



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

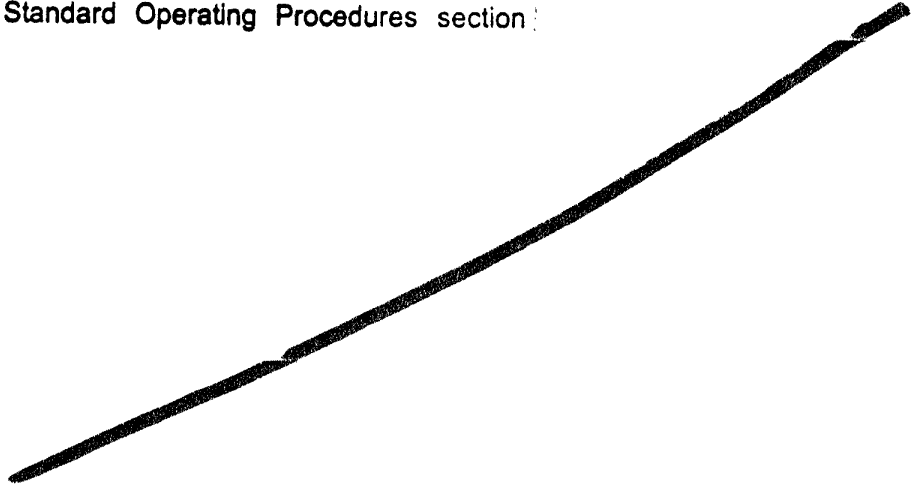
March 31, 1999

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

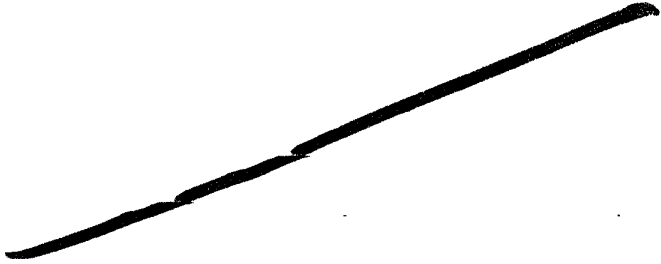
Dear Dr. Collins:

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



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

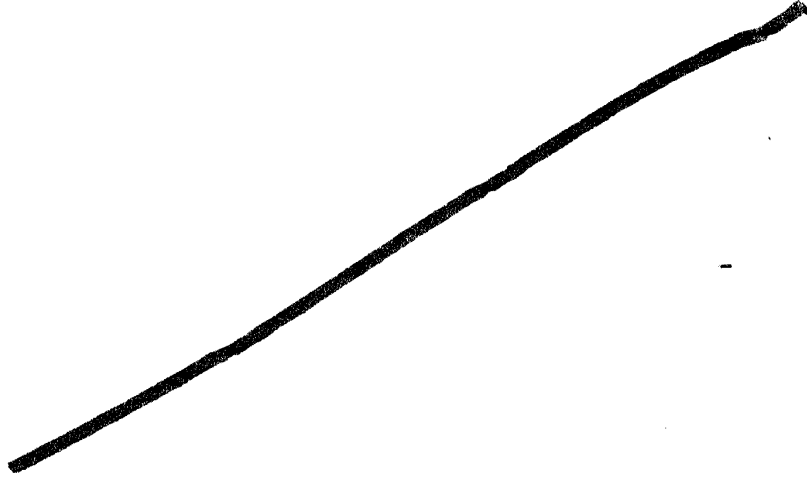


Dr. Collins
March 31, 1999
Page 2 of 5

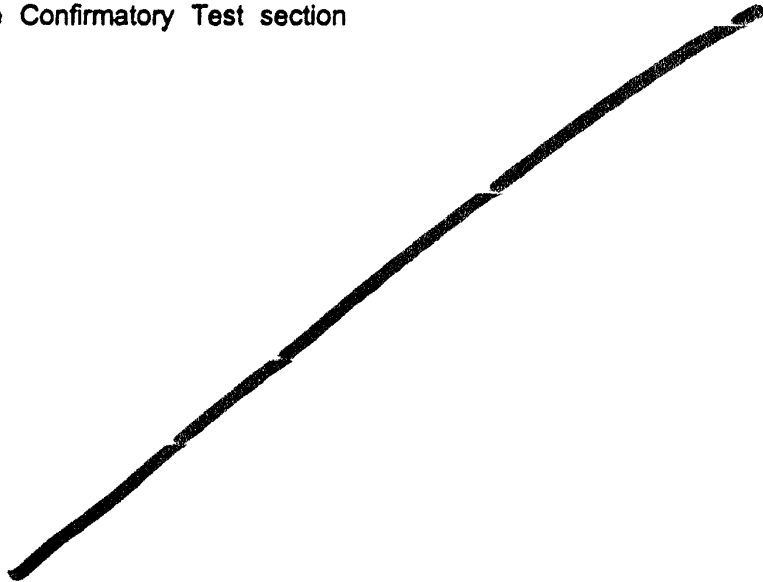
G. The Quality Control section

H. The Initial Test section

Dr. Collins
March 31, 1999
Page 3 of 5



I. The Confirmatory Test section



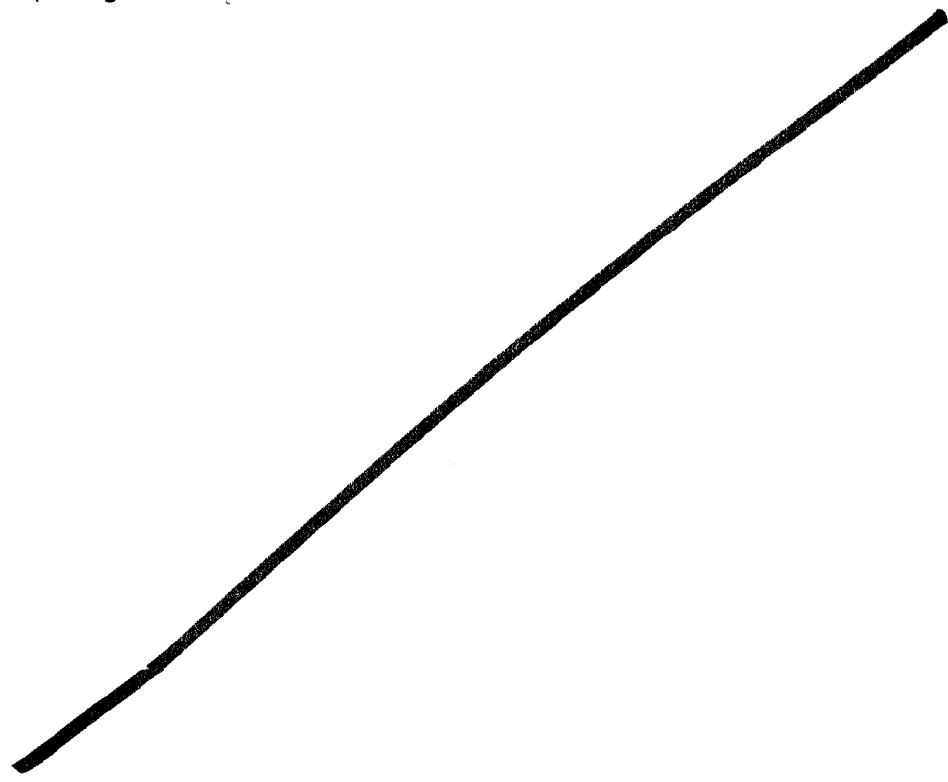
J. The Records Audit section



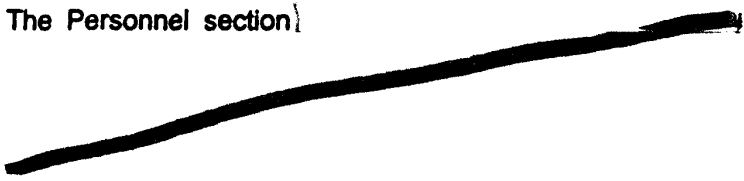
Dr. Collins
March 31, 1999
Page 4 of 5

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K. The Reporting section

A large, thick black diagonal line redacting a significant portion of the page's content.

N. The Personnel section

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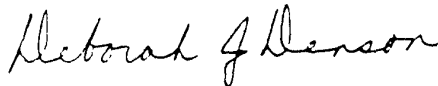
Dr. Collins
March 31, 1999
Page 5 of 5



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/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0094
Document No. Final

Laboratory: MedTox Laboratories, Inc.

Location: St. Paul, MN

Document Reviewed: Application Form
 Inspection Report #M18 Date: 25 February 1999
 Other _____

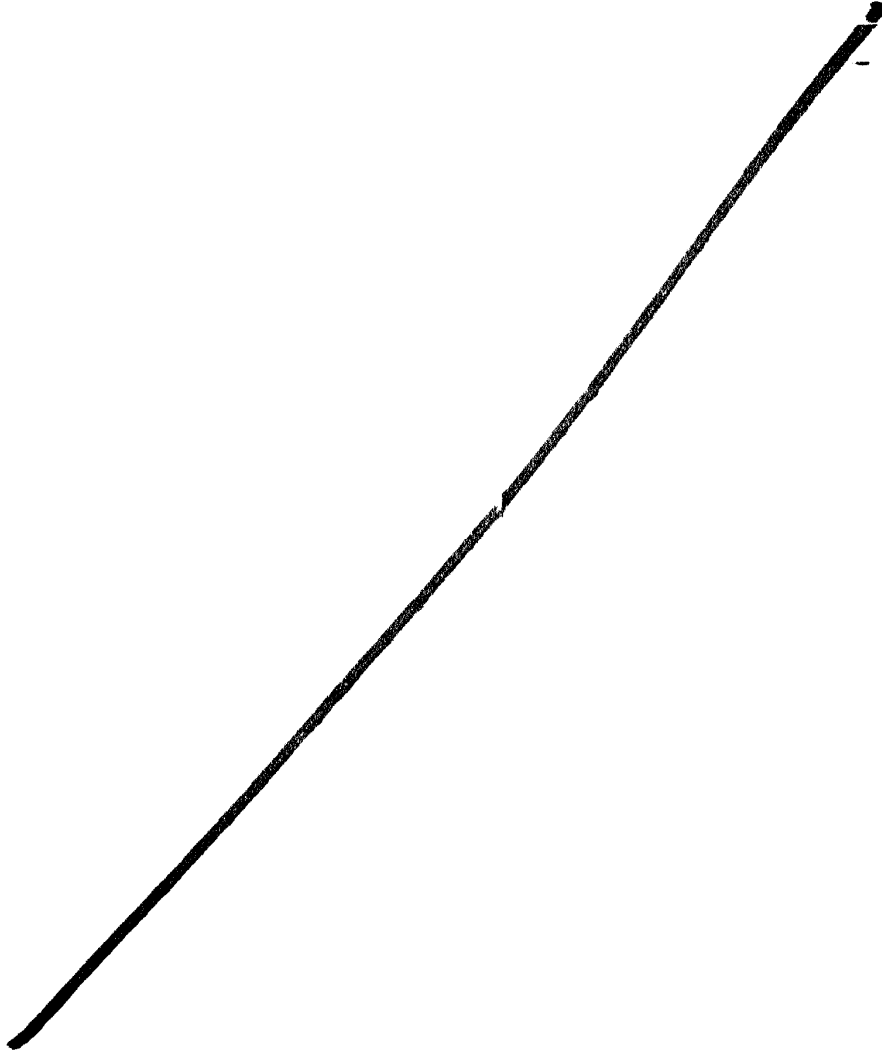
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

