

February 5, 1999

0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratories  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventh 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 issues were raised:

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

[Redacted content]

J. Records Audit section

[Redacted content]

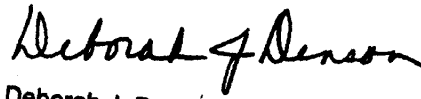
RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the 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. Johnson  
February 5, 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/M7  


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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0149  
Document No. Final

Laboratory: Metro-Lab Legacy Laboratories

Location: Portland, OR

Document Reviewed:  Application Form  
 Inspection Report #M7  
 Other \_\_\_\_\_

Date: 17 December 1998

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.

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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



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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



July 13, 1999

0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratories  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

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

G. The Quality Control section



J. The Records section



Mr. Johnson  
Page 2 of 2  
07/13/99

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

Sincerely,

*Susan Crumpton*  
Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M8

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0149  
Document No. Final

Laboratory: MetroLab-Legacy Laboratory Services

Location: Portland, OR

Document Reviewed:     Application Form  
                               Inspection Report #M8                    Date: 3 June 1999  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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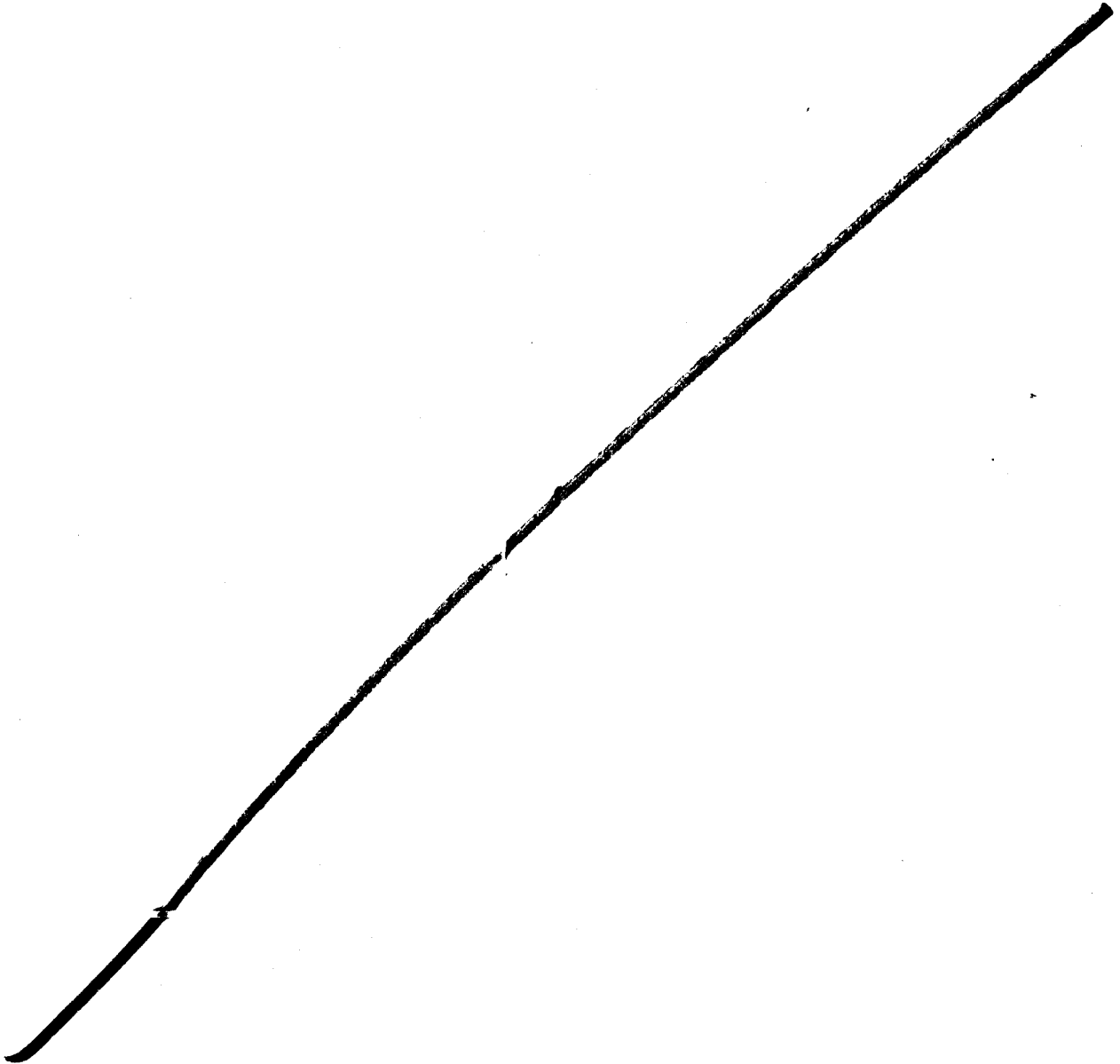
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]



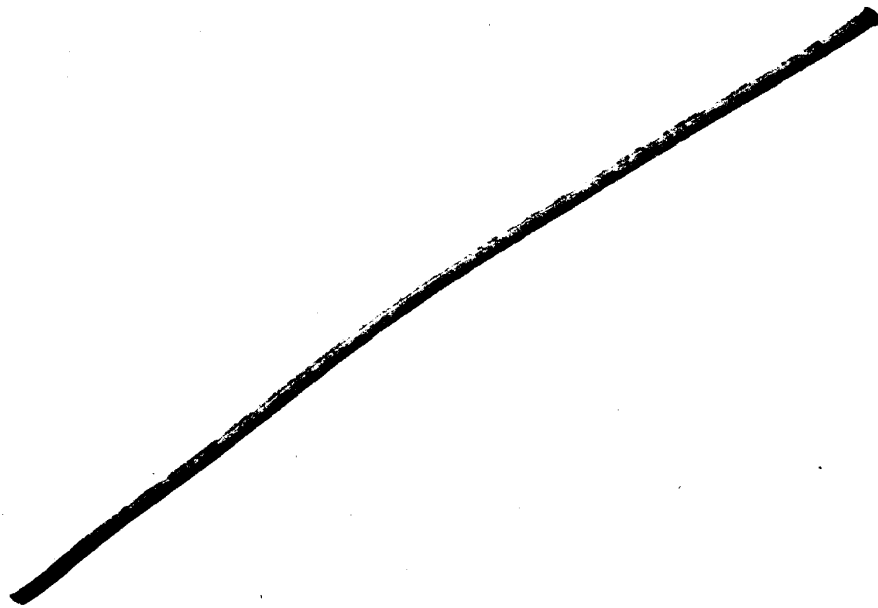
August 6, 1999

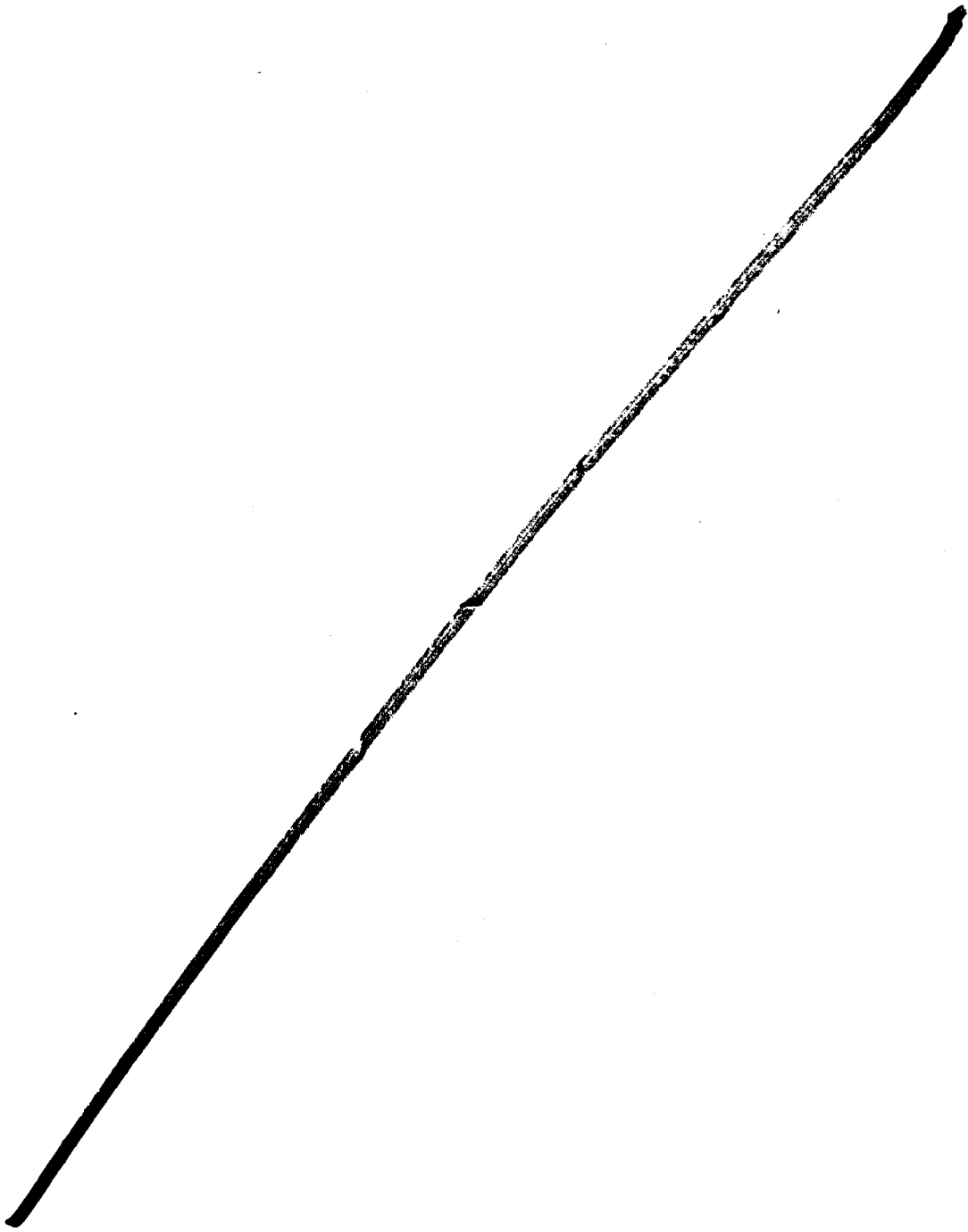
received  
8/17/99 SDC

Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

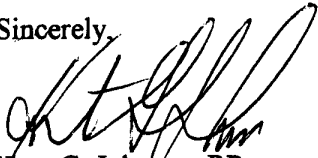
This letter and the enclosed documents are in response to our last maintenance inspection under the National Laboratory Certification Program this past June 1999. Changes in Standard Operating Procedures (SOP) that were not required to be submitted with our response will be noted as being corrected or changed, subject to review on our next maintenance inspection in December of this year.





We hope that all corrective actions indicated in this response letter and the supporting documentation will meet RTI's approval and show our resolve to correct all deficiencies that were noted. If there are any questions in regards to our response, please call me at (503) 413-2069.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kent G. Johnson', written over a horizontal line.

Kent G. Johnson, RP  
Forensic Toxicologist  
Metro Lab

Enclosure

cc. June 99 Inspection File

August 25, 1999

0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratories  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

We have reviewed the material provided in your correspondence of August 6, 1999, submitted in response to issues raised during the eighth maintenance inspection of your laboratory as outlined in our correspondence of July 13, 1999. 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. 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. (919) 541-7043.

Sincerely,



Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M8





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 17, 2000

0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratory Services  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

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

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



G. The Quality Control section





Mr. Johnson  
Page 2 of 2  
01/17/00

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

Sincerely,



Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M9

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0149  
Document No. Final

Laboratory: MetroLab-Legacy Laboratory Services

Location: Portland, OR

Document Reviewed:     Application Form  
                               Inspection Report #M9                      Date: 2 December 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



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]



February 15, 2000

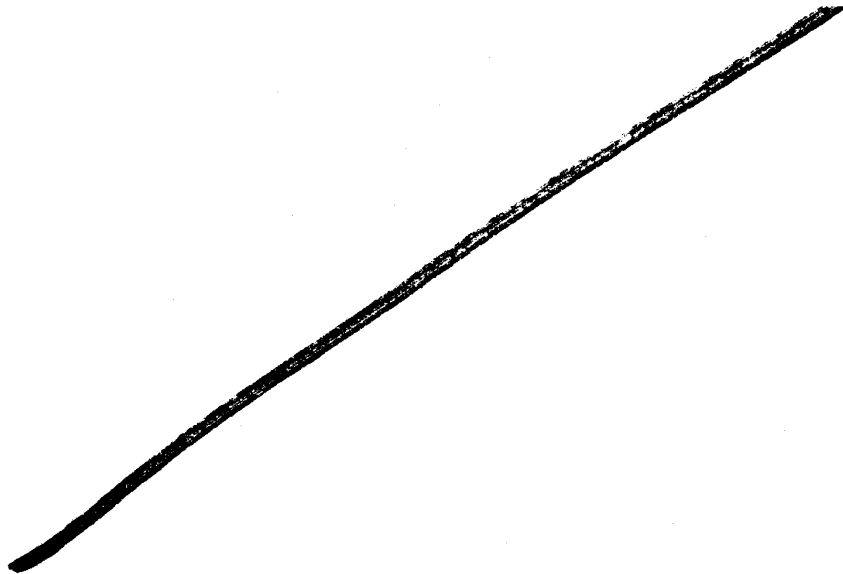
**received**  
2/16/00 SDK

Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter and the enclosed documents are in response to our last maintenance inspection under the National Laboratory Certification Program this past Dec. 1999. Changes in Standard Operating Procedures (SOP) that were not required to be submitted with our response will be noted as being corrected or changed, subject to review on our next maintenance inspection in December of this year.

F Chain-of-Custody, Accessioning, and Security issues are as follows:



G. The Quality Control Sections issue:

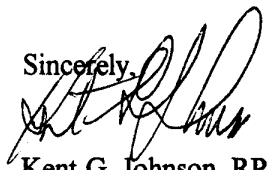
[Redacted content]

N. The Personnel section issues are as follow:

[Redacted content]

We hope that all corrective actions indicated in this response letter and the supporting documentation would meet RTI's approval and show our resolve to correct all deficiencies that were noted. If there are any questions in regards to our response, please call me at (503) 413-2069.

Sincerely,



Kent G. Johnson, RP  
Forensic Toxicologist  
Metro Lab

Enclosure

cc. Dec 99 Inspection File

August 9, 2000

0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratory Services  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

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

E. The Standard Operating Procedures (SOP) section

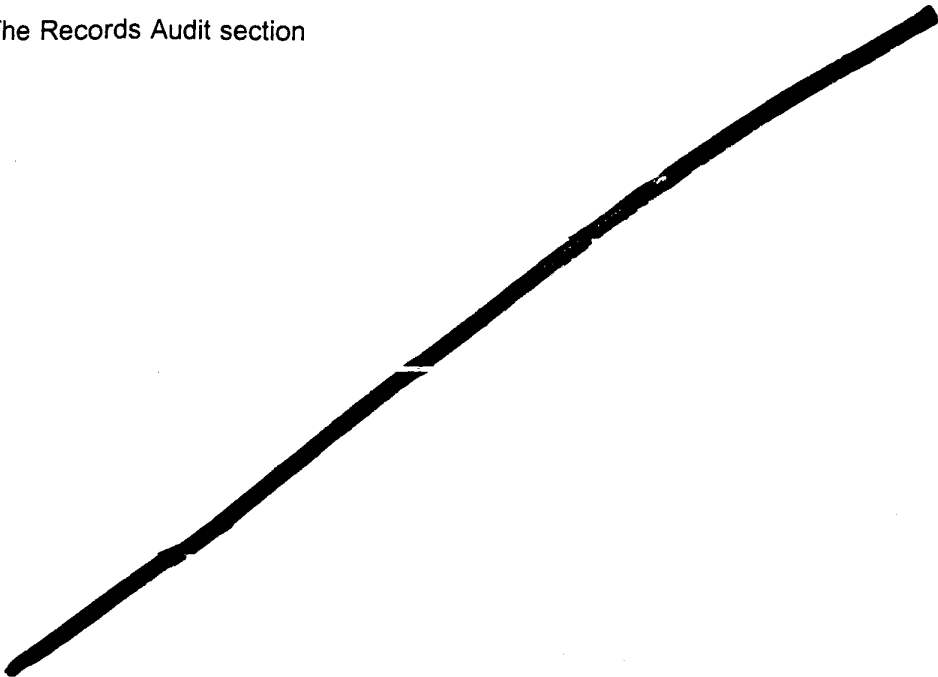


F. The Chain of Custody, Accessioning, and Security section



A thick, black, slightly curved horizontal line redacting a line of text.

G. The Records Audit section

A thick, black, curved line redacting a line of text.

H. The Initial Tests section

A thick, black, slightly curved horizontal line redacting a line of text.

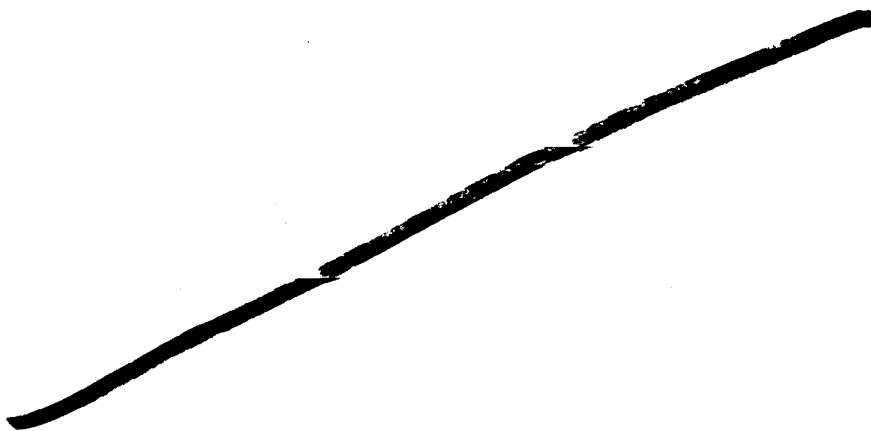
I. The Confirmatory Tests section

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J. The Records Audit section

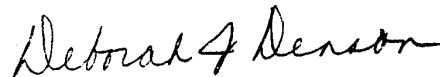


Mr. Johnson  
August 9, 2000  
Page 4 of 4

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 R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

Enclosure  
cc: Project Files/M10



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**NATIONAL LABORATORY CERTIFICATION PROGRAM**

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**Document Review and Critique**

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Laboratory I.D. Number: 0149  
Document No. Final

Laboratory: MetroLab-Legacy Laboratory Services

Location: Portland, OR

Document Reviewed:     Application Form  
                               Inspection Report #M10                    Date: 8 June 2000  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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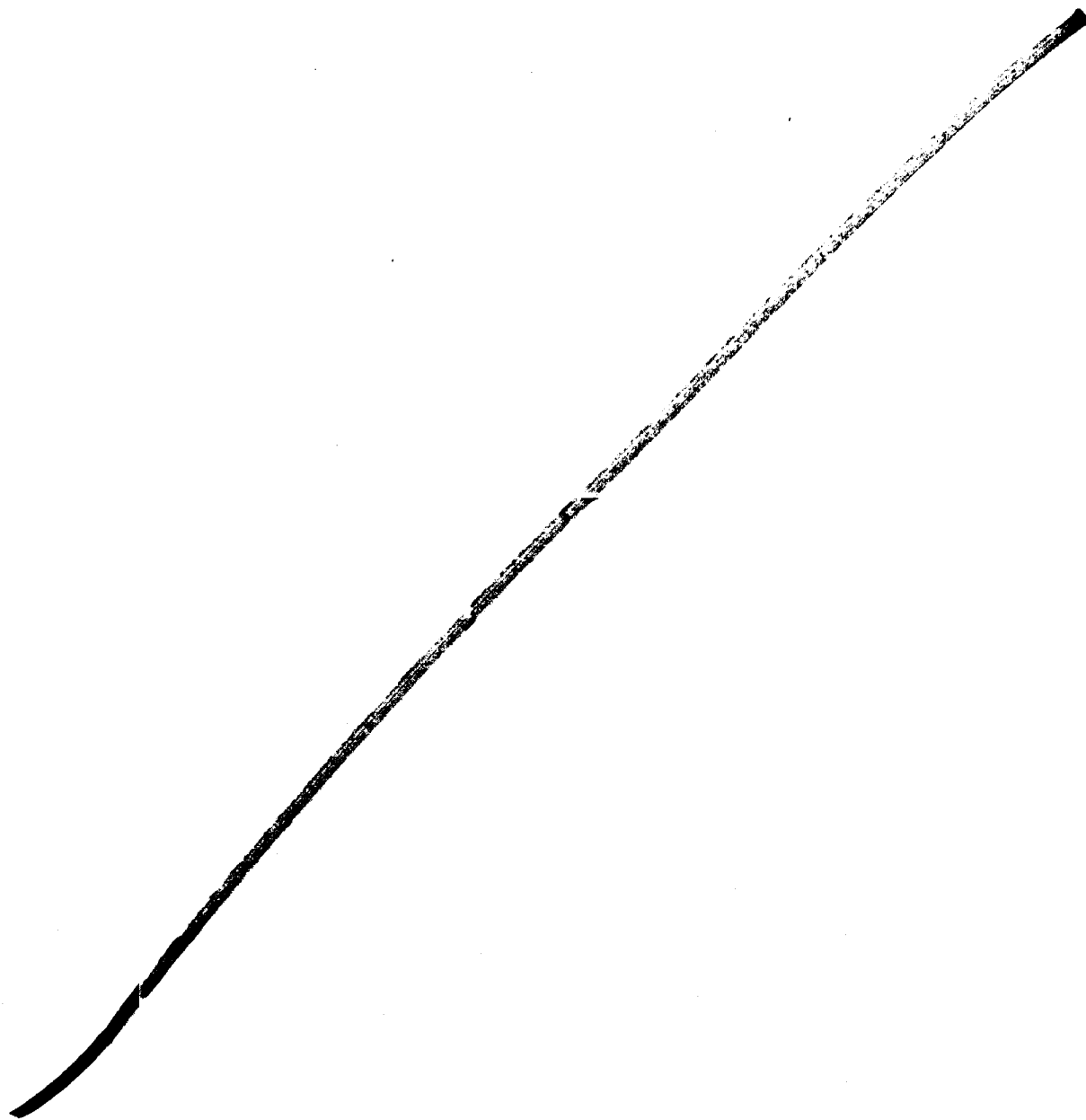
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

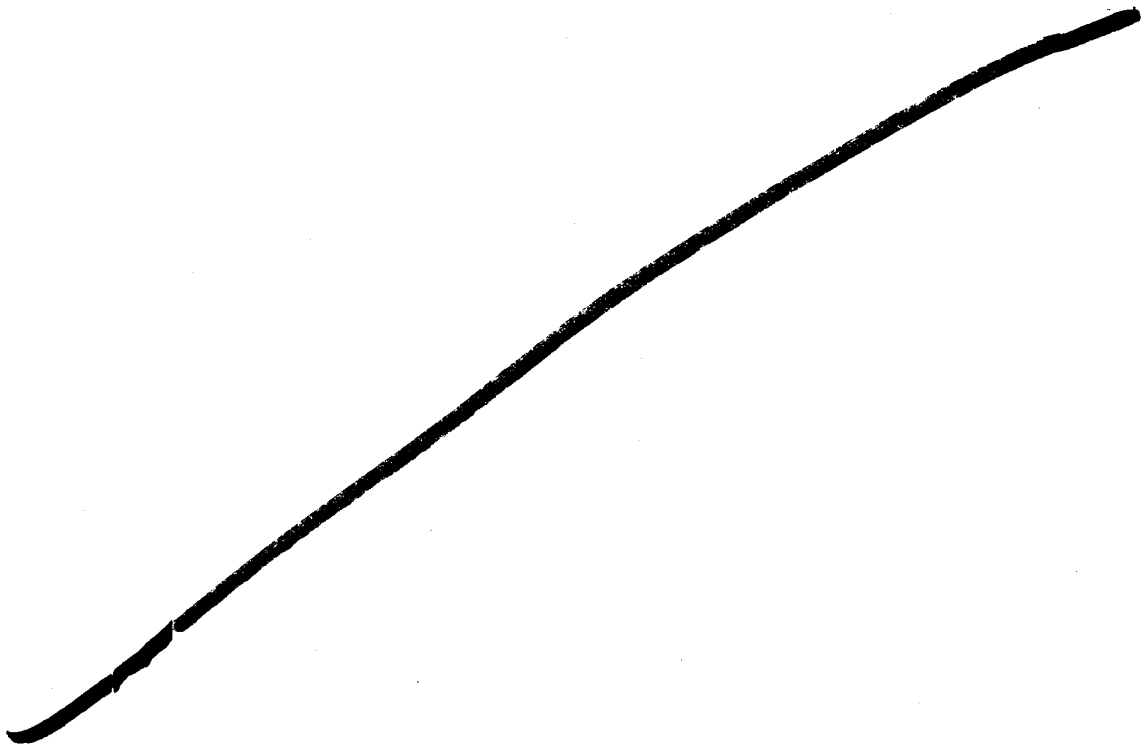
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





