



RESEARCH TRIANGLE INSTITUTE

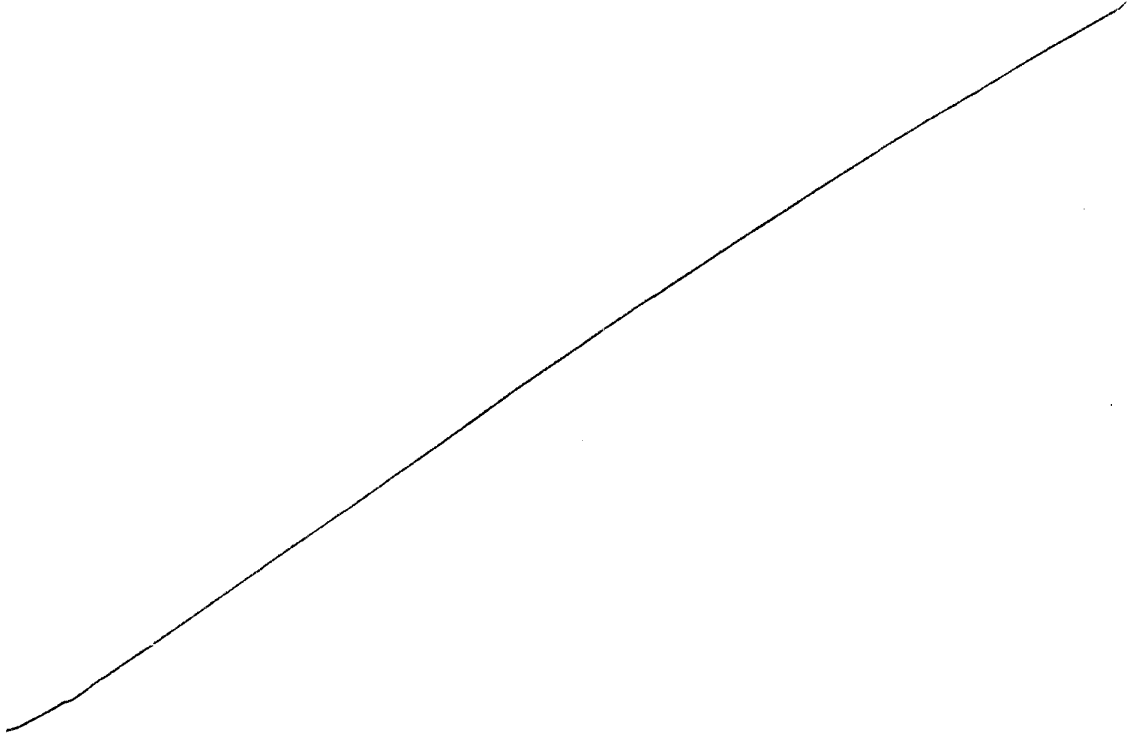
National Laboratory Certification Program

March 17, 1999

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

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



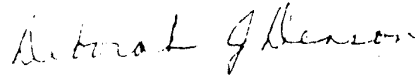
Dr. Hemphill
March 17, 1999
Page 2 of 3

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.

Dr. Hemphill
March 17, 1999
Page 3 of 3

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

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M14



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0443

Document No. Final

Laboratory: Cox Health Systems

Location: Springfield, MO

Document Reviewed: Application Form
 Inspection Report #M14 Date: 11 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

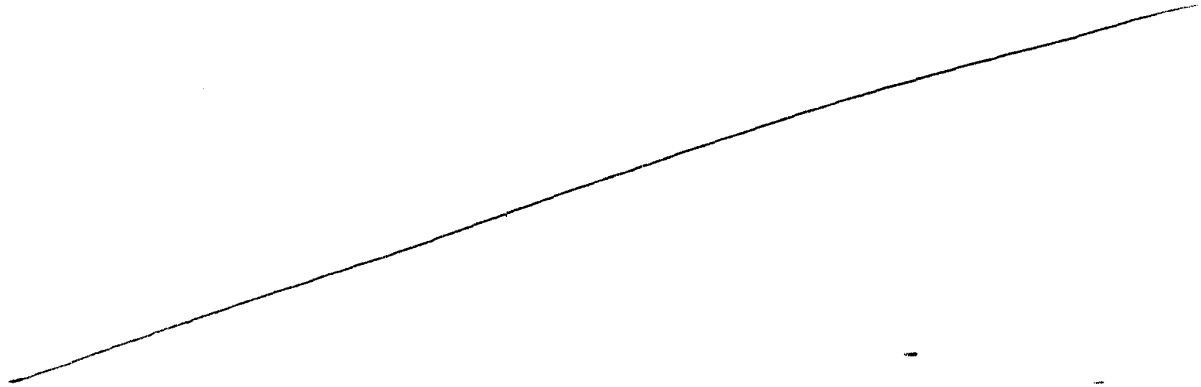


Section F. Chain-of-Custody, Accessioning, and Security

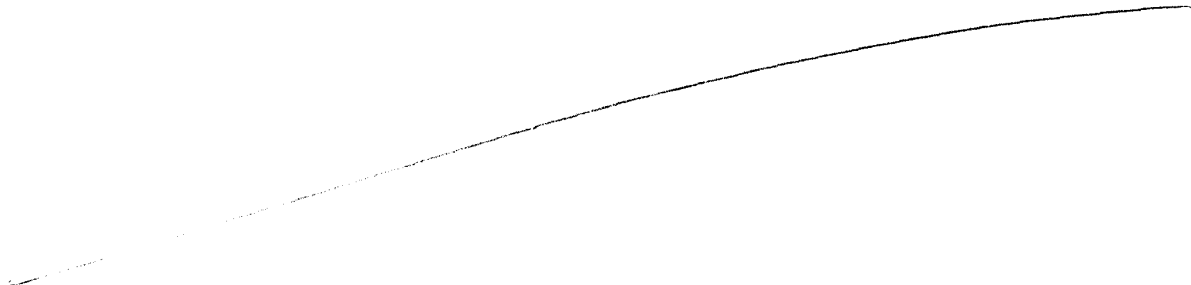


Section G. Quality Control

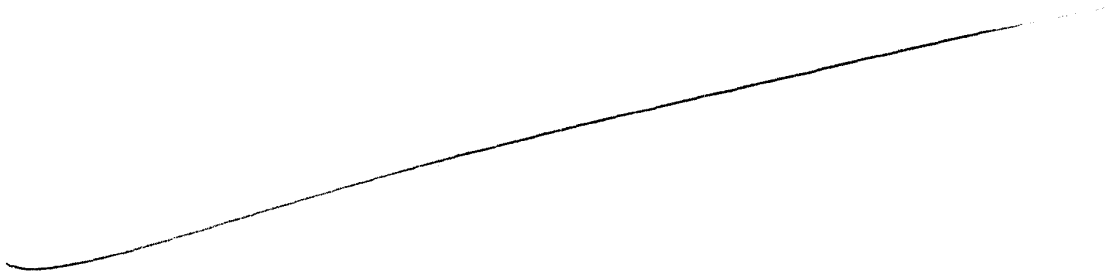




Section H. Initial Tests



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

COX TOXICOLOGY

COX MEDICAL CENTER NORTH
1423 NORTH HILFERSON AVENUE
SPRINGFIELD, MISSOURI 65802
417-COX-3093
800-876-3652

received
4/28/99 DD

Lab 0443

April 14, 1998

Deborah J. Denson
NLCP-RTI
P.O. Box 12194
Research Triangle Park, North Carolina 27709

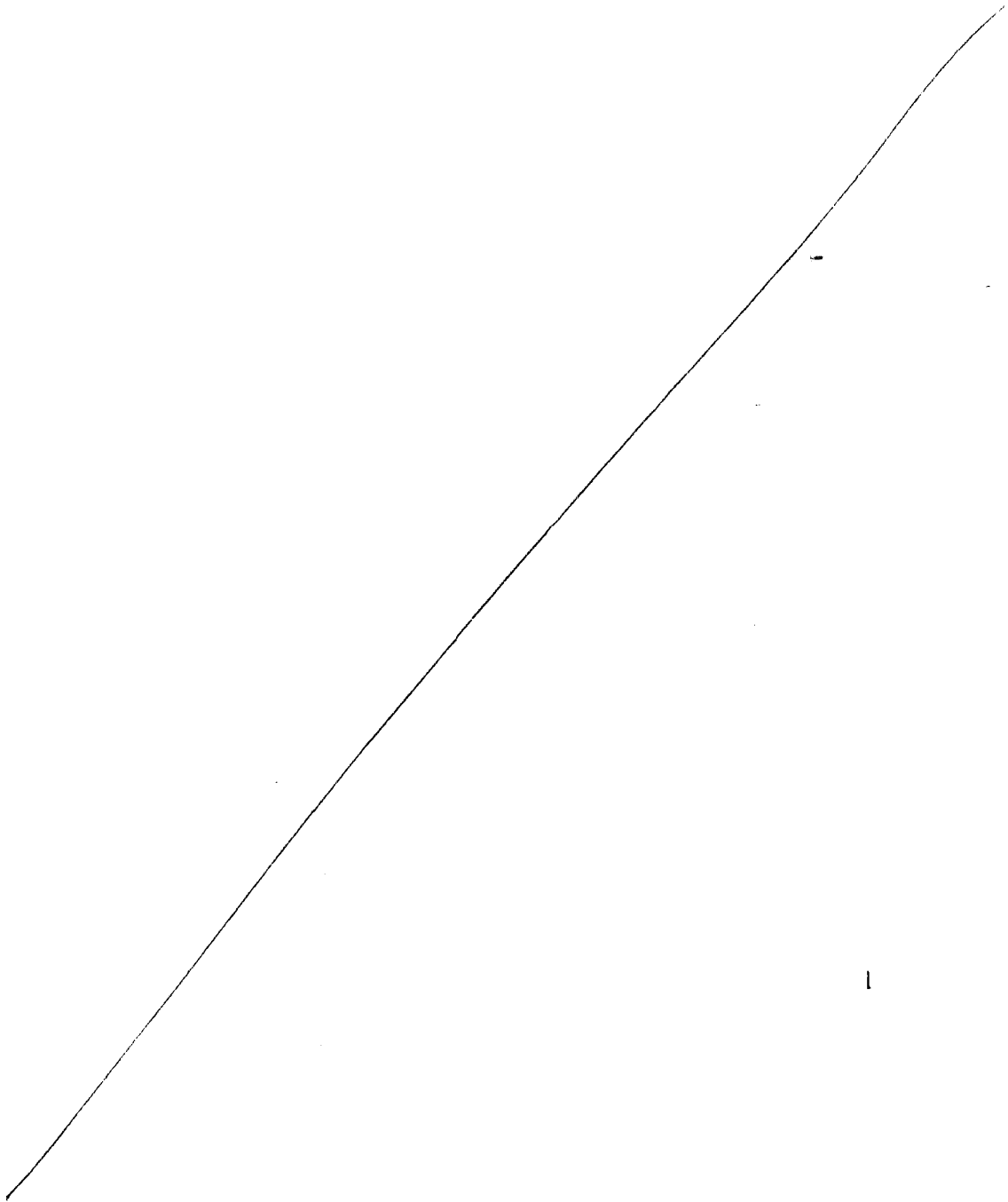
Subject: Fourteenth Maintenance Inspection; Response, Lab 0443.

Dear Inspection Analyst:

Please find enclosed, response to our fourteenth maintenance inspection.

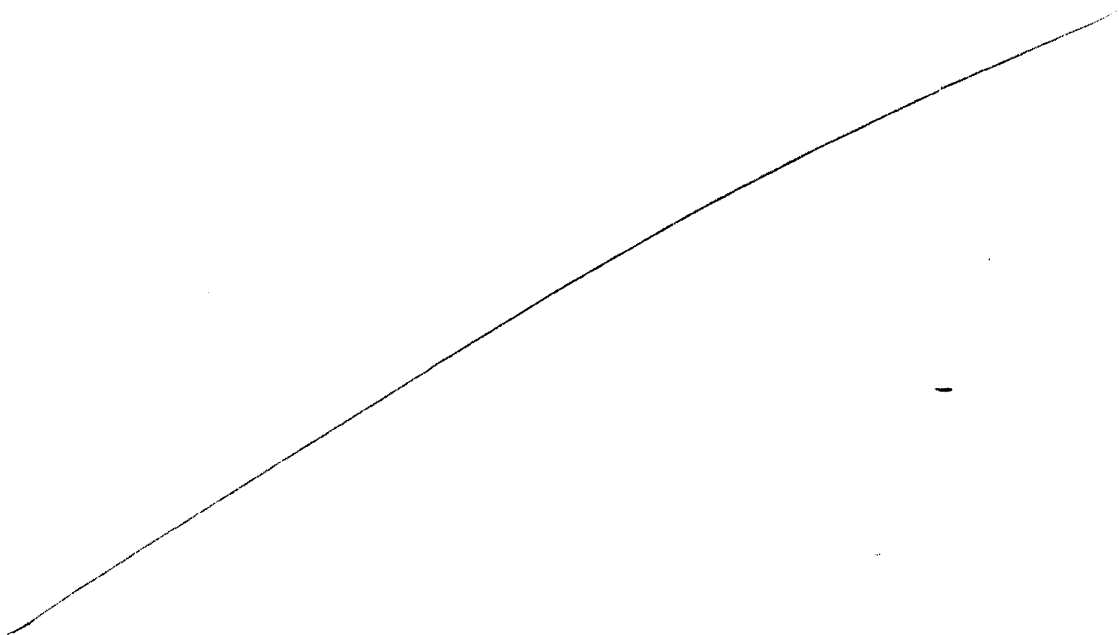
A DIVISION OF
COX
HEALTH SYSTEMS

An Equal Opportunity/Affirmative Action Employer / Services provided on a non-discriminatory basis



1

I Confirmatory Tests



Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill". The signature is written in black ink and is positioned below the word "Respectively,".

W.D. Hemphill, Ph.D., DABFT

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 5, 1999

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the material provided in your correspondence of April 14, 1999, submitted in response to issues raised during the fourteenth inspection of your laboratory as outlined in our correspondence of March 17, 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,

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

Deborah J. Denson
NLCP Inspection Analyst

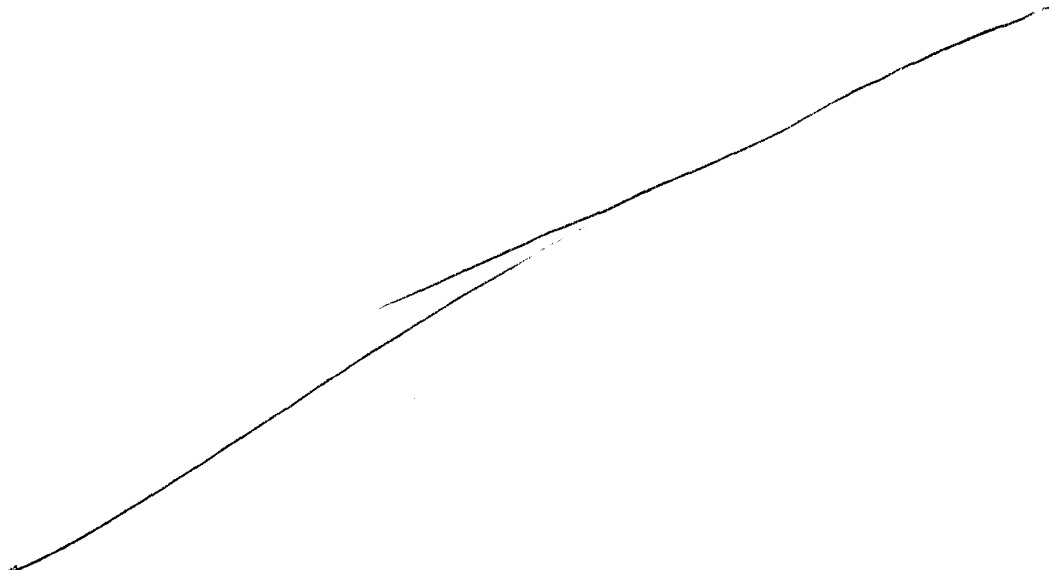
cc: Project Files/M14

September 27, 1999

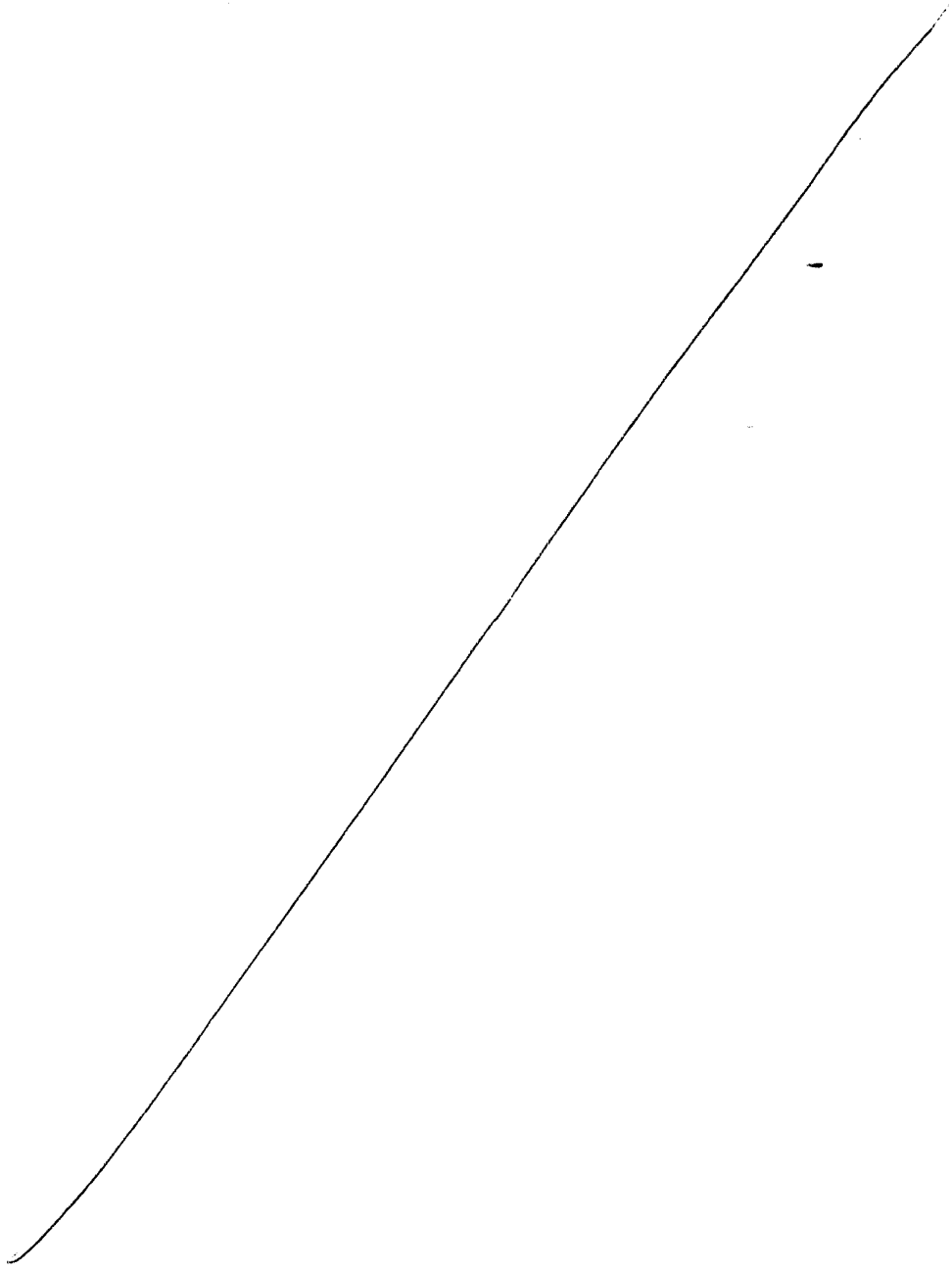
0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

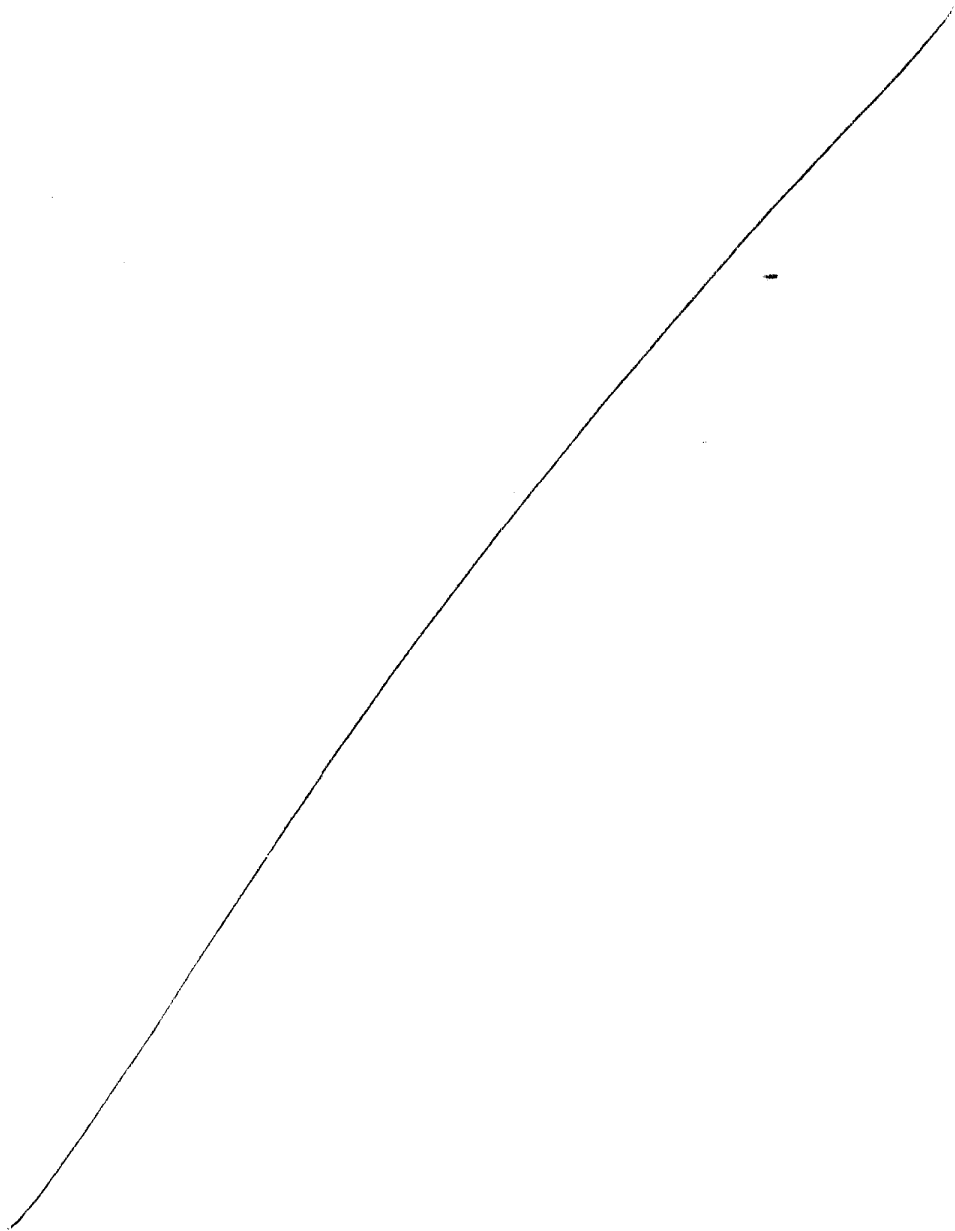
The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is unacceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following remedial actions:



Dr. Hemphill
Page 2 of 4
09/27/99



Dr. Hemphill
Page 3 of 4
09/27/99



The laboratory must submit, within 5 calendar days of receipt of this letter, a plan to complete all remedial actions. Once this plan is approved, the laboratory will have a maximum

Dr. Hemphill
Page 4 of 4
09/27/99

of 30 calendar days to implement the plan and to complete all necessary remedial actions. If the laboratory fails to provide and execute an approved plan, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be suspended and/or revoked. The laboratory should also review the enclosed critique and take all necessary corrective actions.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to sustain acceptable performance in the inspection phase of this program may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the Mandatory Guidelines.

In responding to the issues raised, please organize the material in accordance with the item numbers listed in the text of this letter. If we can be of assistance or answer any questions, 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/443

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0443
Document No. Final

Laboratory: Cox Health Systems

Location: Springfield, MO

Document Reviewed: Application Form
 Inspection Report #M15 Date: August 19, 1999
 Other _____

