintenance inspection of your laboratory as outlined in our correspondence of February 10, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following issues were raised during our review of the laboratory's submission:



Mr. Rutter
Page 2 of 2
03/17/00

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 Technical Analyst

cc: Dr. Michael Baylor
Project Files/M1



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 22, 2000

0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

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

Mr. Rutter
August 22, 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/M2



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M2 Date: 22 June 2000
 Other _____

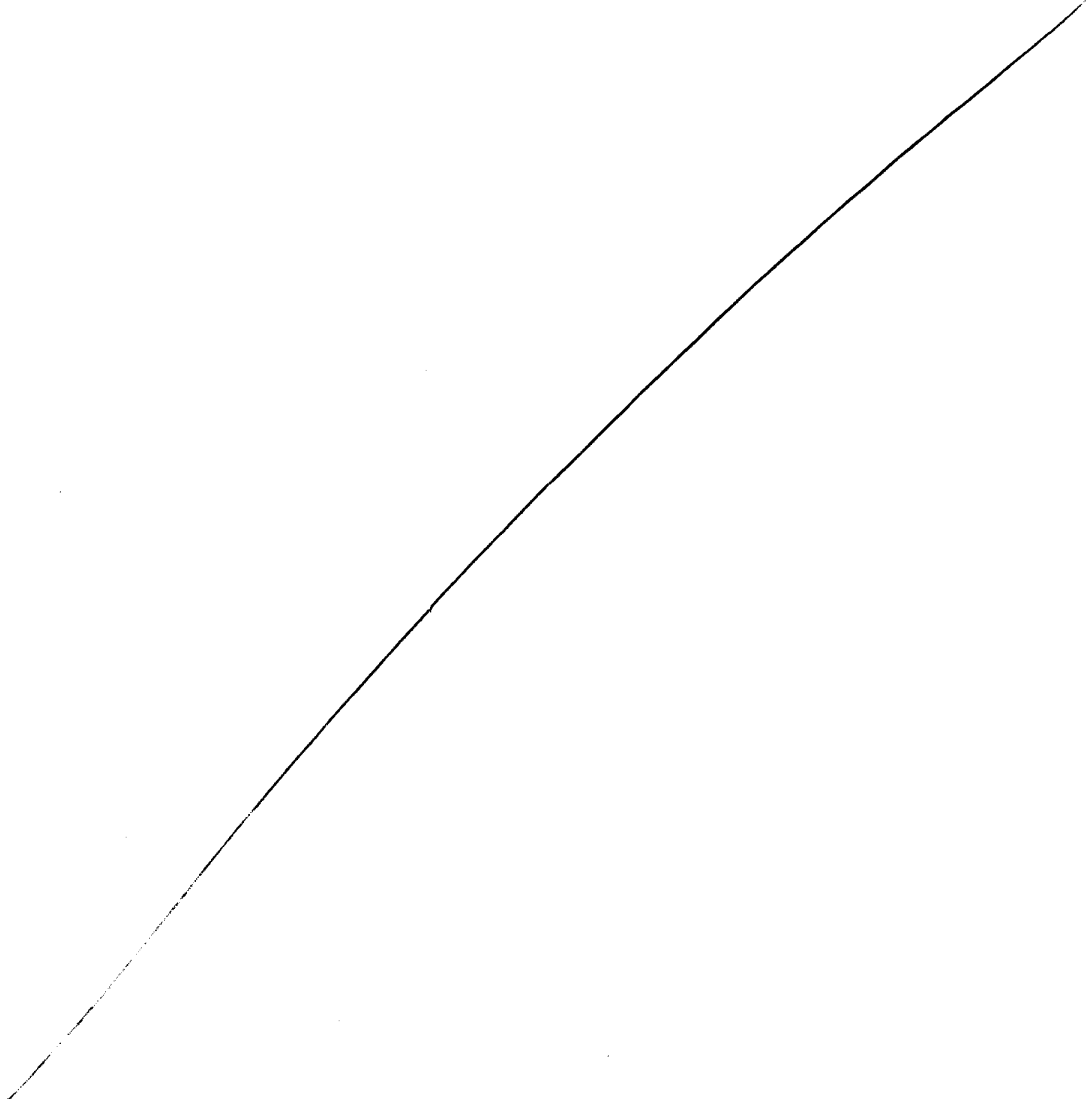
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

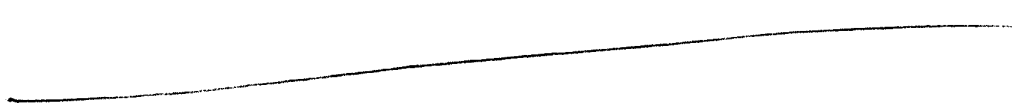
Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 16, 2001

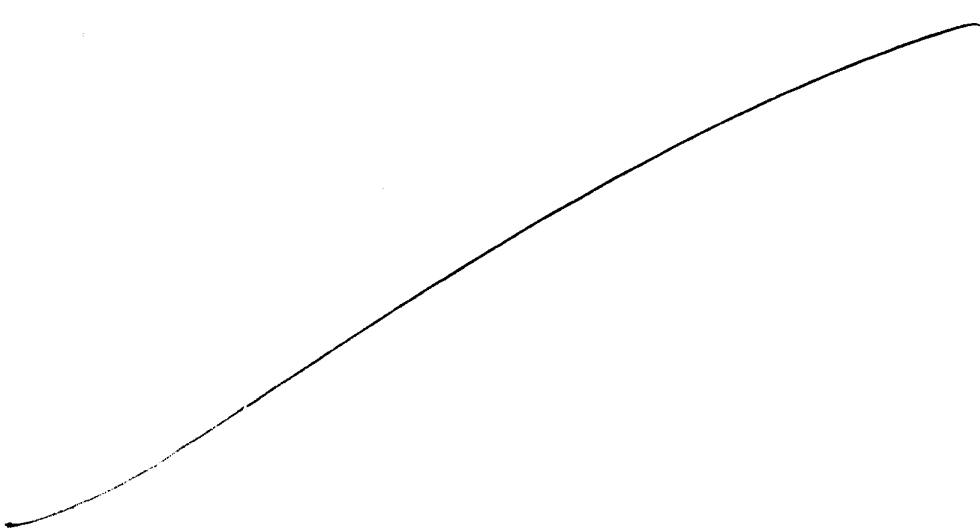
0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the third 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 appeared to meet most of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Mr. Rutter
Page 2 of 2
02/16/01



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/M3



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M3 Date: 14 December 2000
 Other _____


Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.


Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

The following deficiencies were identified, 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 and Quality Assurance



Section H. Initial Tests



Section I. Specimen Validity Tests



Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel