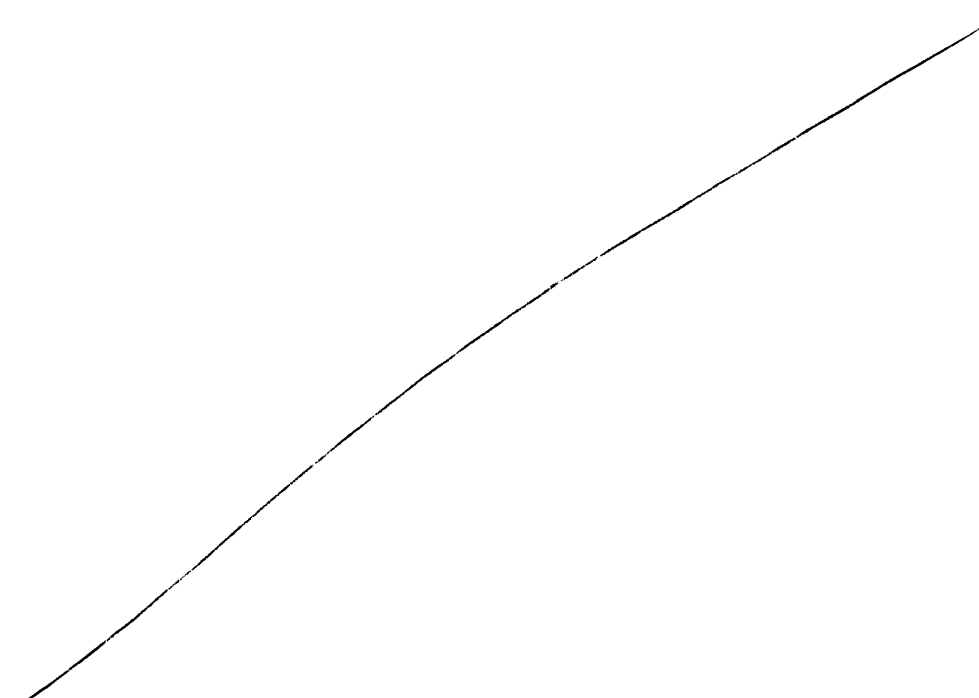


January 8, 1999

0168
Dr. Michael Fowler
St. Anthony Hospital (Toxicology Laboratory)
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73102

Dear Dr. Fowler:

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 highly acceptable. However, the following issue was raised:



Dr. Fowler
Page 2 of 2
01/08/99

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

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

Document Reviewed: Application Form
 Inspection Report #M16 Date: 19 November 1998
 Other _____

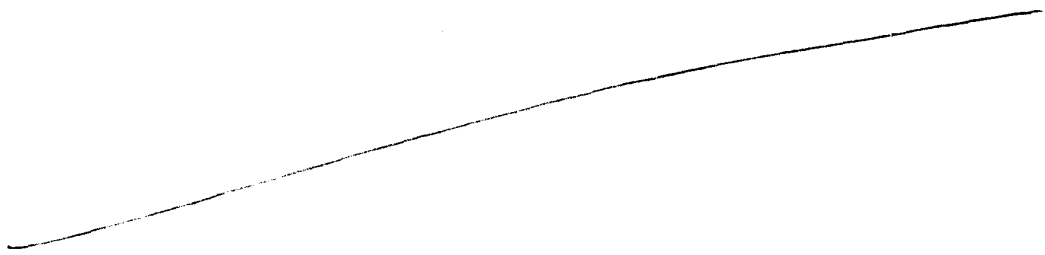
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



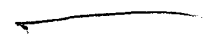
Section F. Chain-of-Custody, Accessioning and Security



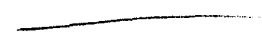
Section G. Records Audit



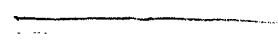
Section H. Personnel



Section I. Reagents



Section J. Quality Control and Standards



Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

July 8, 1999

0168
Dr. Michael Fowler
St. Anthony Hospital (Toxicology Laboratory)
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73102

Dear Dr. Fowler:

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.

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 review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

Document Reviewed: Application Form
 Inspection Report #M17 Date: 20 May 1999
 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

December 23, 1999

0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

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

Enclosure

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

Document Reviewed: Application Form
 Inspection Report #M18 Date: 19 November 1999
 Other _____

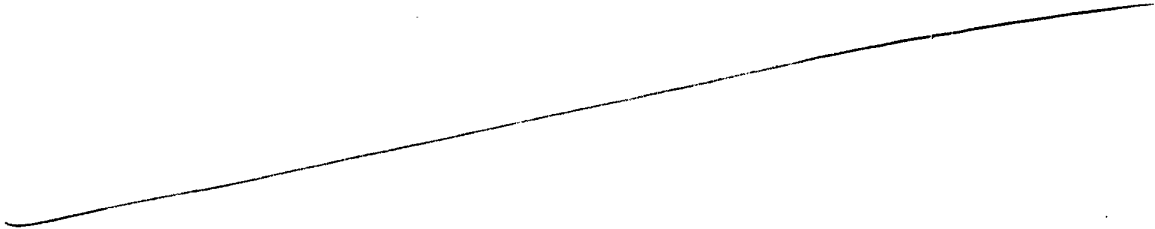
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

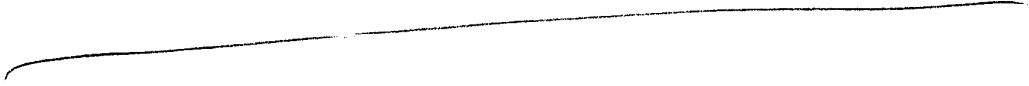
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

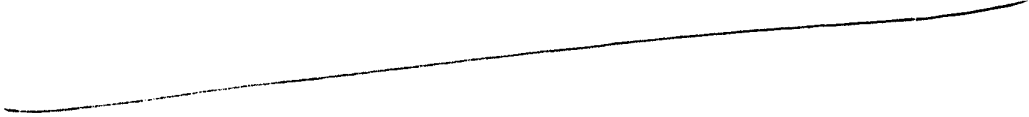
Section E. Standard Operating Procedures - Procedures Manual



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

July 17, 2000

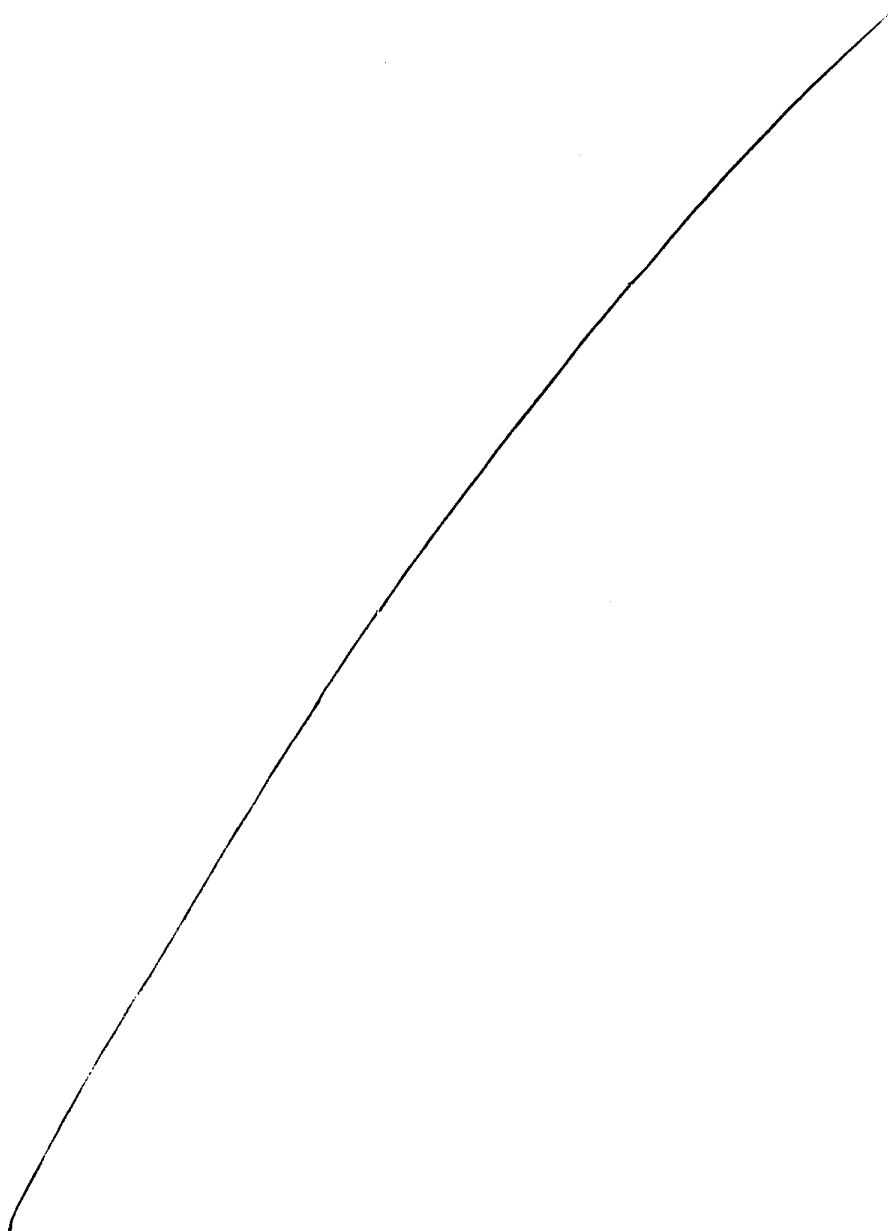
0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

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



Dr. Fowler
July 17, 2000
Page 2 of 3

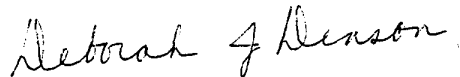


Dr. Fowler
July 17, 2000
Page 3 of 3

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

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

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

Document Reviewed: Application Form
 Inspection Report #M19 Date: 18 May 2000
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

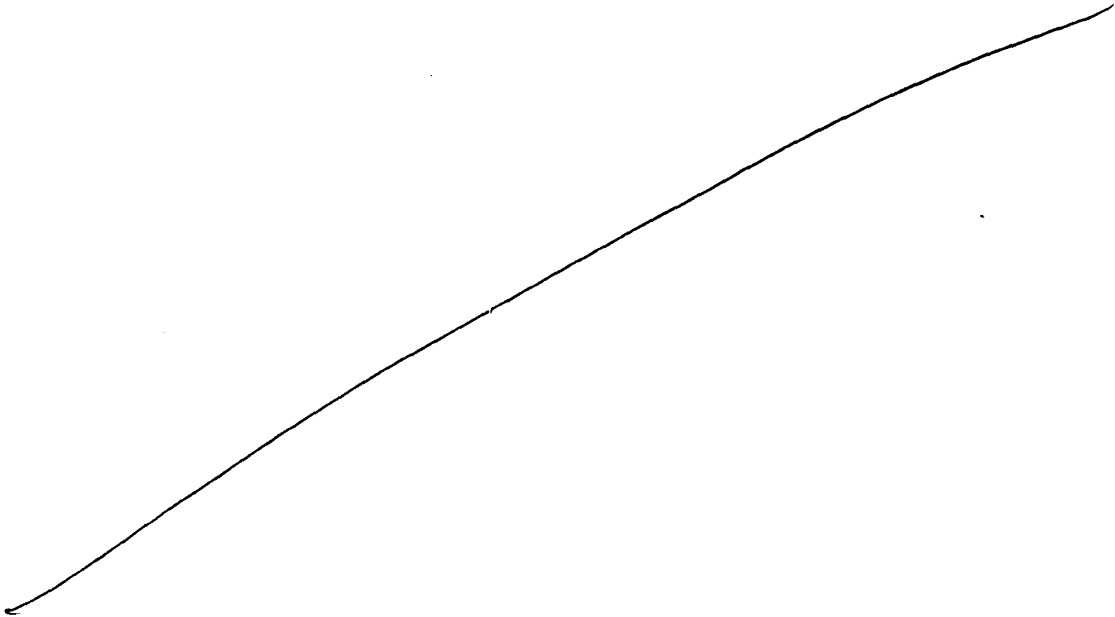
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

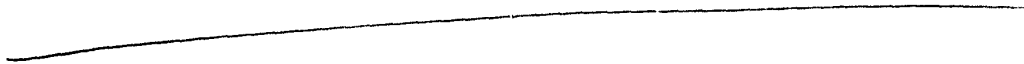
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

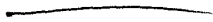
Section F. Chain-of-Custody, Accessioning, and Security



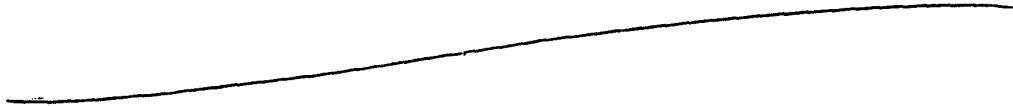
Section G. Quality Control

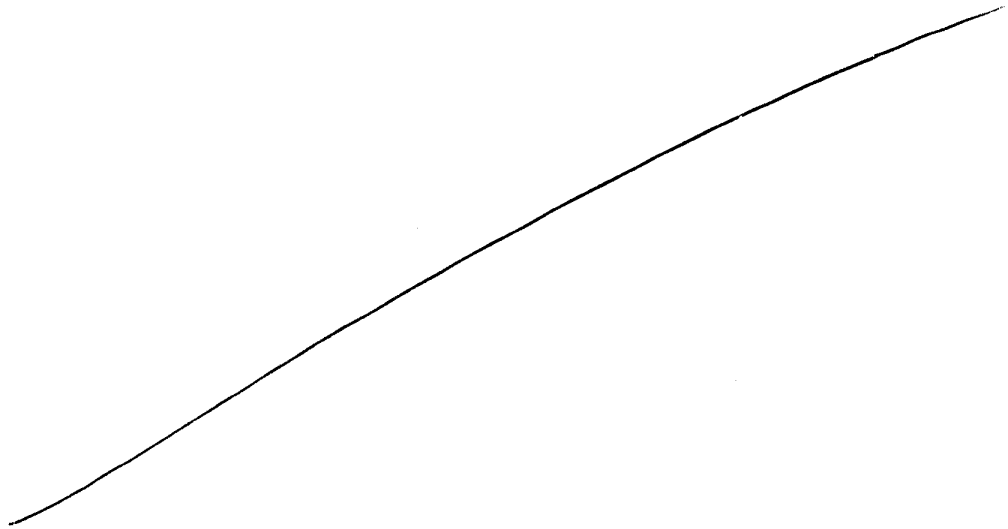


Section H. Initial Tests

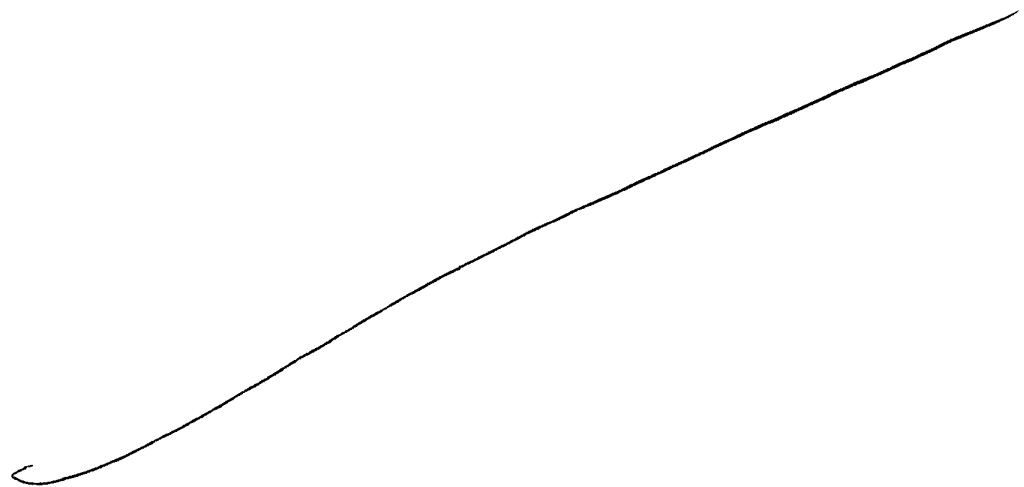


Section I. Confirmatory Tests






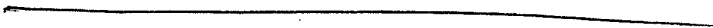
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel





St. Anthony

received
8/21/00 DD

1000 North Lee Street
Post Office Box 205
Oklahoma City, Oklahoma 73101

(405) 272-7000

A MEMBER OF THE SSM HEALTH CARE SYSTEM

August 16, 2000

Ms. Debby Denson
NLCP
RTI
3040 Cornwallis Rd.
PO Box 12194
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

Attached you will find our responses to the Inspection Report #M19. If you have questions or need more information please contact me at _____