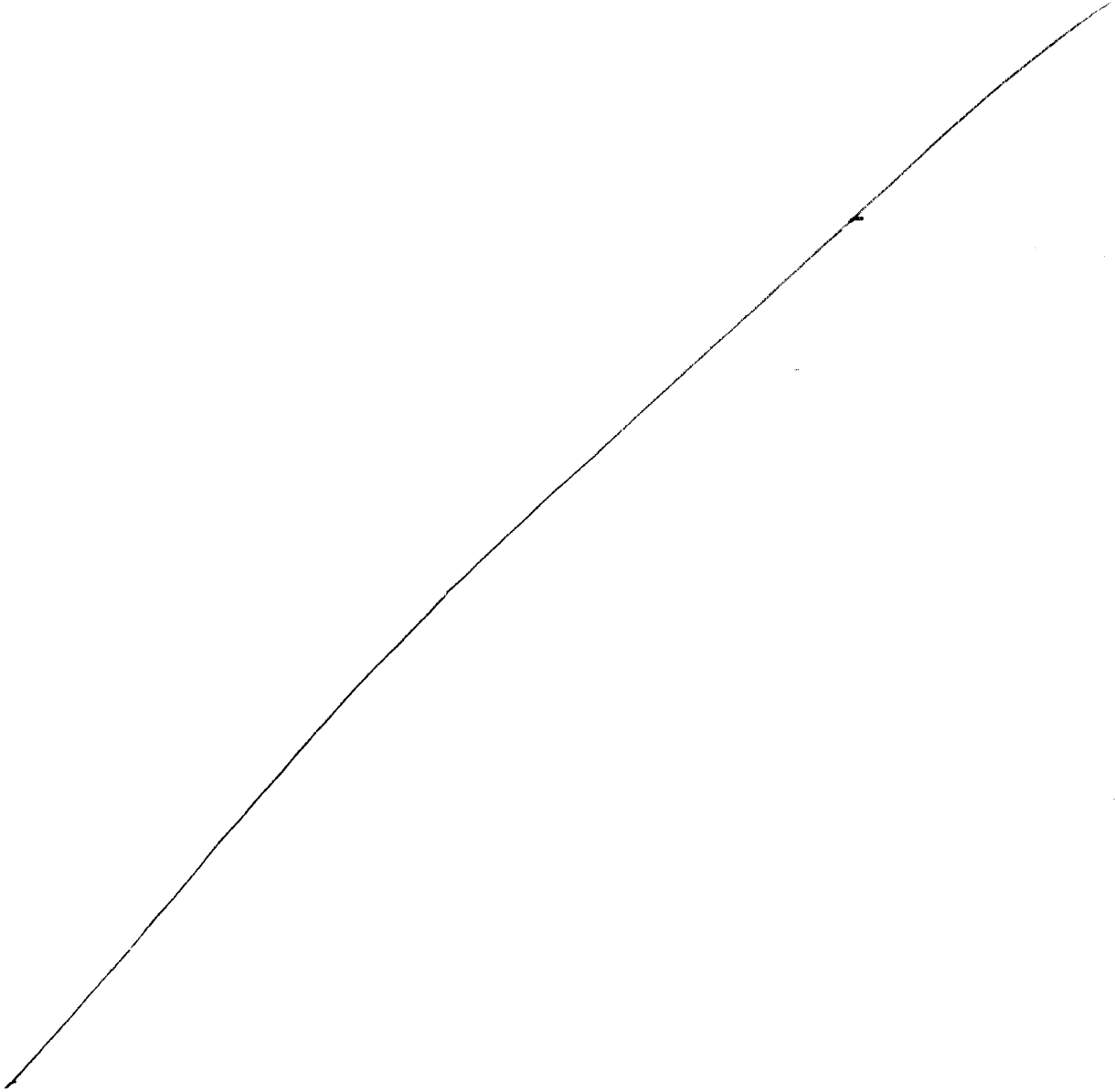
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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 not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required for continued certification.

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
10/7/99 SPC

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Page 1 of 2

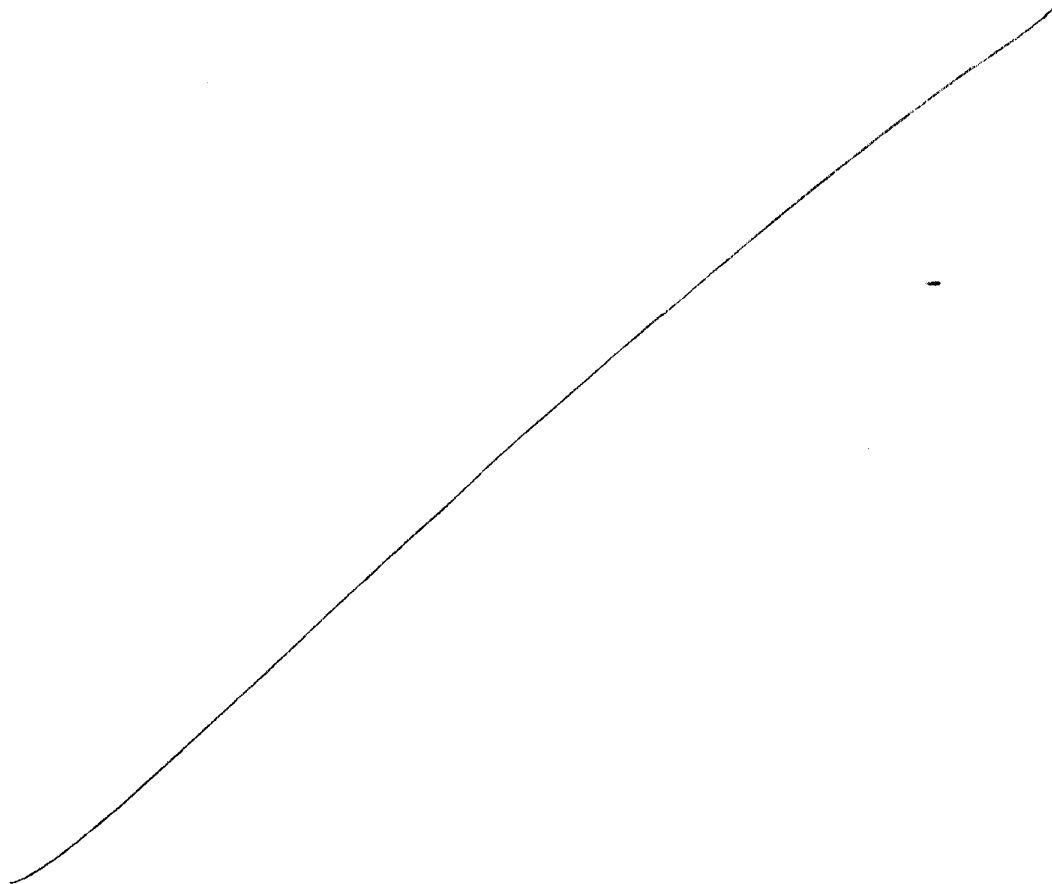
LAB 0443

October 3, 1999

Susan Crumpton
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Subject: M15 Plan for completion of remedial actions

Ms. Crumpton:



Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill".

W.D. Hemphill, Ph.D., DABFT



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 15, 1999

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of October 3, 1999, provided in response to the deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of September 27, 1999. The plan to correct the deficiencies noted was found acceptable with the following exceptions:

[A large, faint, handwritten-style line is drawn across the page, likely indicating a signature or a placeholder for a signature.]

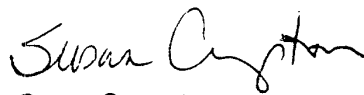


Dr. Hemphill
Page 2 of 2
10/15/99

The laboratory must submit the final report within 30 calendar days of receipt of this letter. This report must include supporting documentation to demonstrate completion of the planned remedial actions and to address the issues raised in this correspondence.

If you have any questions or want to further clarify any of these issues, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/443

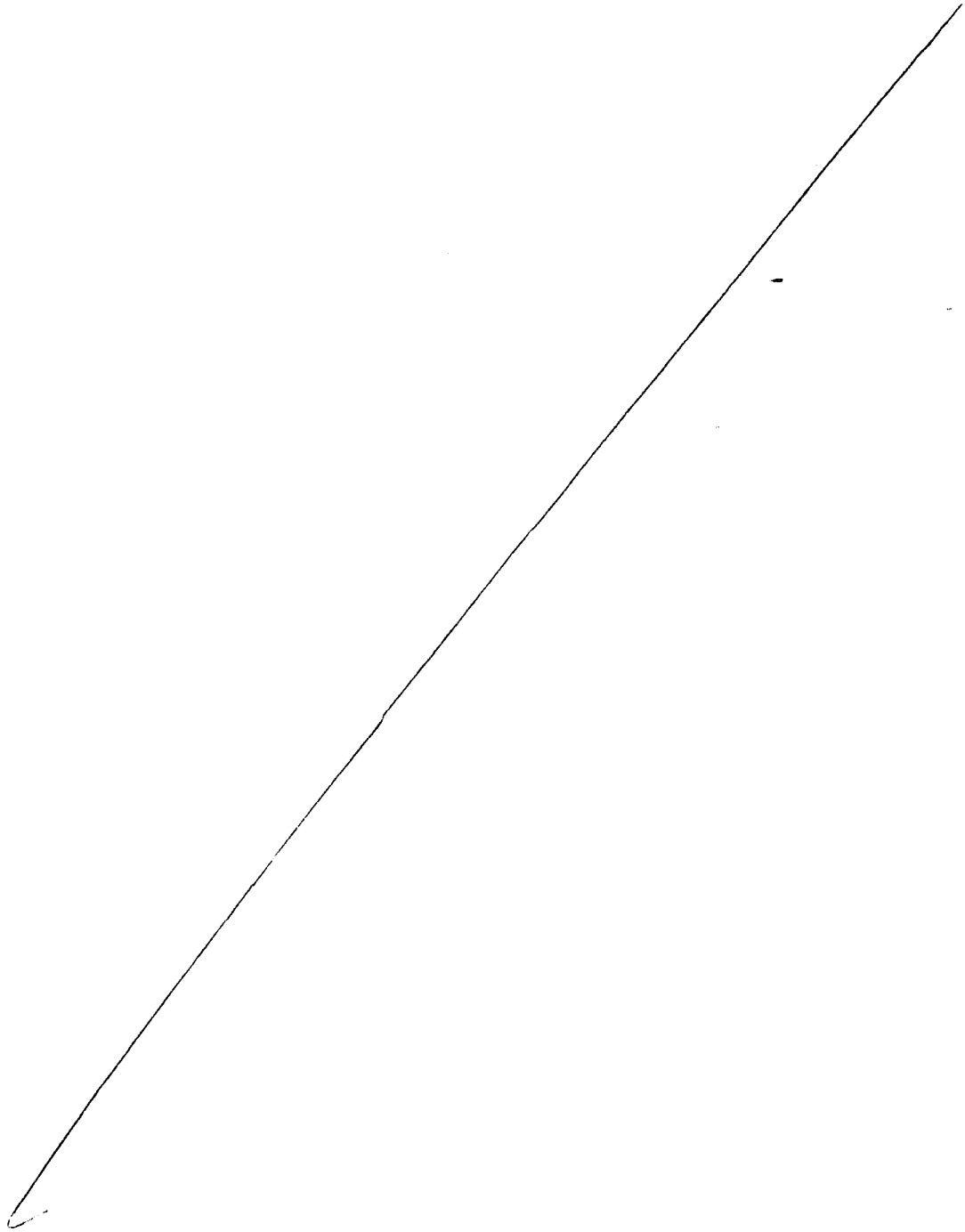
November 12, 1999

LAB 0443

Susan Crumpton
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Subject; Maintenance Inspection 15 corrective actions

Ms. Crumpton:



Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill".

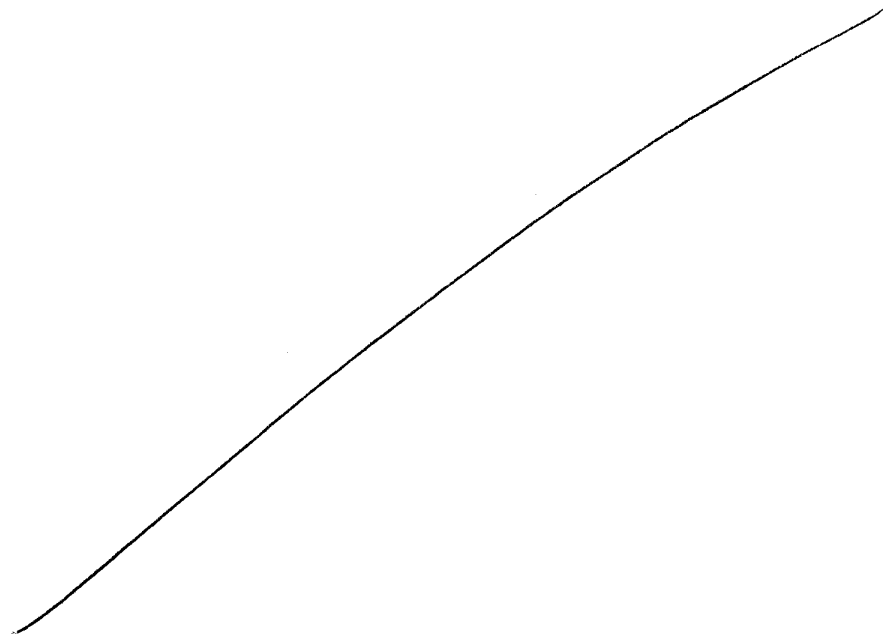
W.D. Hemphill, Ph.D., DABFT

December 10, 1999

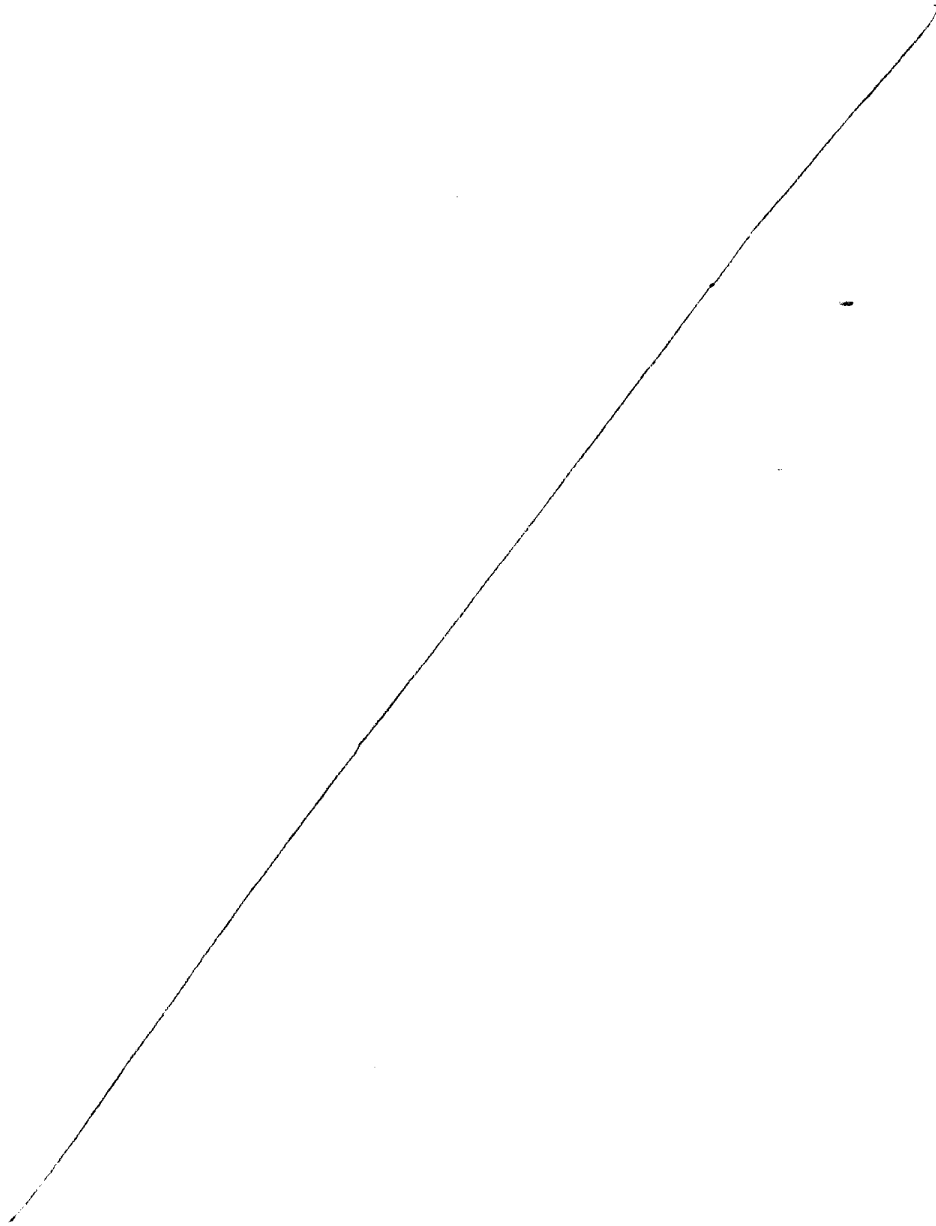
0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

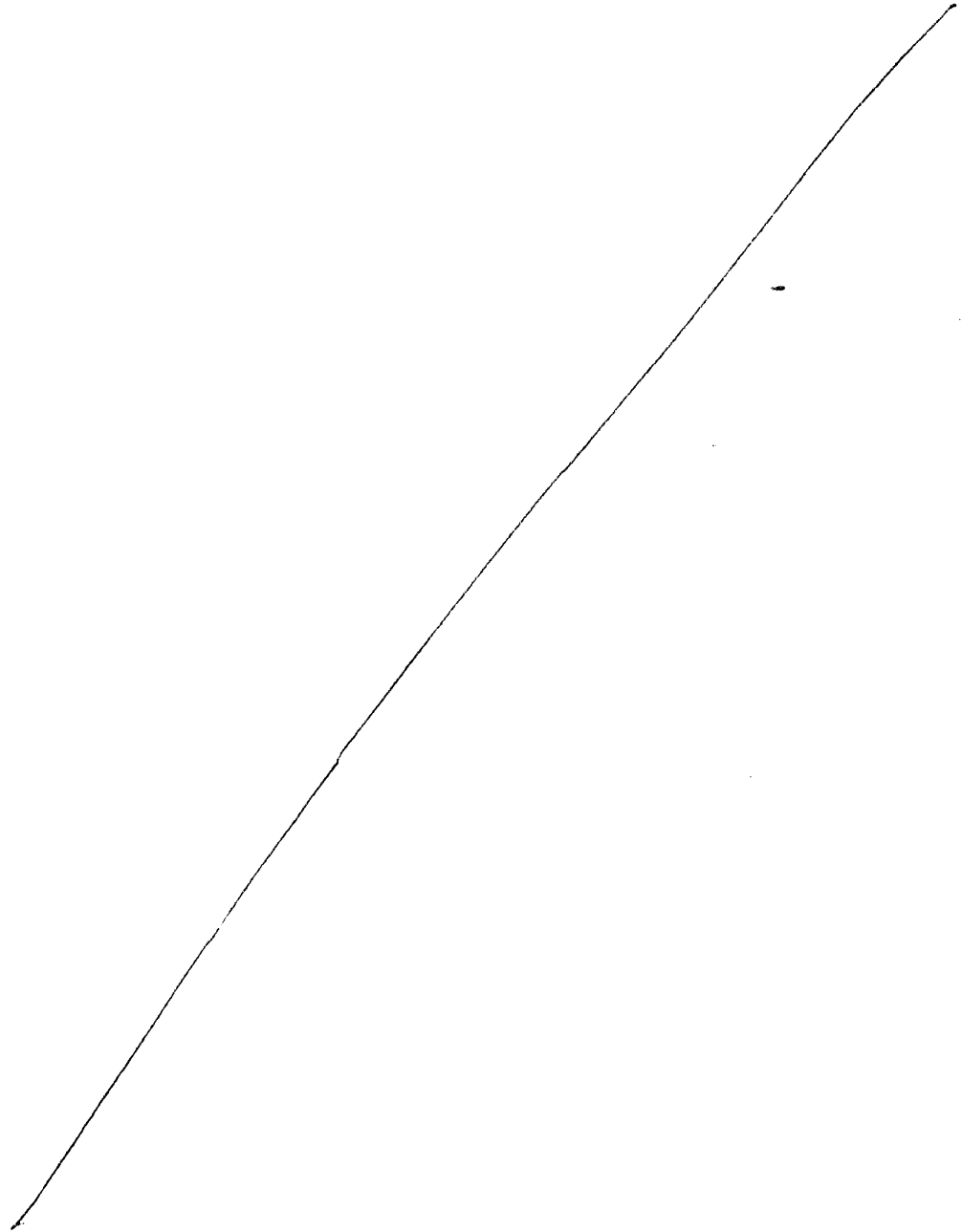
We have reviewed the material provided in your correspondence of November 12, 1999, submitted in response to deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of September 27 and October 15, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most issues. However, as detailed below, some issues remain or were raised during our review of the submitted material:



Dr. Hemphill
Page 2 of 4
12/10/99



Dr. Hemphill
Page 3 of 4
12/10/99



Dr. Hemphill
Page 4 of 4
12/10/99

The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP) upon receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to correct deficiencies may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the HHS Guidelines.

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 Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M14



COX NORTH • 1423 N. Jefferson Ave. • Springfield, MO 65802 • 417/269-3000

Page 1 of 2

LAB 0443

December 20, 1999

received
12/23/99 SDC

Susan Crumpton
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Subject: Maintenance Inspection 15 corrective actions from Dec. 10, 1999 letter.

Ms. Crumpton:

Please find enclosed documentation supporting corrective actions in regard to the above letter.

Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill". The signature is written in black ink and is positioned above the printed name.

W.D. Hemphill, Ph.D., DABFT



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 7, 2000

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the material provided in your correspondence of December 20, 1999, submitted in response to remaining deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of December 10, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the deficiencies raised.

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 Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M15



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 31, 2000

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete all corrective actions described in the critique and cover letter:

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



Dr. Hemphill
March 31, 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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Enclosure
cc: Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0443
Document No. Final

Laboratory: Cox Health Systems

Location: Springfield, MO

Document Reviewed: Application Form
 Inspection Report #M16 Date: 10 February 2000
 Other _____

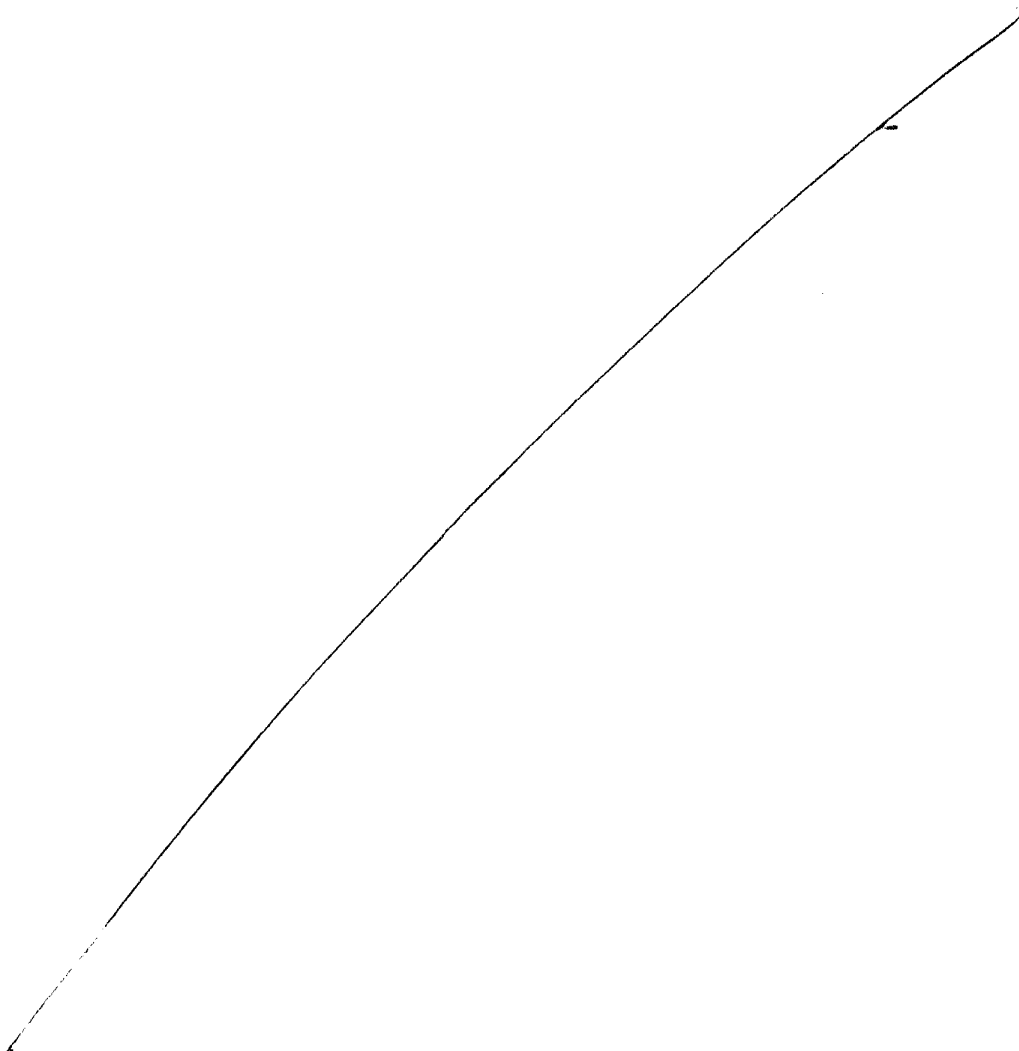
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



Toxicology phone: 417/269-3093 LAB 0443
fax: 417/269-8856

April 30, 2000

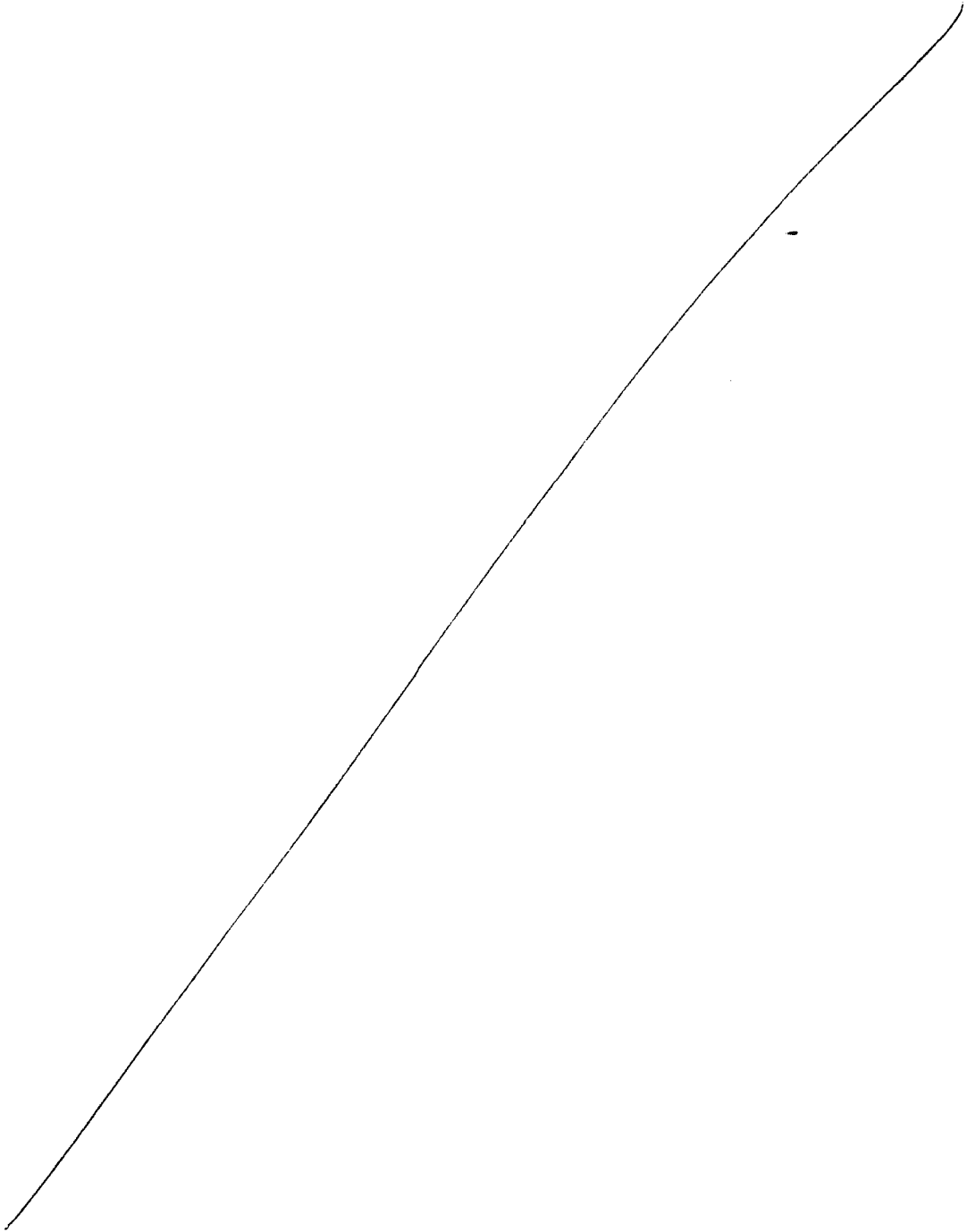
Deborah J. Denson
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