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



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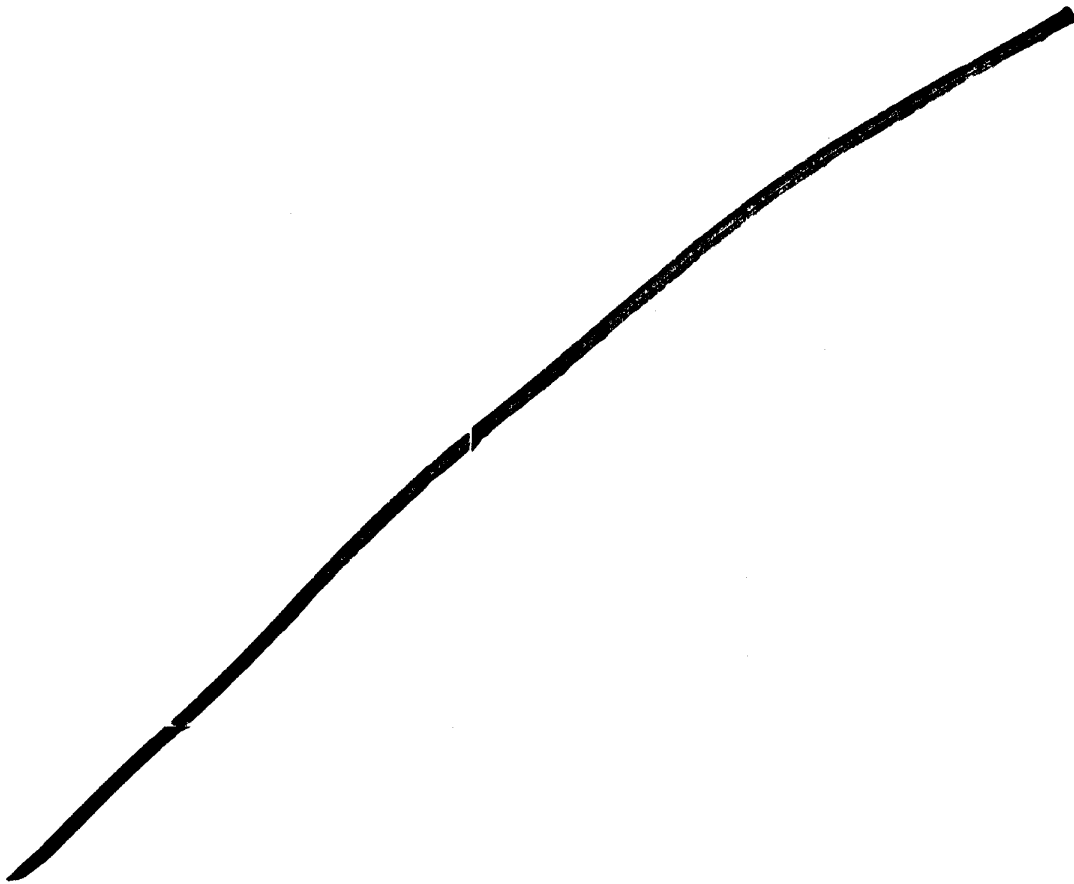
Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests



Section J. Records Audit



Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]





**received**  
9/29/00 DJ

September 26, 2000

Deborah J. Denson  
NLCP Technical Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

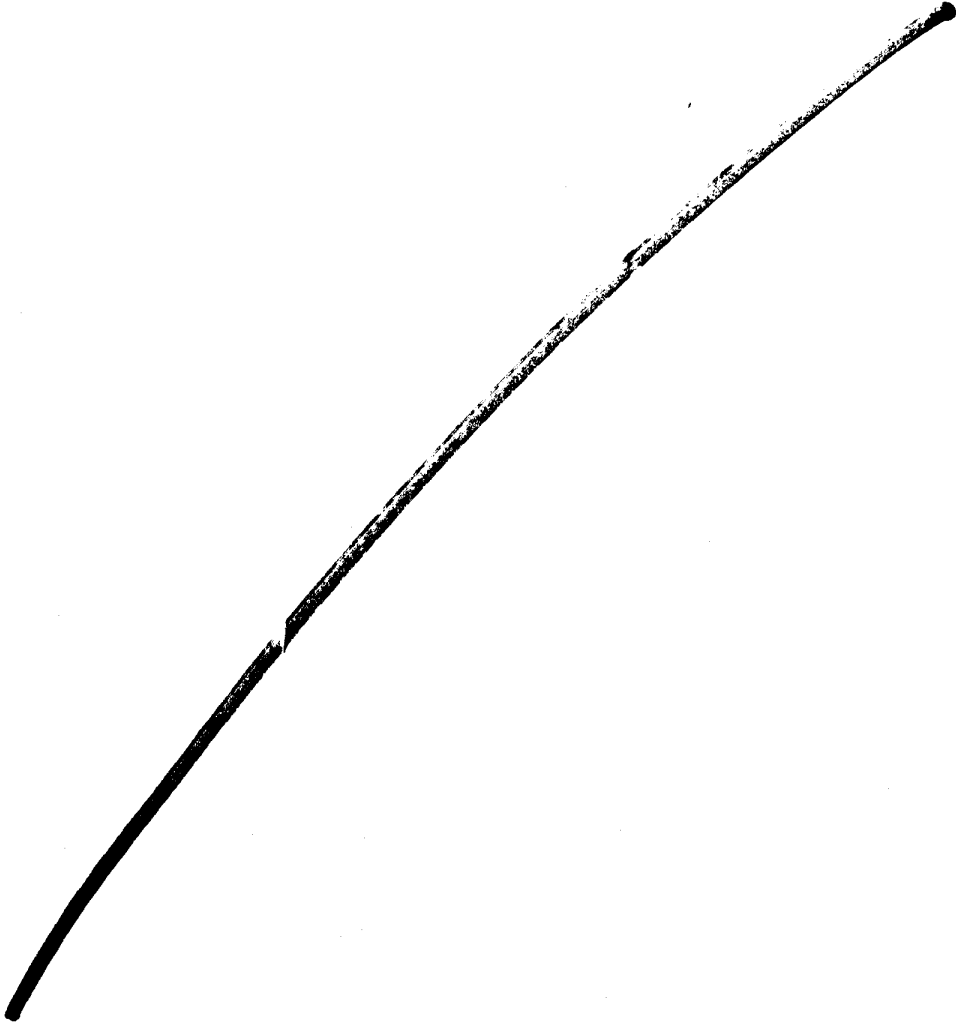
Dear Ms. Denson:

This letter and the enclosed documents are in response to our last maintenance inspection under the National Laboratory Certification Program this past June 2000. Changes in Standard Operating Procedures (SOP) that were not required to be submitted with our response will be noted as being corrected or changed, subject to review on our next maintenance inspection in December of this year.

**E. The Standard Operating Procedures:**

**F. Chain of Custody, Accessioning and Security Section:**

**G. Records Audit:**



**H. The initial test section:**

[Redacted content]

**I. The confirmatory test section:**

[Redacted content]

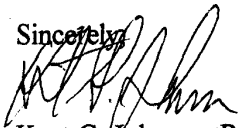
**J. The Records Audit:**

[Redacted content]

**J. The Records Audit:**

We hope that all corrective actions indicated in this response letter and the supporting documentation would meet RTI's approval and show our resolve to correct all deficiencies that were noted. If there are any questions in regards to our response, please call me at (503) 413-2069.