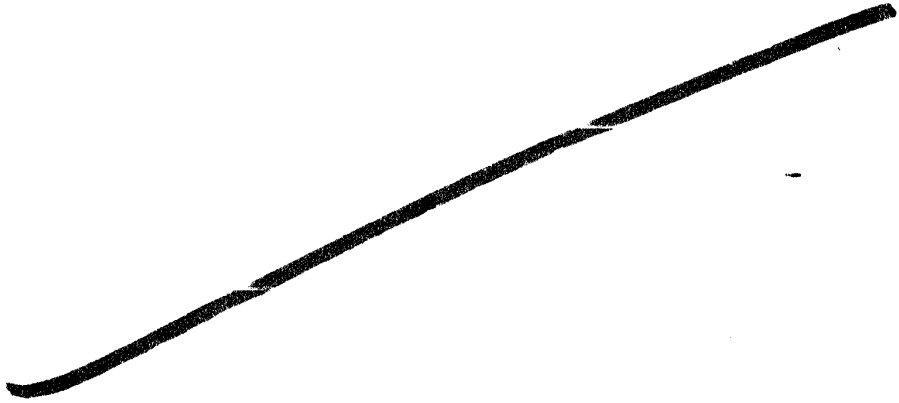
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



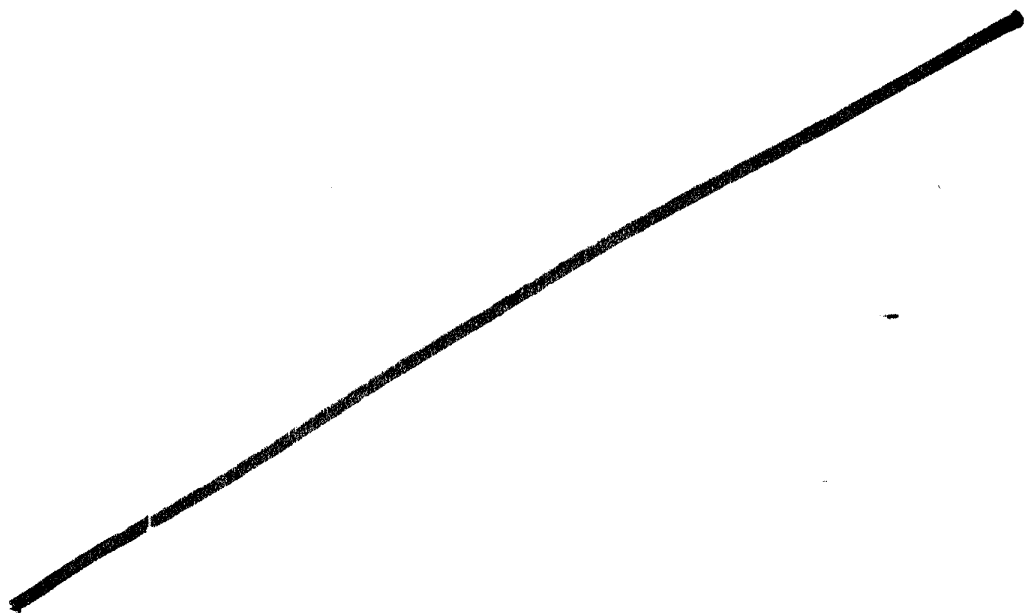
Section G. Quality Control



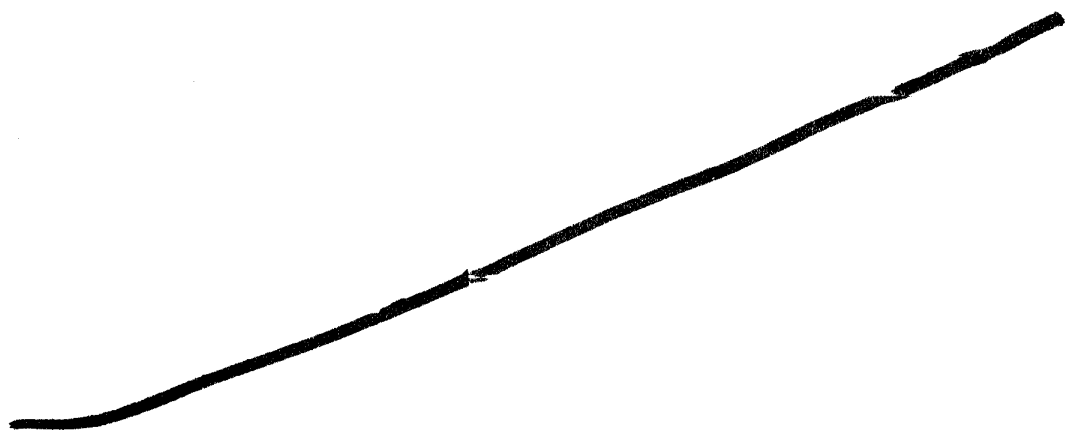
Section H. Initial Tests



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



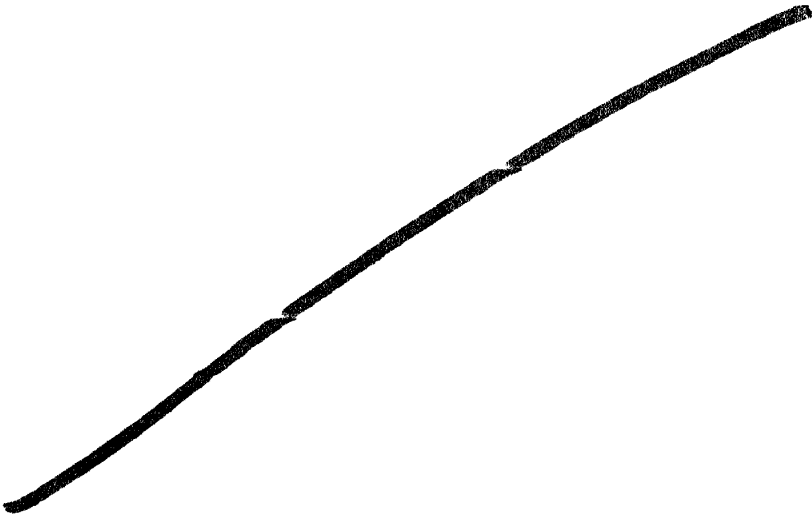
May 6, 1999

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


Dear Ms. Denson:

Enclosed is our response to the critique of our eighteenth maintenance inspection under the National Laboratory Certification Program (NLCP). The response is organized according to the items listed in your correspondence of March 31, 1999.