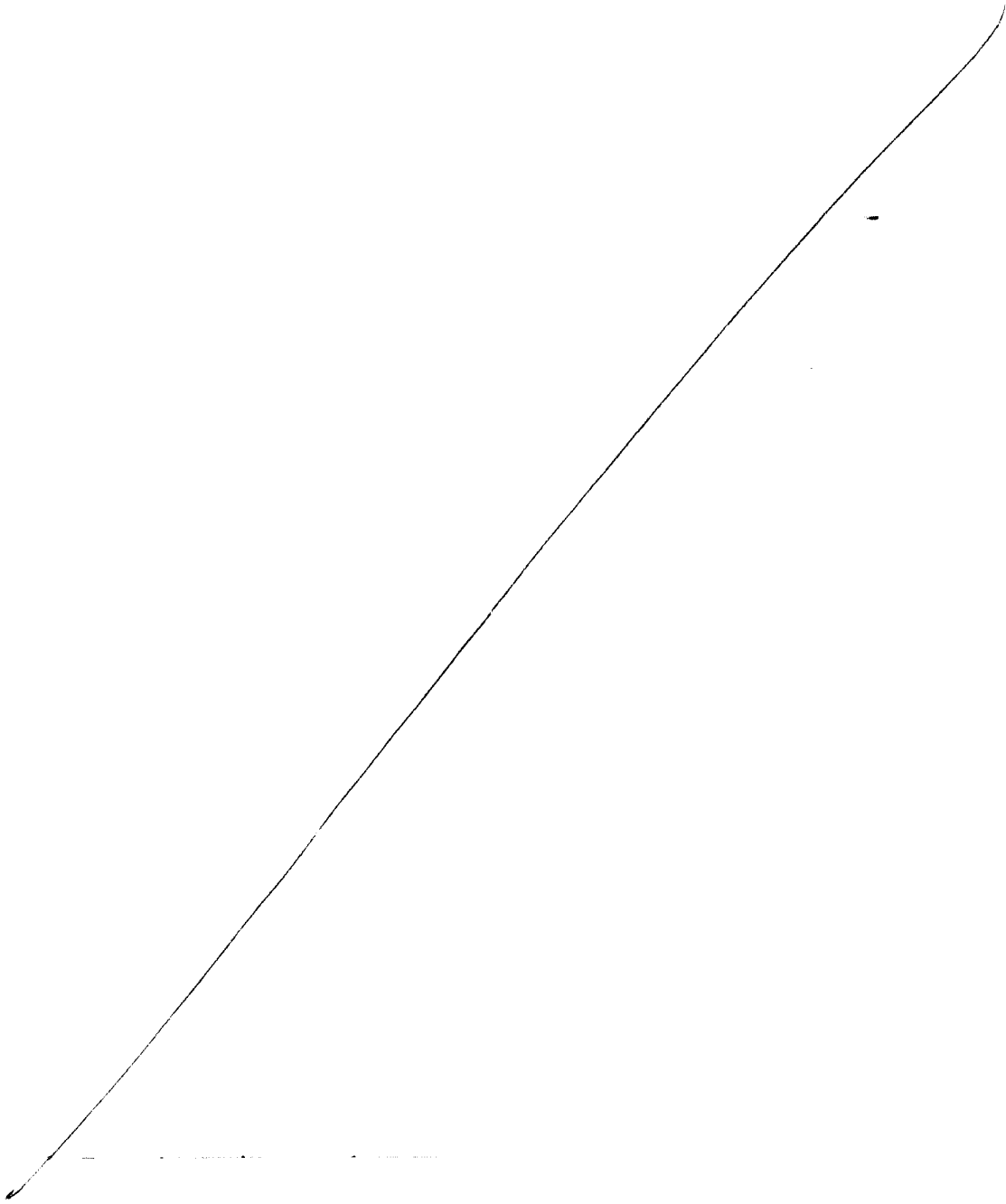
Subject: Maintenance Inspection 16, Corrective Actions

Ms. Denson:

Please find enclosed documentation supporting the corrective actions that have been put in place in regard to Maintenance Inspection 16. For SOPs that have had only a few changes, the changes are noted by use of *italics*. For SOPs that have had numerous changes, the entire SOP is enclosed.

E Standard Operating Procedures – Procedures Manual





Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill". The signature is written in black ink and is positioned above the printed name.

W.D. Hemphill, Ph.D., DABFT

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 16, 2000

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the material provided in your correspondence of April 30, 2000 (received May 11, 2000), submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of March 31, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

|

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory 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 Baylor, Ph.D. at (919) 541-7043.

Sincerely,

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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M16

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 17, 2000

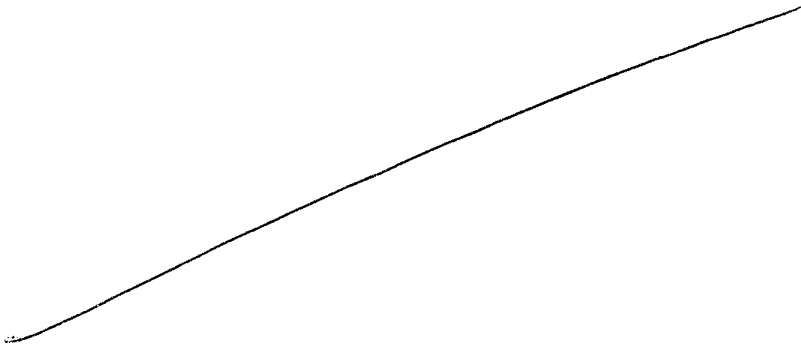
0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



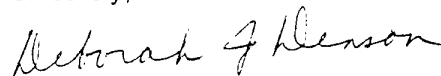
Dr. Hemphill
October 17, 2000
Page 2 of 2



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/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0443
Document No. Final

Laboratory: Cox Health Systems

Location: Springfield, MO

Document Reviewed: Application Form
 Inspection Report # M17
 Other _____

Date: 10 August 2000

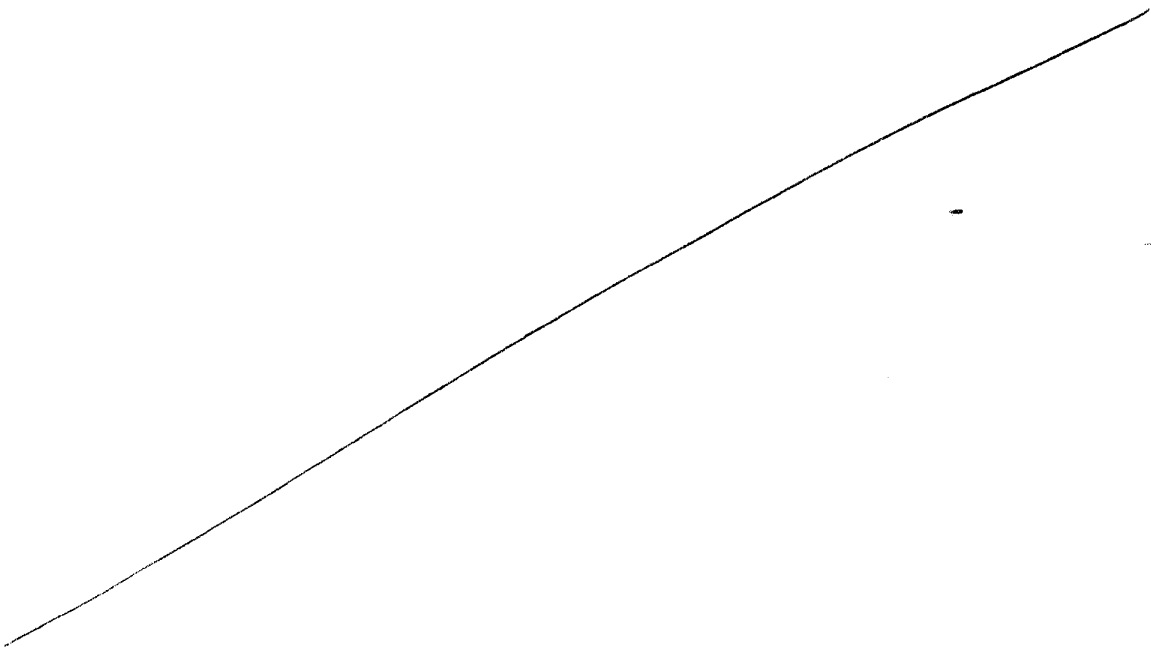
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