Sincerely,



Kent G. Johnson, RP  
Forensic Toxicologist  
Metro Lab

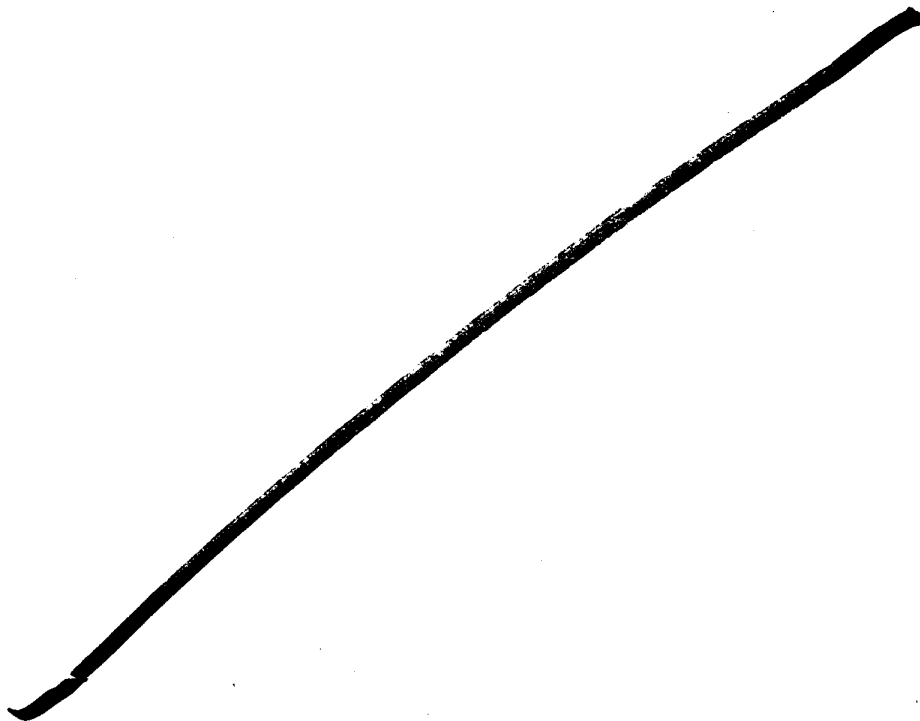
Enclosure

October 17, 2000

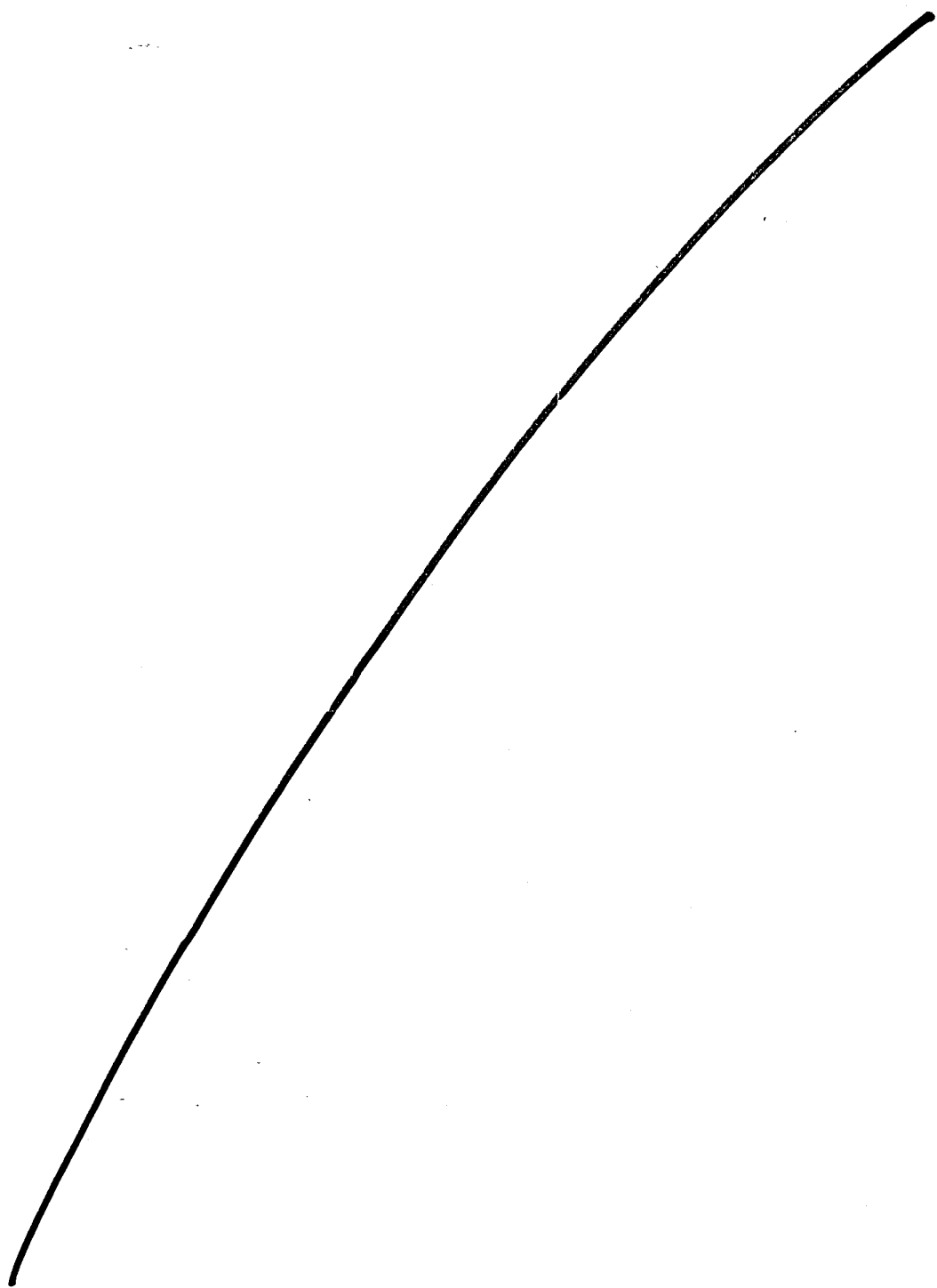
0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratory Services  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

We have reviewed the material provided in your correspondence of September 26, 2000 submitted in response to issues raised during the tenth maintenance inspection of your laboratory as outlined in our correspondence of August 09, 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:




Mr. Johnson  
October 17, 2000  
Page 2 of 3



001

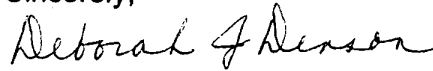
Mr. Johnson  
October 17, 2000  
Page 3 of 3



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) 541-7265 or Michael R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M10

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0149  
Document No. Final

Laboratory: MetroLab-Legacy Laboratory Services

Location: Portland, OR

Document Reviewed:      Application Form  
                               Inspection Report #M11             Date: 7 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