_____. Thank you for your consideration.

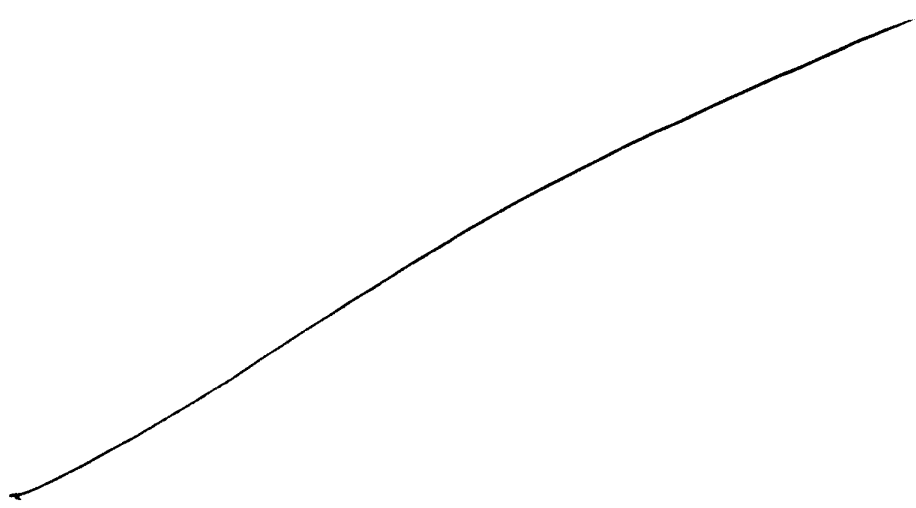
Sincerely,

Michael W. Fowler, Ph.D.
Director of Toxicology

HHS Inspection Response
St. Anthony Toxicology Laboratory
Lab ID# 0168
Inspection Report #M19