E. Standard Operating Procedures

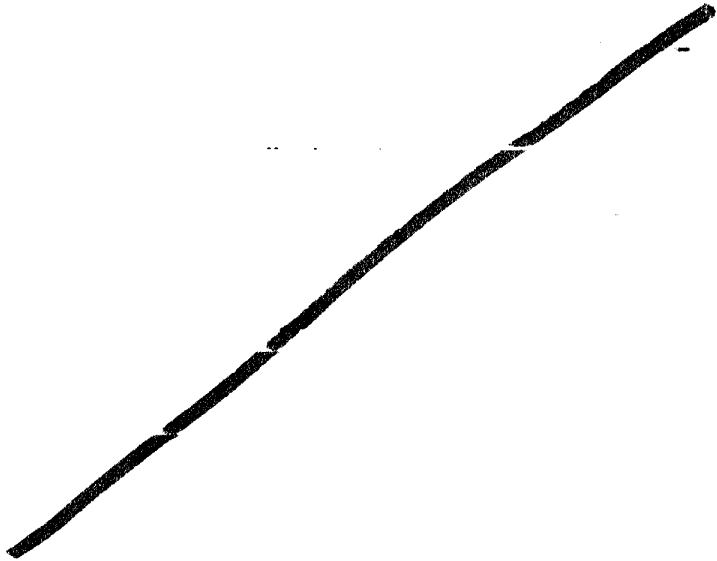


F. Chain of Custody, Accessioning and Security






G. Quality Control



H. Initial Tests




I. Confirmatory Tests




J. Records Audit



K. Reporting



N. Personnel





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 25, 1999

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

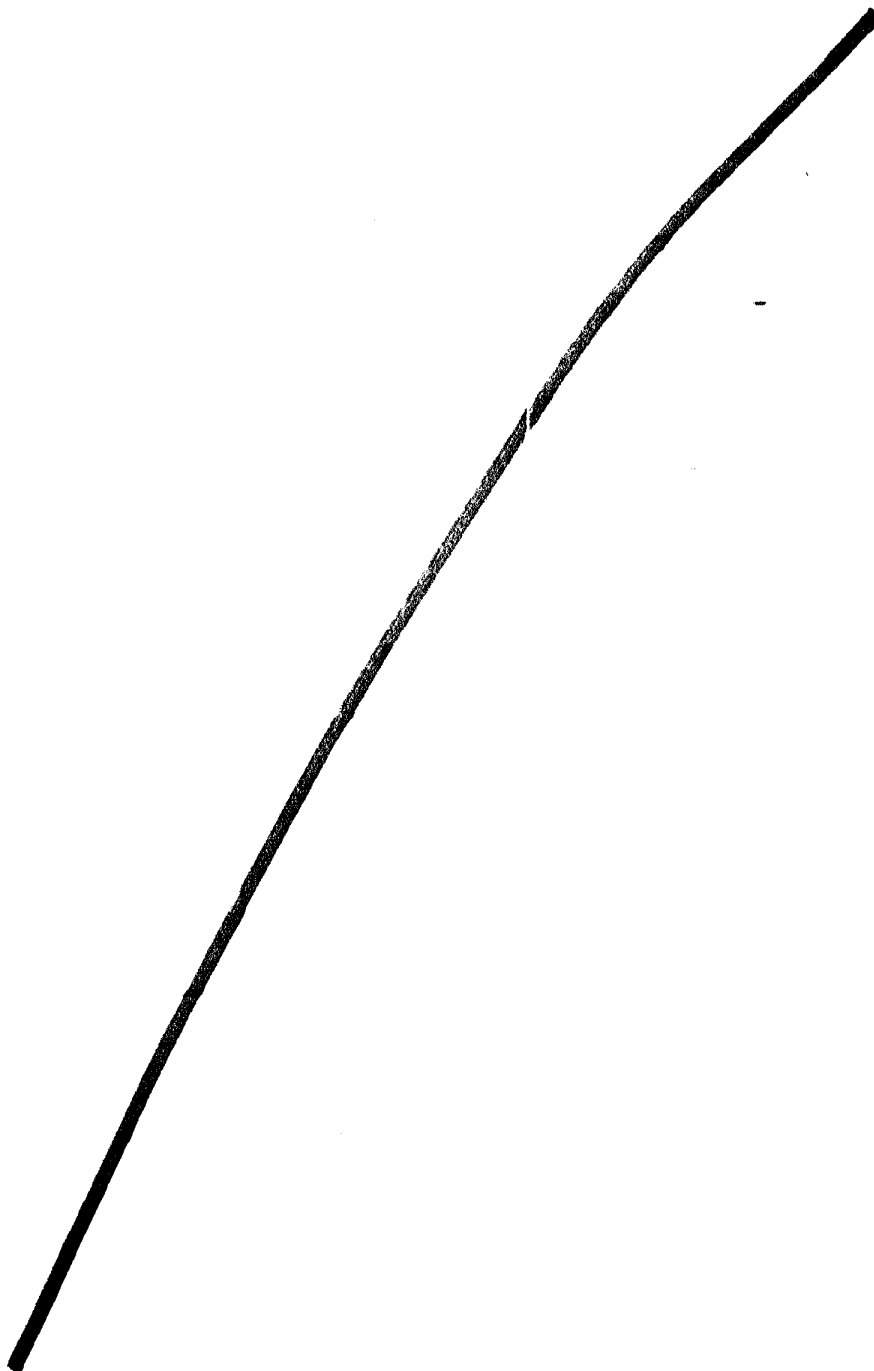
Dear Dr. Collins:

We have reviewed the material provided in your correspondence of May 6, 1999, submitted in response to issues raised during the eighteenth inspection of your laboratory as outlined in our correspondence of March 31, 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 summary of our review:


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Dr. Collins
May 25, 1999
Page 2 of 3



Dr. Collins
May 25, 1999
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 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,



Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M18



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 28, 1999

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112


Dear Dr. Collins:

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

E. The Standard Operating Procedures (SOP) section



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



Dr. Collins
October 28, 1999
Page 2 of 4

[Redacted]

G. The Quality Control section

[Redacted]

I. The Confirmatory Tests section

[Redacted]

Dr. Collins
October 28, 1999
Page 3 of 4

J. The Records Audit 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 Inspection Analyst

Dr. Collins
October 28, 1999
Page 4 of 4

Enclosure

cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0094
Document No. Final

Laboratory: MedTox Laboratories, Inc.