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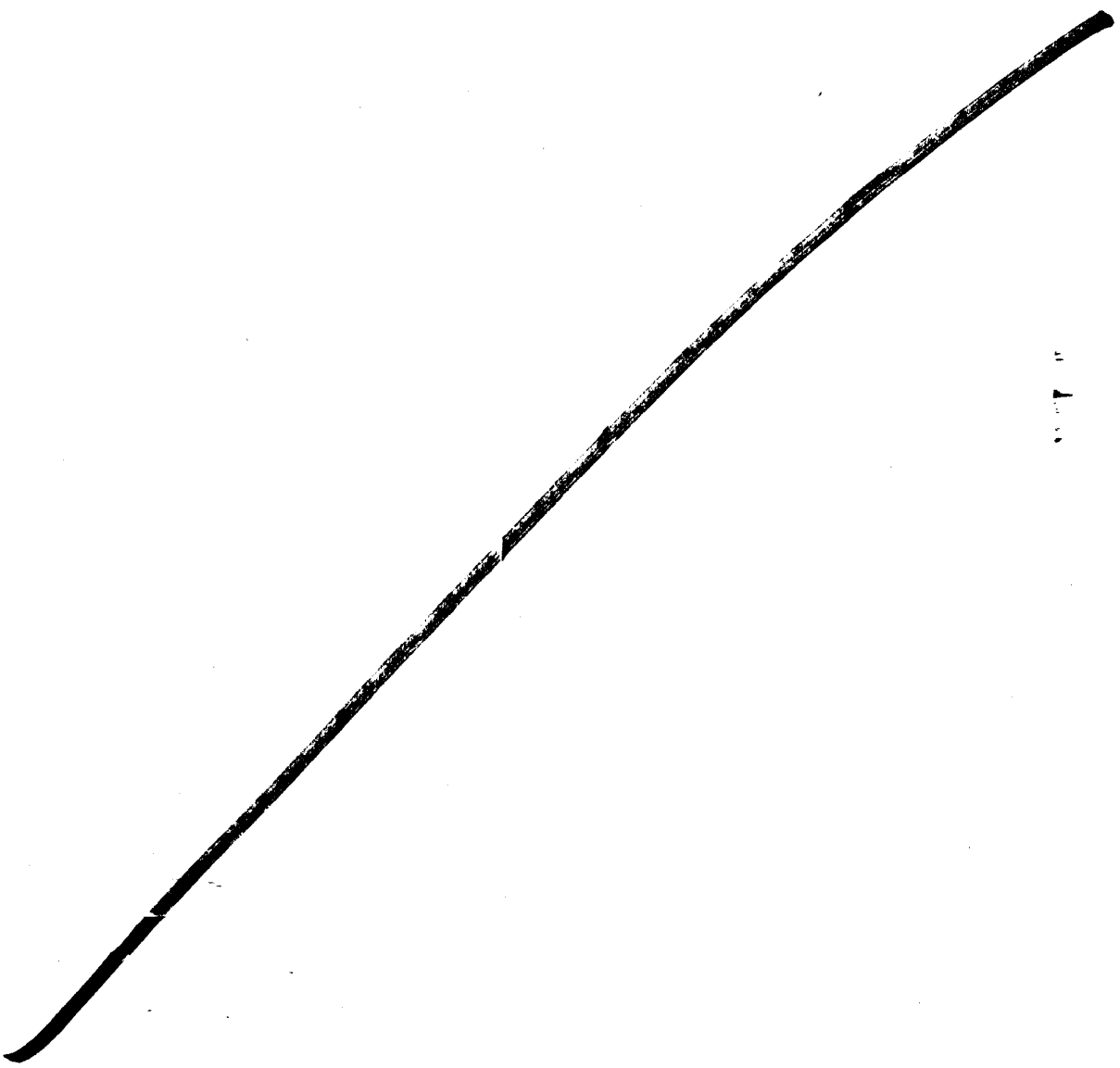
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet a number of the minimum technical criteria required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

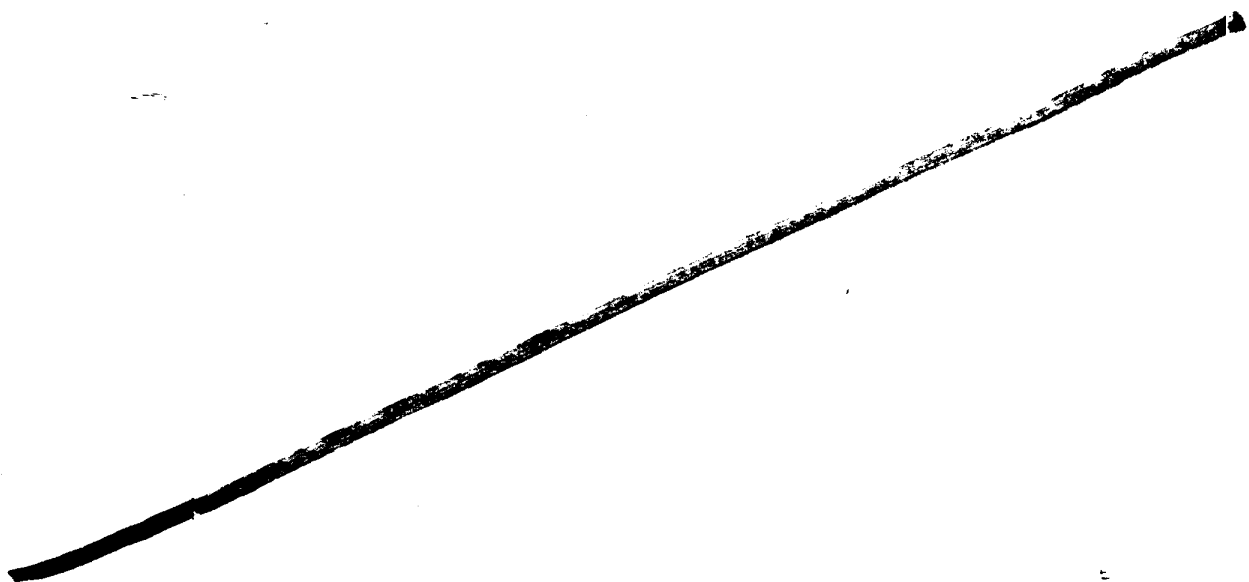
Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before the next inspection.



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



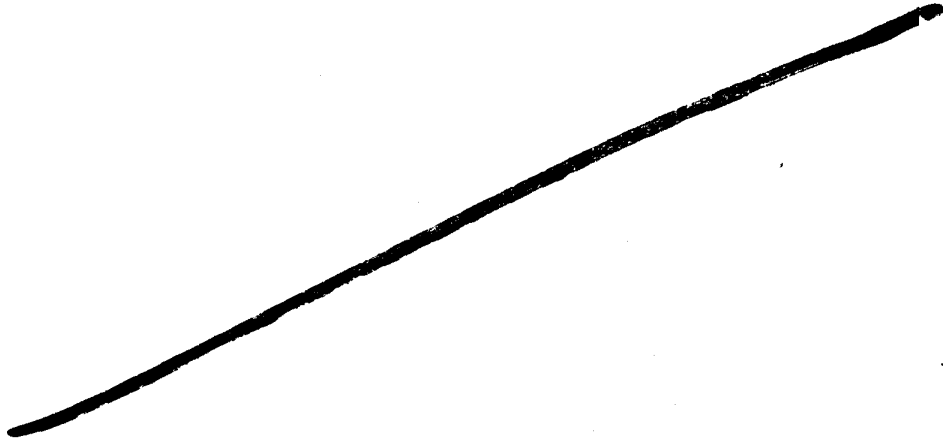
Section L. Certification and Reporting



Section M. Laboratory Information Management System (LIMS)