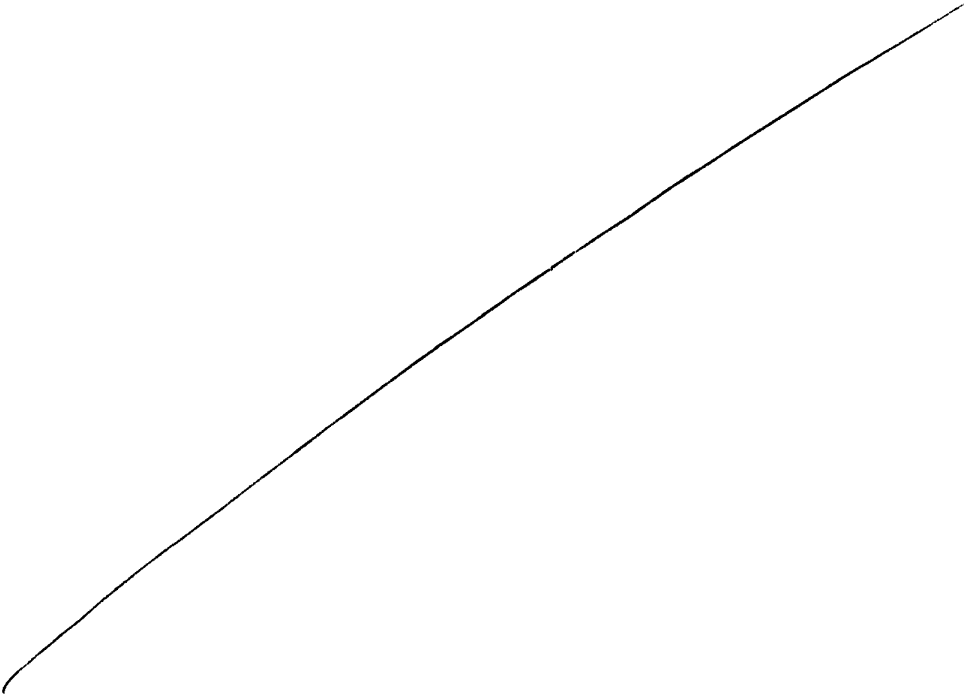
Issue #1

F. The Chain of Custody, Accessioning, and Security



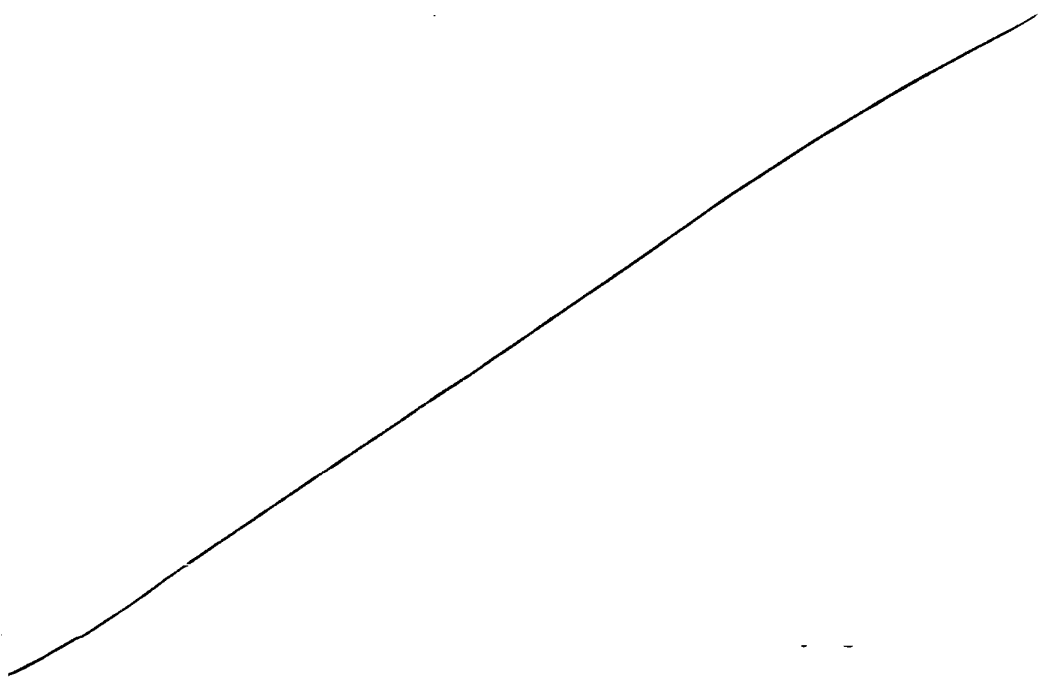
Issue #2

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



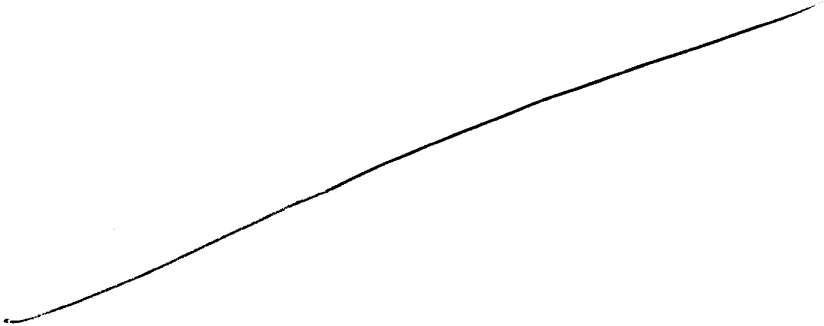
Issue #3

F. The Chain of Custody, Accessioning, and Security



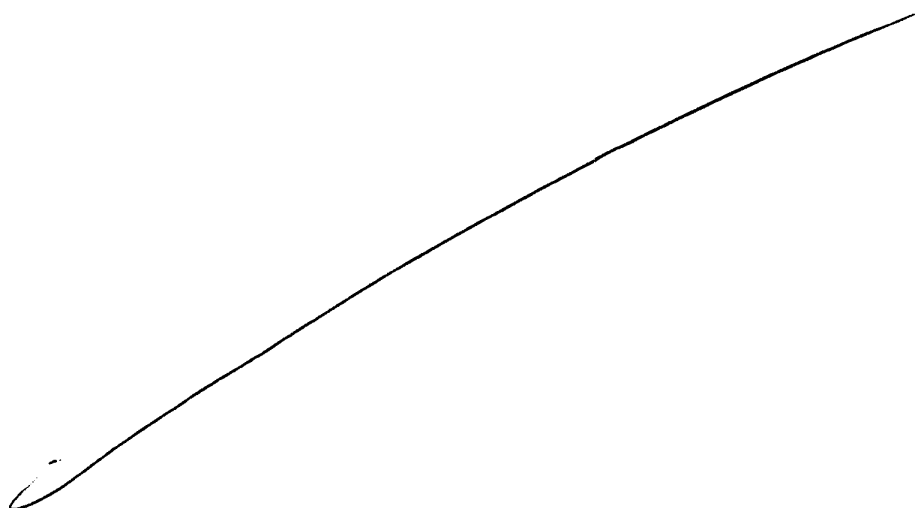
Issue #4

I. The Confirmatory Test sector _____



Issue #5

I. The Confirmatory Test section



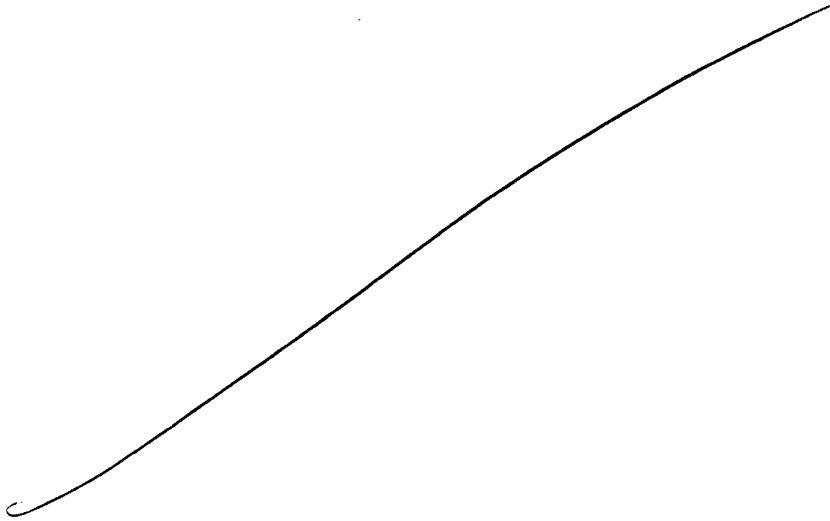
Issue #6

J. The Records Audit



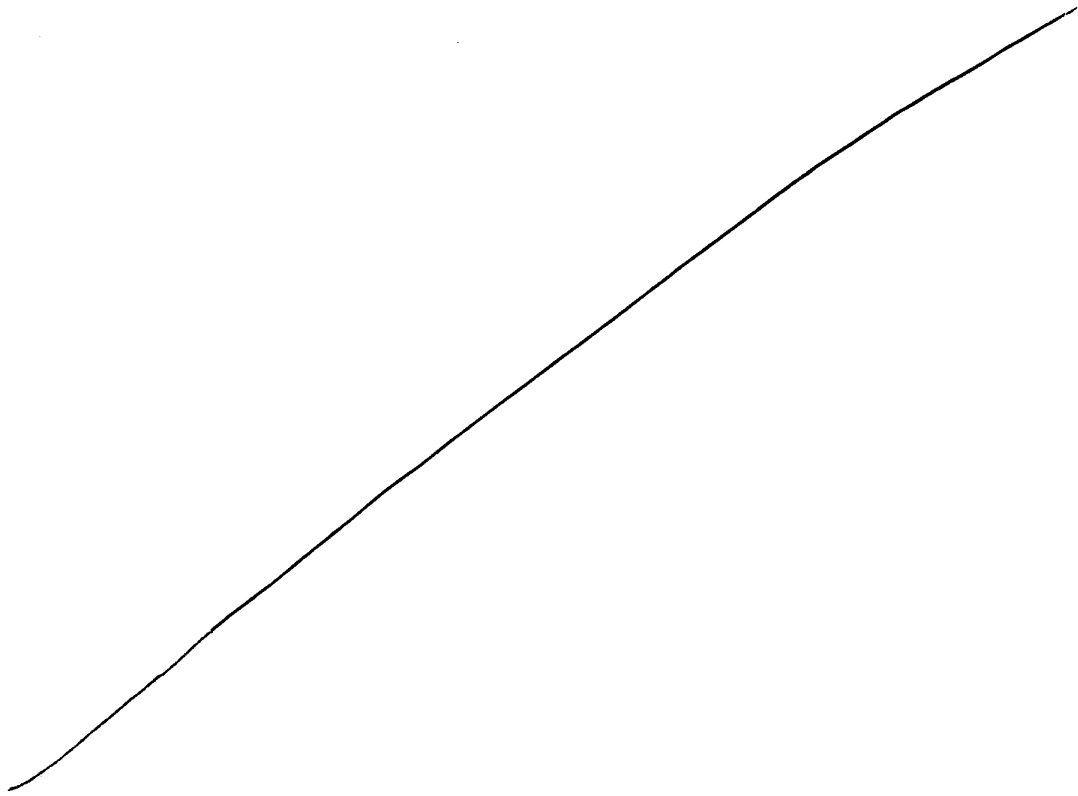
Issue #7

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