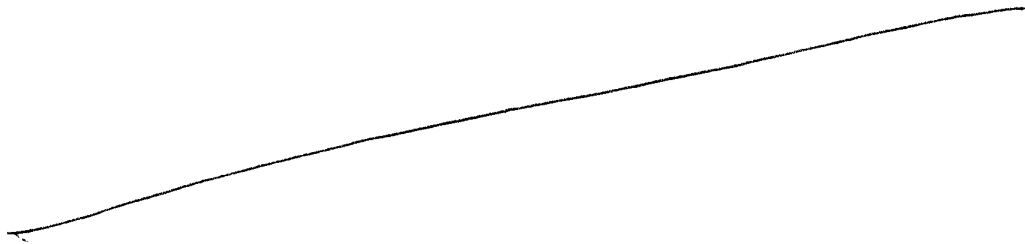
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



Toxicology phone: 417/269-3093 LAB 0443
fax: 417/269-8856

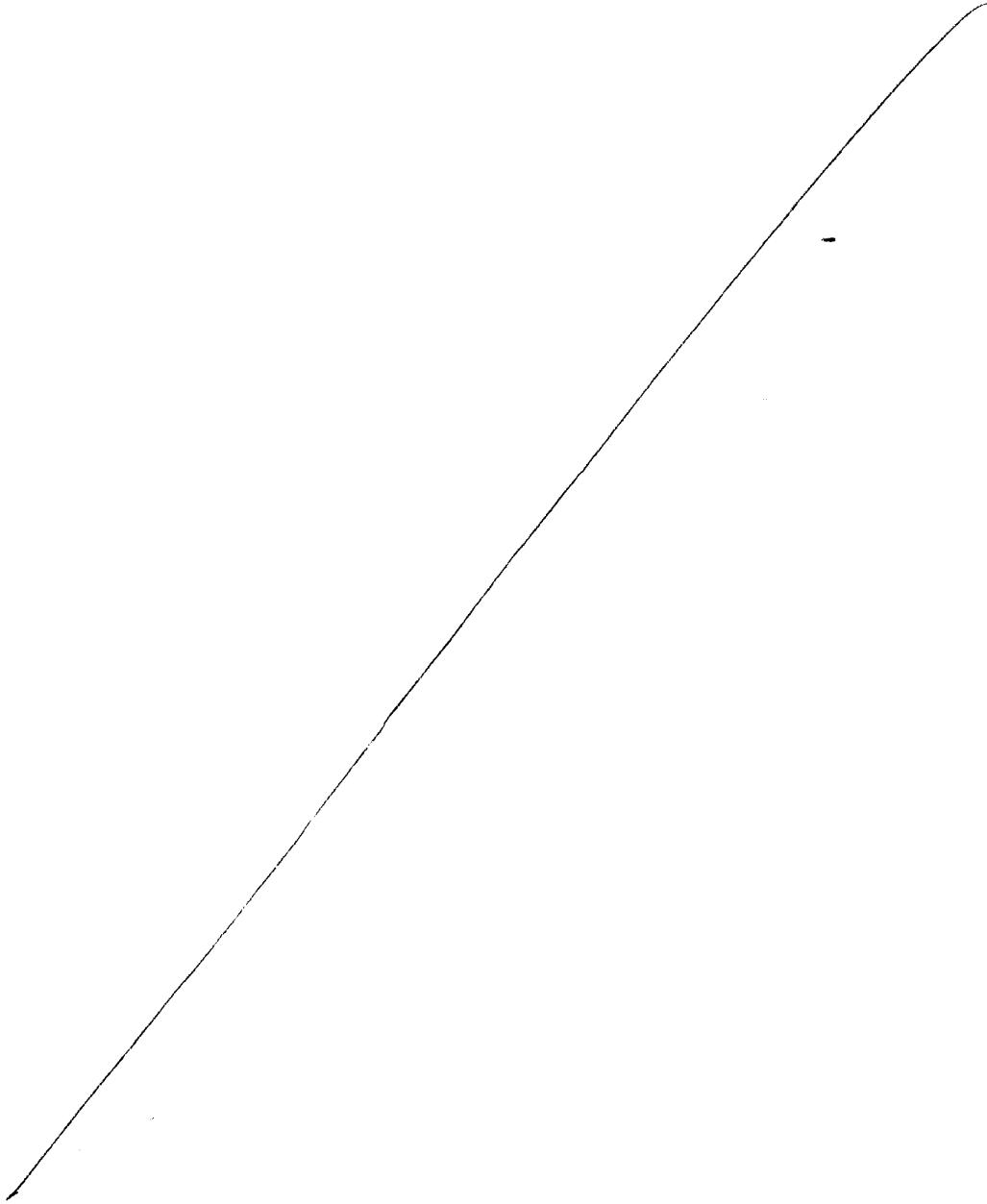
Nov 25, 2000

Deborah J. Denson
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Subject: Maintenance Inspection 17, Corrective Actions

Ms. Denson:

Please find enclosed documentation supporting the corrective actions that have been put in place in regard to Maintenance Inspection 17. For SOPs that have had only a few changes, the changes are noted by use of *italics*. For SOPs that have had numerous changes, the entire SOP is enclosed



Respectively,

A handwritten signature in cursive script, appearing to read "W.D. Hemphill".

W.D. Hemphill, Ph.D., DABFT



RESEARCH TRIANGLE INSTITUTE

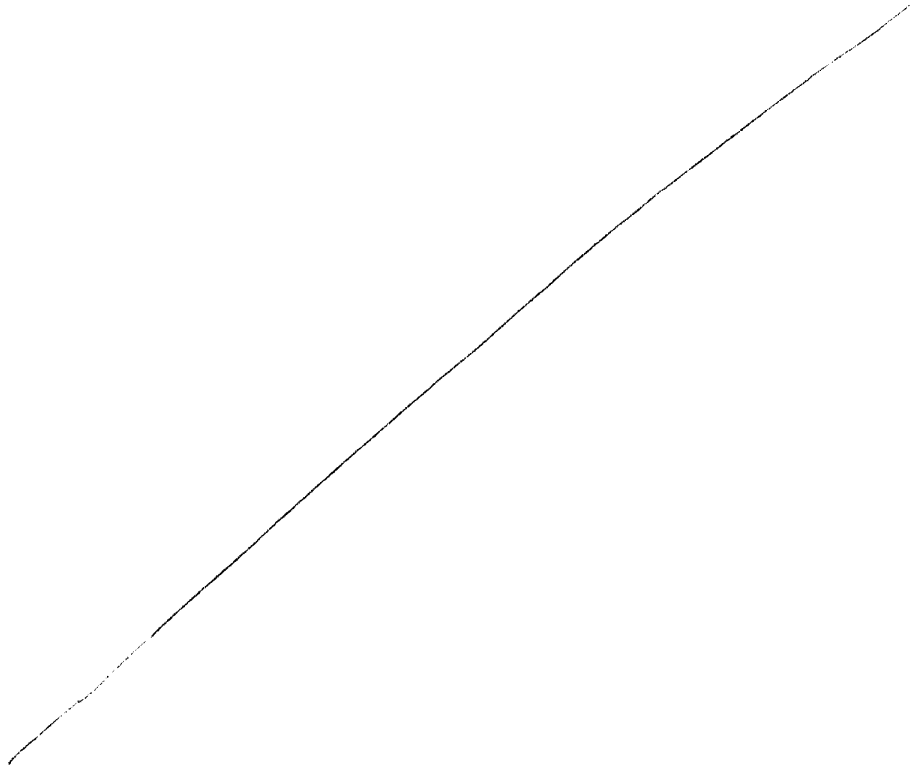
National Laboratory Certification Program

December 18, 2000

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the material provided in your correspondence of November 25, 2000, submitted in response to issues raised during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of October 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 summary of our review:



Dr. Hemphill
December 18, 2000
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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 Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/443