Section N. Personnel



RESEARCH TRIANGLE INSTITUTE



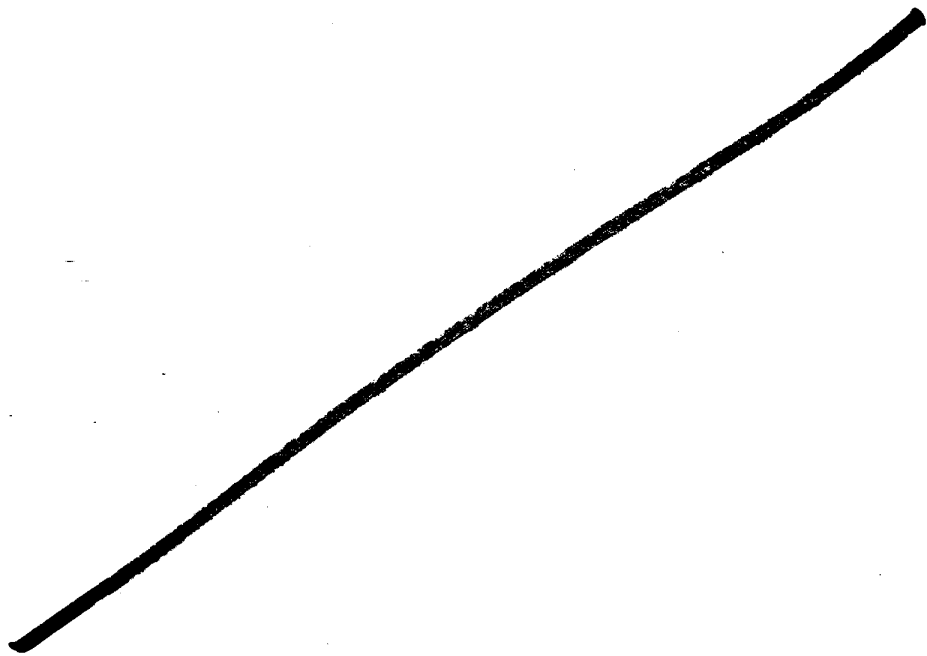
National Laboratory Certification Program

January 29, 2001

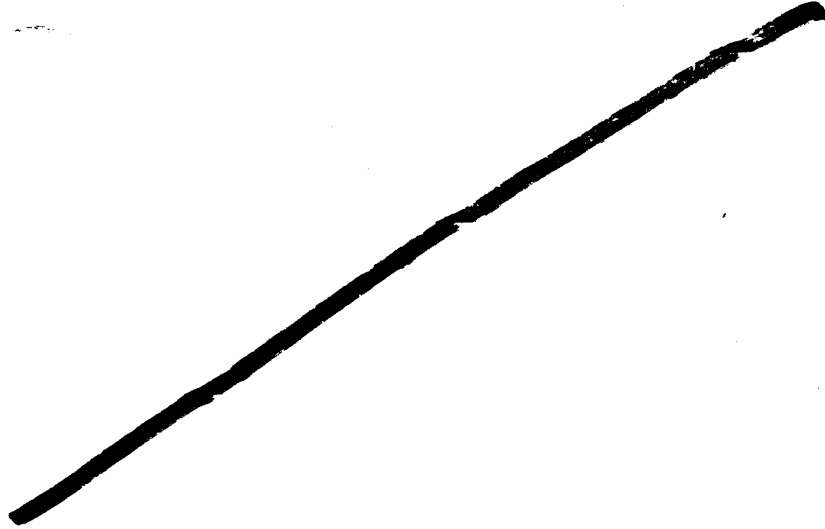
0149  
Mr. Kent G. Johnson  
MetroLab-Legacy Laboratory Services  
1225 NE 2nd Avenue  
Portland, OR 97232

Dear Mr. Johnson:

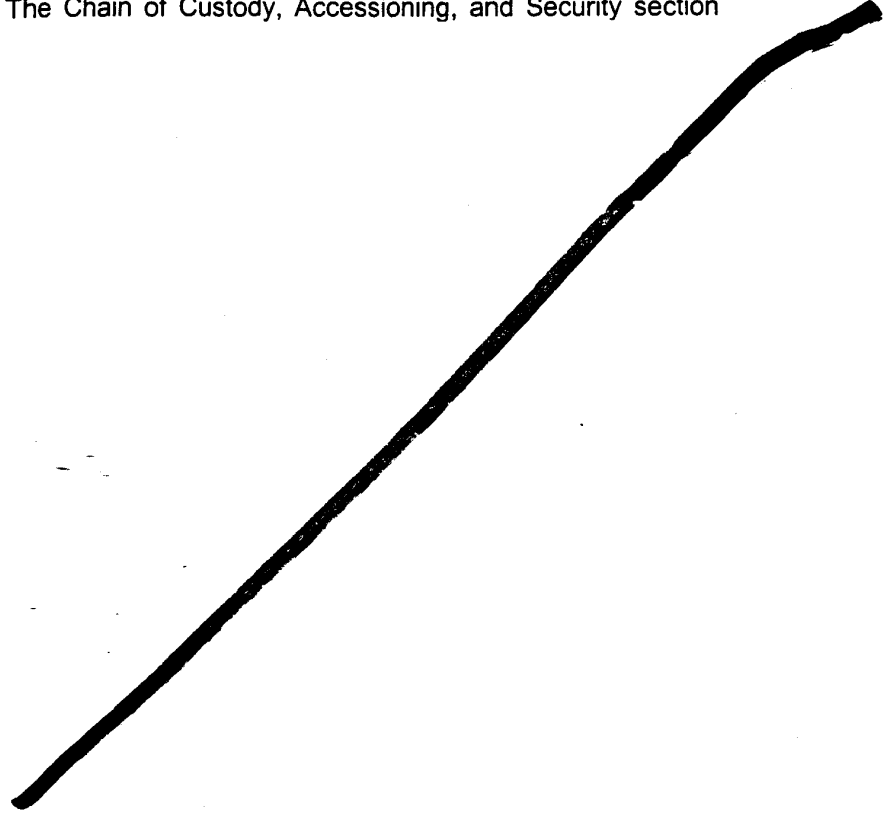
The enclosed critique was developed from the inspection reports of the inspectors who conducted the eleventh maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet a number of the minimum technical criteria. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:



Mr. Johnson  
Page 2 of 5  
01/29/01



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



Mr. Johnson  
Page 3 of 5  
01/29/01

[REDACTED]

G. The Quality Control and Quality Assurance section

[REDACTED]

H. The Initial Tests section

[REDACTED]

N. The Personnel section

[REDACTED]

Mr. Johnson  
Page 4 of 5  
01/29/01



11



Mr. Johnson  
Page 5 of 5  
01/29/01

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

Sincerely,



Susan Crumpton  
NLCP Technical Analyst

Enclosure

cc: Project Files/149