Location: St. Paul, MN

Document Reviewed: Application Form
 Inspection Report #M19 Date: 26 August 1999
 Other _____

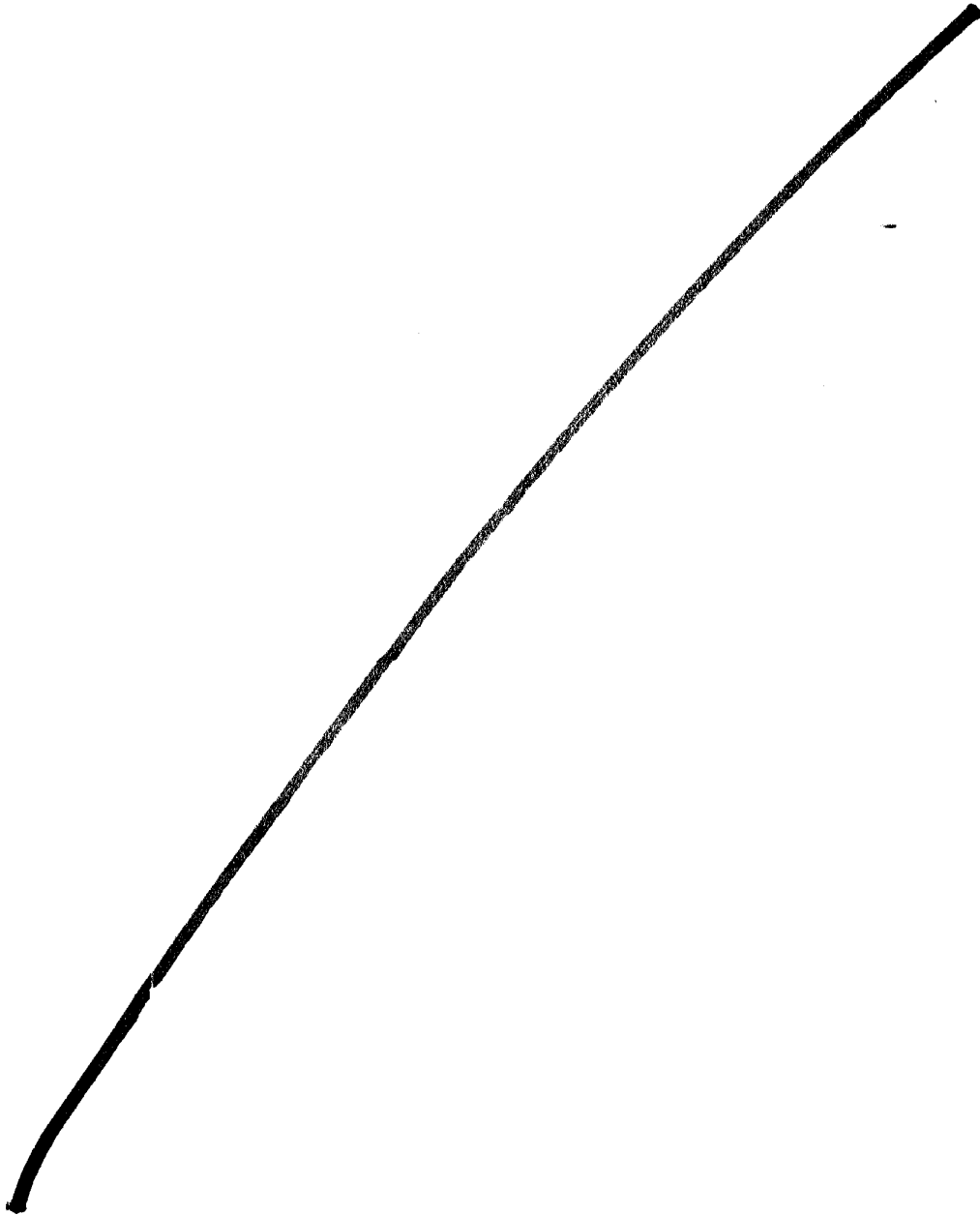
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

[Redacted]

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]




November 18, 1999

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

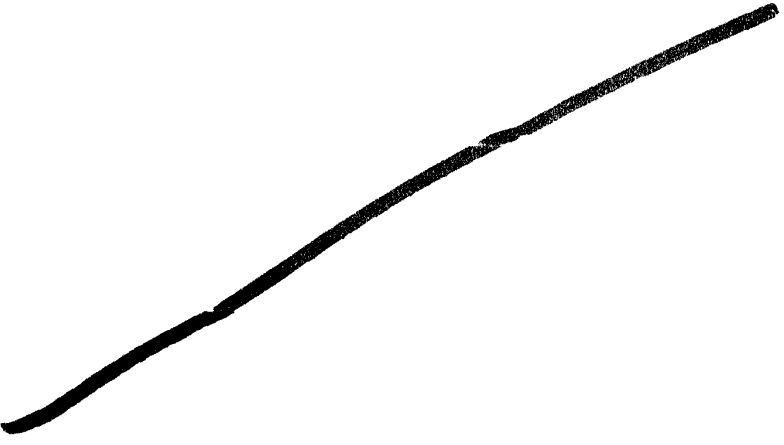
Dear Ms. Denson:

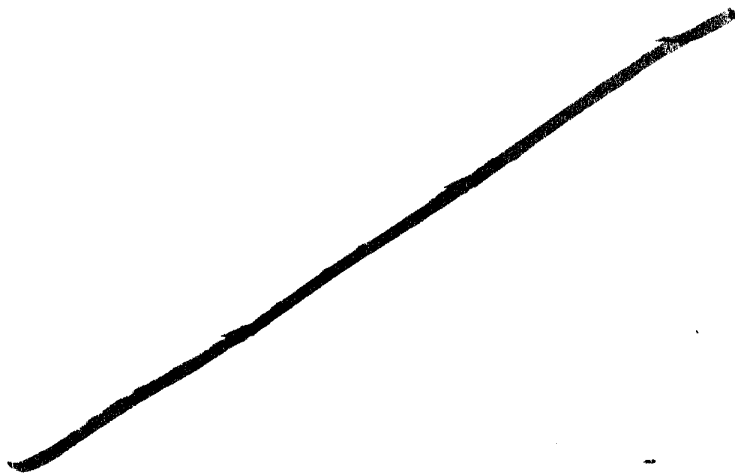
Enclosed is our response to the critique of our nineteenth maintenance inspection under the National Laboratory Certification Program (NLCP). The response is organized according to the items listed in your correspondence of October 28, 1999.