Issue #8

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

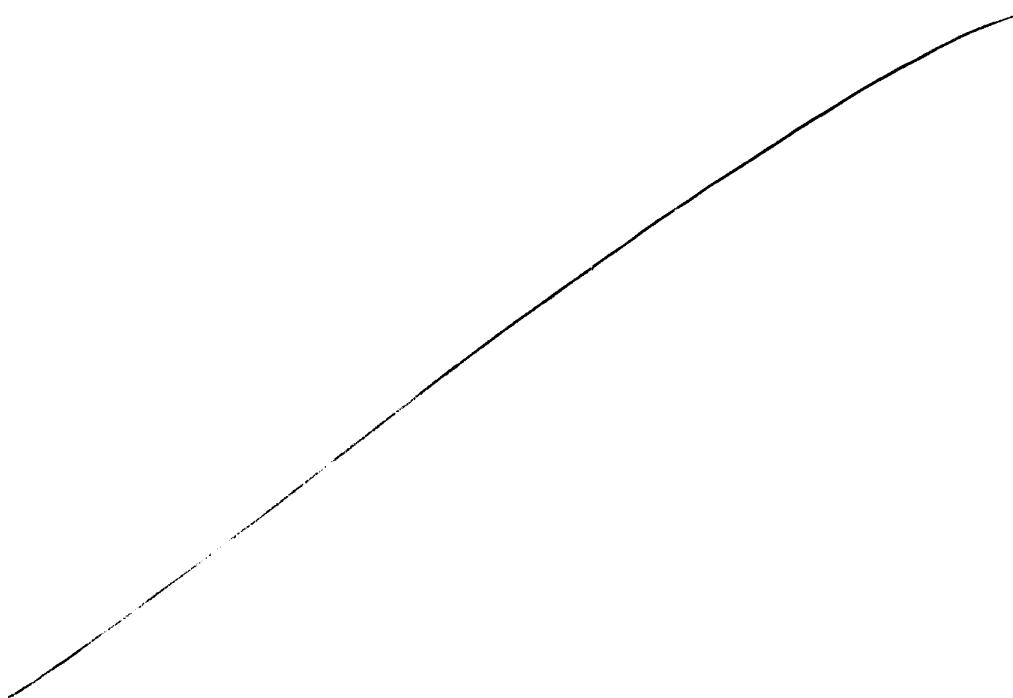


August 31, 2000

0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

We have reviewed the material provided in your correspondence of August 16, 2000, submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of July 17, 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:



Dr. Fowler
August 31, 2000
Page 2 of 2

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory 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/M19

RESEARCH TRIANGLE INSTITUTE



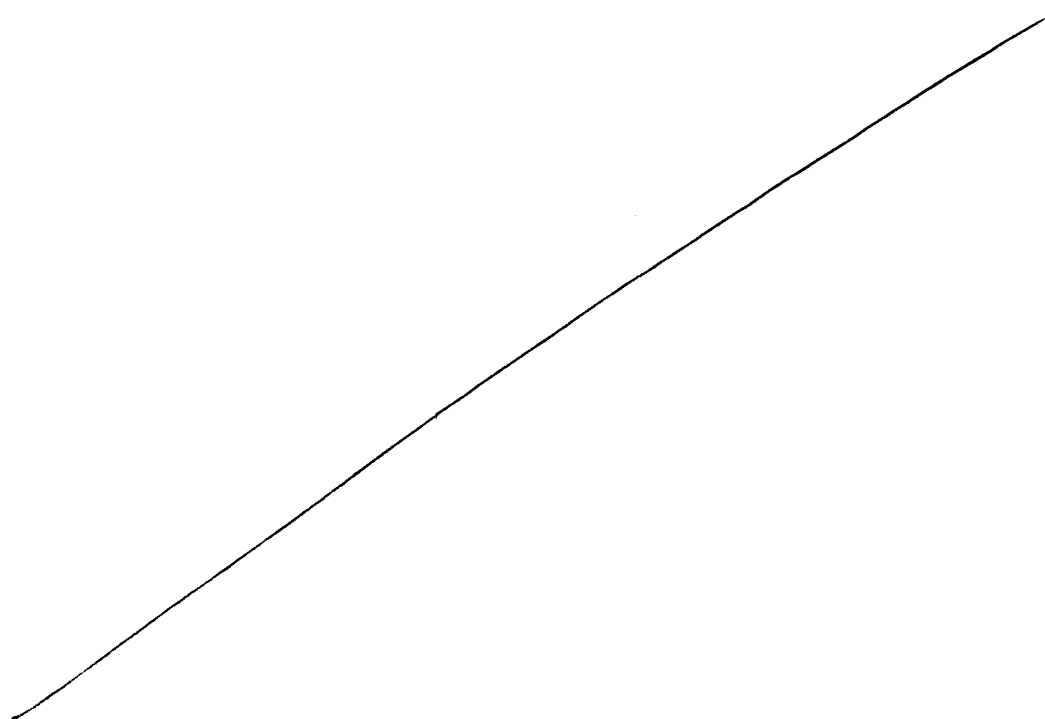
National Laboratory Certification Program

February 9, 2001

0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

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 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.



Dr. Fowler
February 9, 2001
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 R. 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: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

Document Reviewed: Application Form
 Inspection Report #M20 Date: 30 November 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

HHS Inspection Response

ITEM #1

J. The Confirmatory Tests sector. 


RESPONSE