E. Standard Operating Procedures

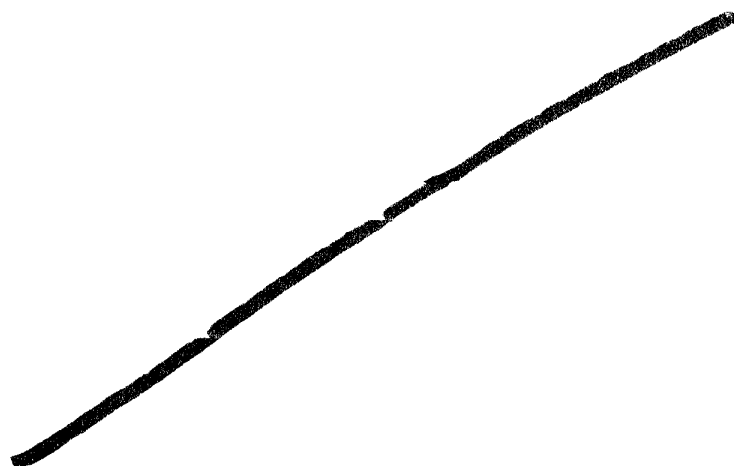


F. Chain of Custody, Accessioning and Security

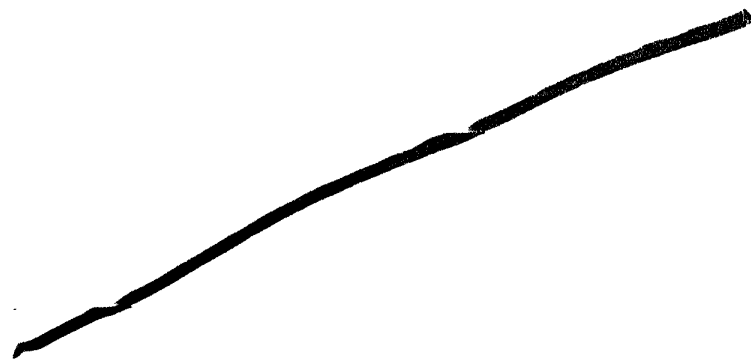




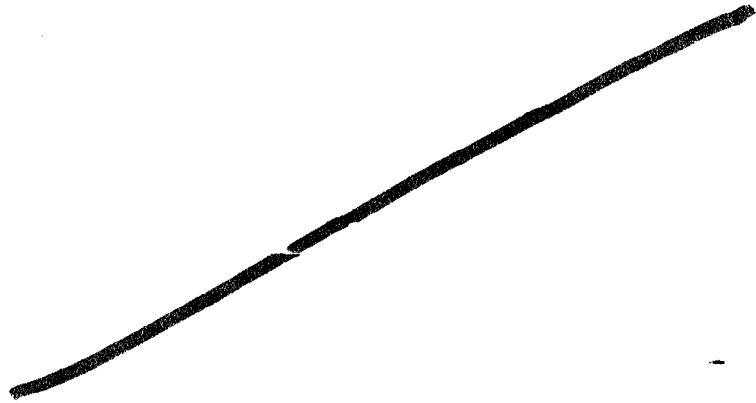
G. Quality Control



I. Confirmatory Tests



J. Records Audit



This addresses each of the issues raised in the inspection critique. Please notify me if additional information or documentation is required.

Sincerely,

A handwritten signature in black ink, appearing to read "JAC", with a long horizontal flourish extending to the right.

Jennifer A. Collins, Ph.D.
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 3, 1999

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

Dear Dr. Collins:

We have reviewed the material provided in your correspondence of November 18, 1999 submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of October 28, 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. 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,

Deborah J. Denson
Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M19





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 4, 2000

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

Dear Dr. Collins:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth 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 section



I. The Confirmatory Tests section



Dr. Collins
April 4, 2000
Page 2 of 2

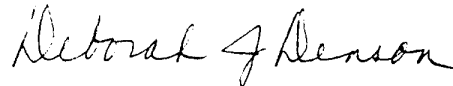
J. The Records Audit section



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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M20



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0094
Document No. Final

Laboratory: MedTox Laboratories, Inc.

Location: St. Paul, MN

Document Reviewed: Application Form
 Inspection Report #M20 Date: 17 February 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

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

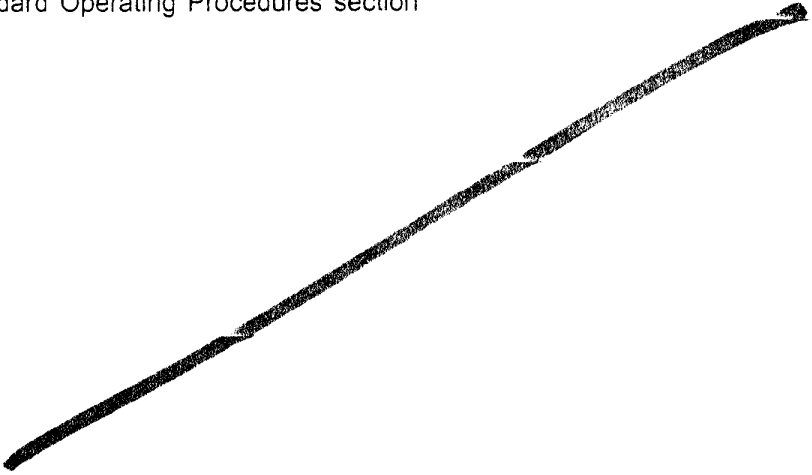
October 27, 2000

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

Dear Dr. Collins:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-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 highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

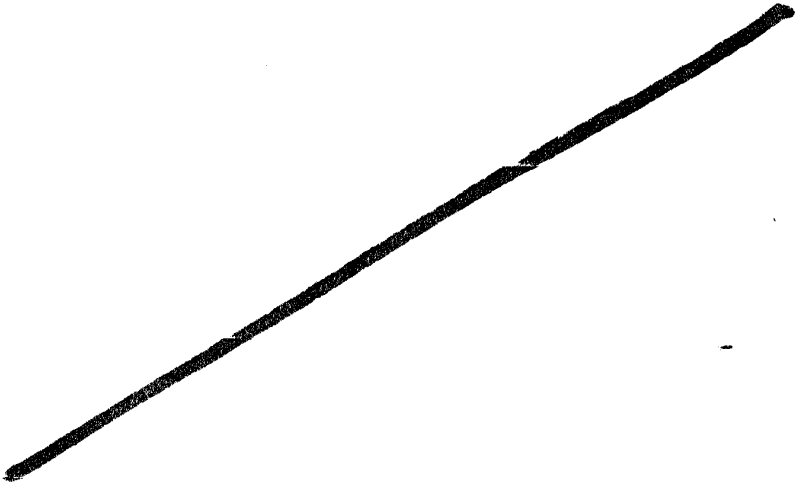
E. The Standard Operating Procedures section

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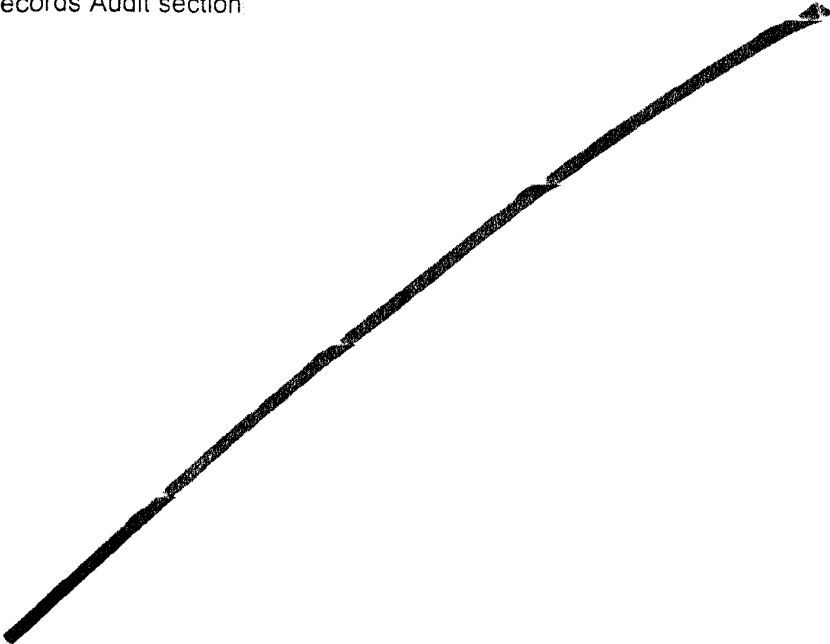
F. The Chain-of-Custody, Accessioning, and Security section

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I. The Confirmatory Tests section



J. The Records Audit section



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

Dr. Collins
October 27, 2000
Page 3 of 3

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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0094
Document No. Final

Laboratory: MedTox Laboratories, Inc.

Location: St. Paul, MN

Document Reviewed: Application Form
 Inspection Report #M21 Date: 24 August 2000
 Other _____

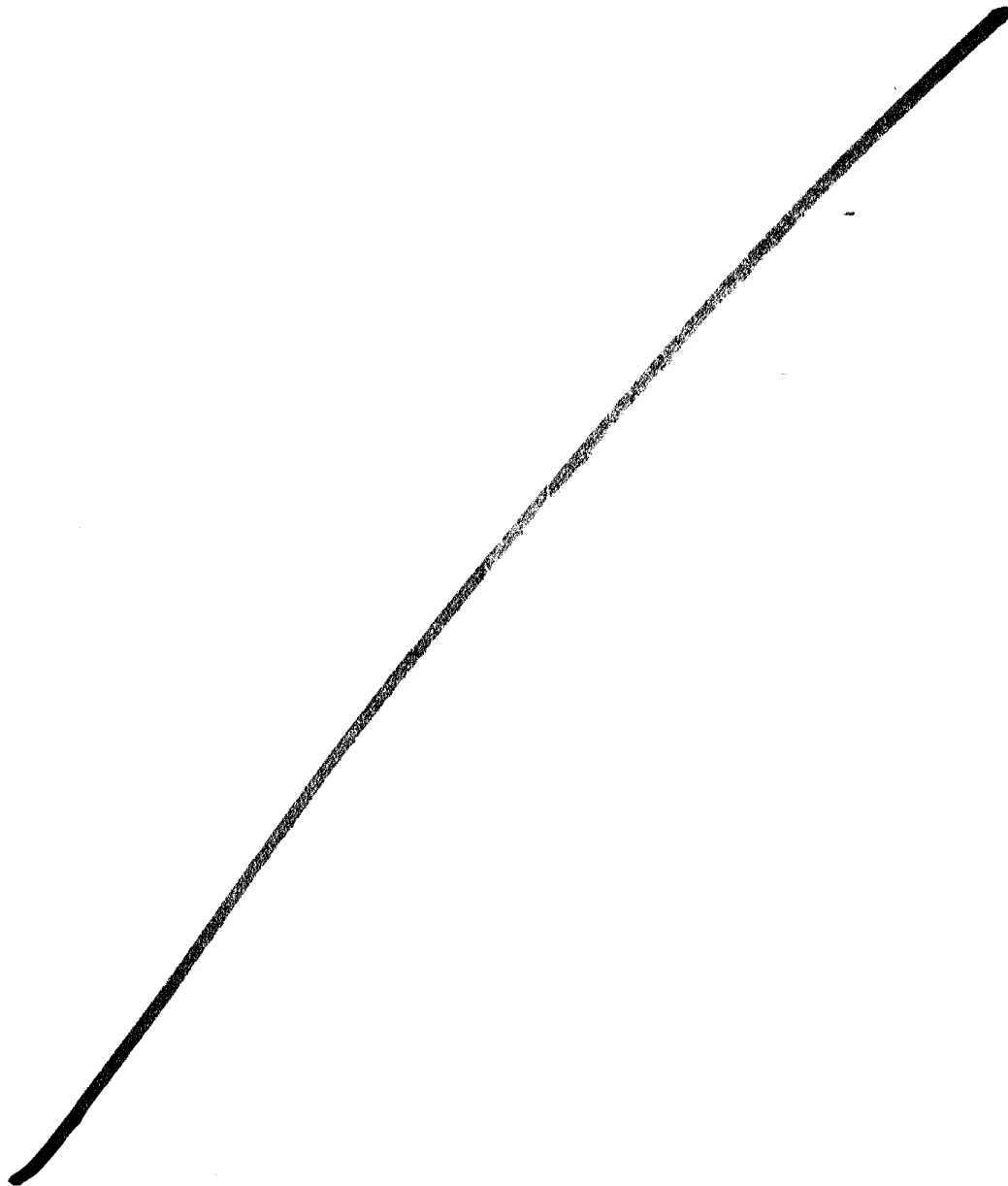
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



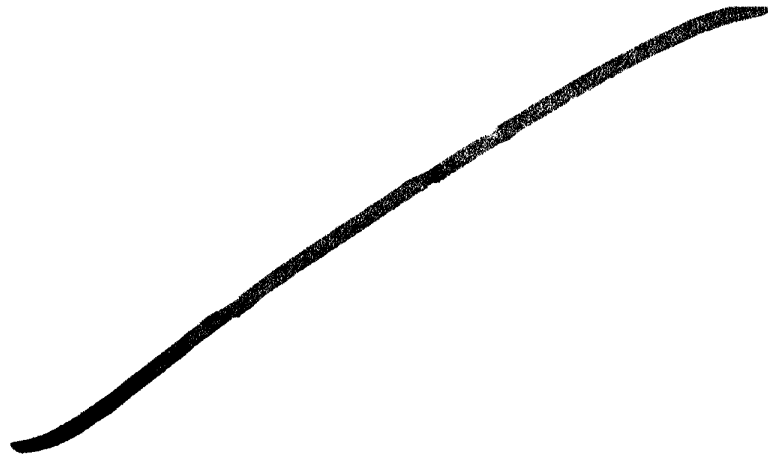
Section G. Quality Control



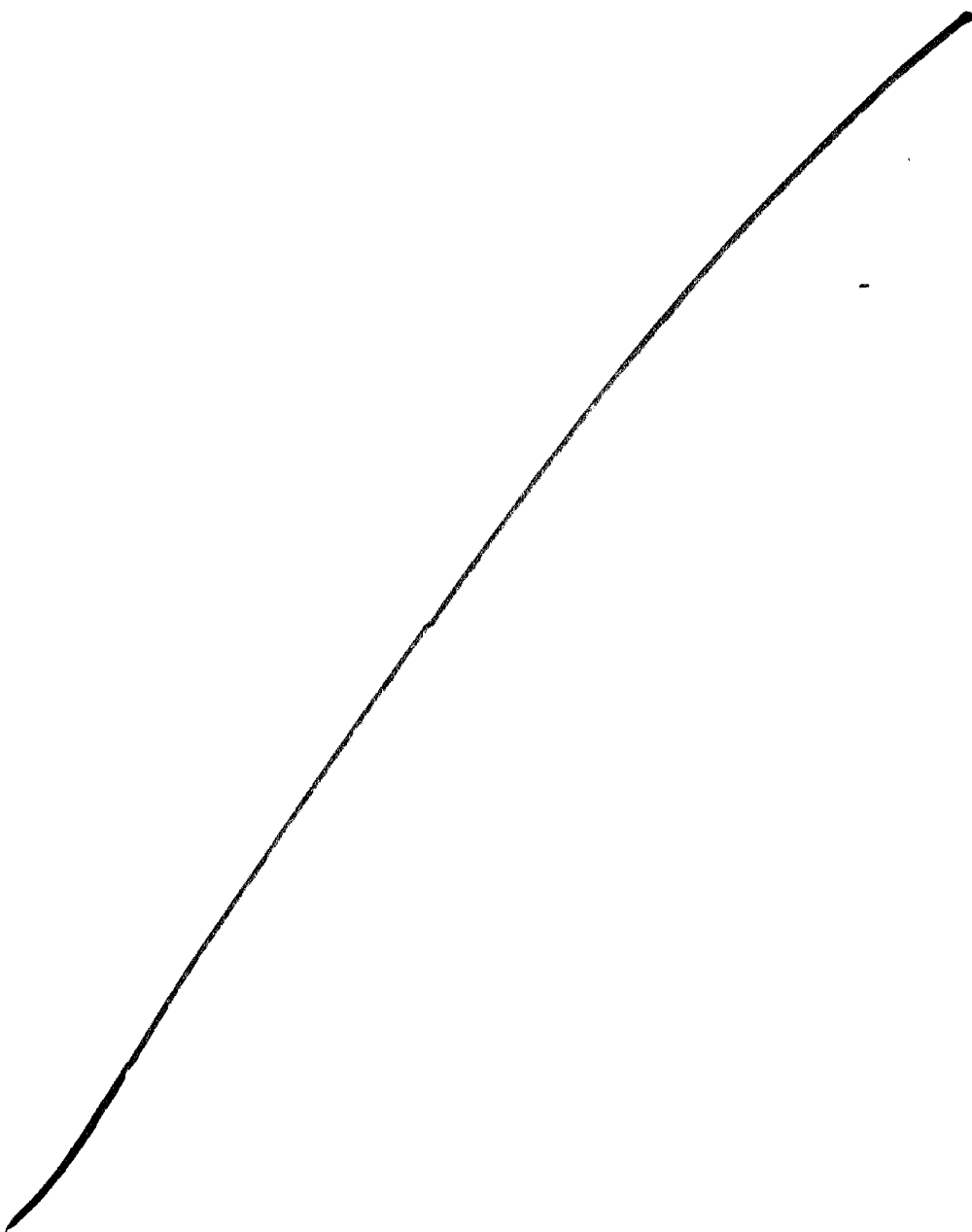
Section H. Initial Tests



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

