RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 25, 1999

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
University of Missouri Hospital & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

Dear Mr. Cary:

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 highly acceptable. However, the laboratory must correct/clarify the following issues raised:

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.

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194
Telephone 919-541-6709 • Fax 919-541-7042

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 D. Crumpton

Susan D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M15 Date: 3 December 1998
[ ] Other _____

Status: [XX] 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:

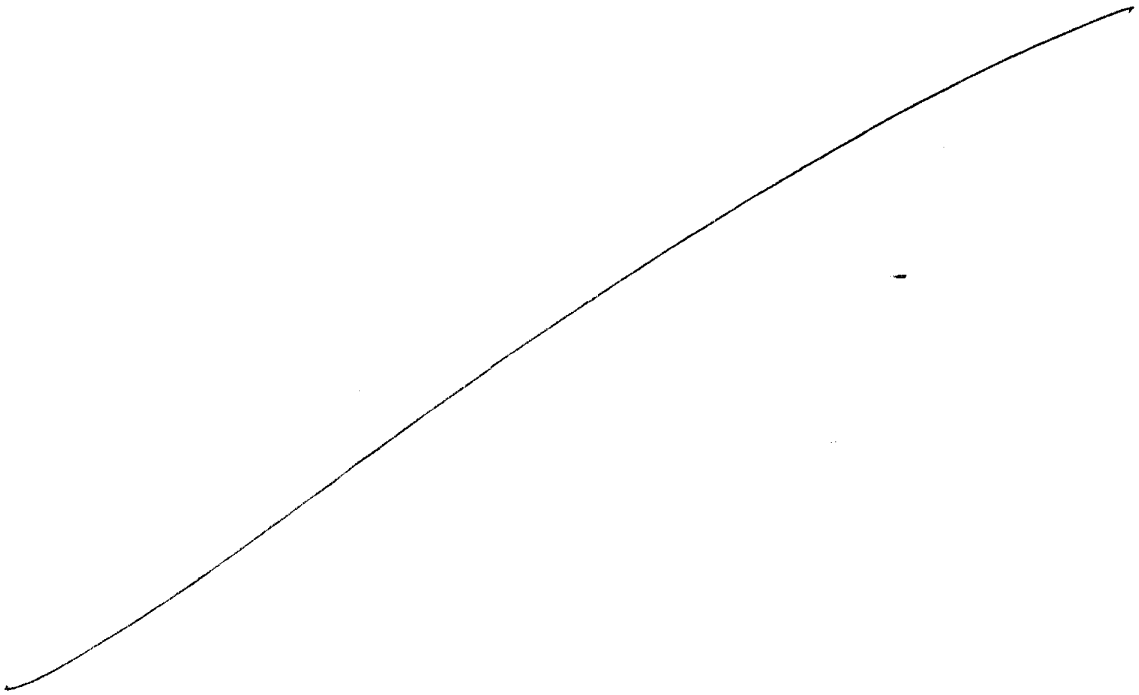
Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control

Section H. Initial Tests

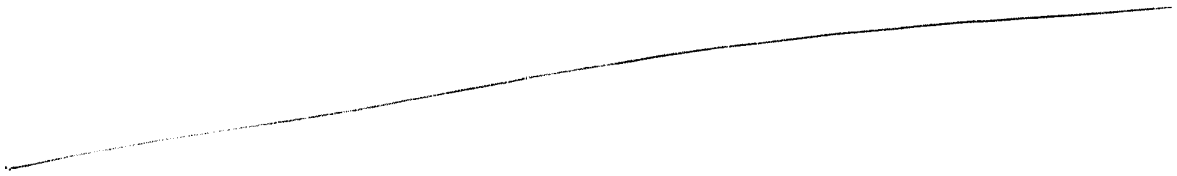
Section I. Confirmatory Tests



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 15, 1999

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
Univ. of MO Hosp & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

Dear Mr. Cary:

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 issues were raised:

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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 Inspection Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M16 Date: 10 June 1999
[ ] Other _____

Status: [XX] 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

January 12, 2000

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
Univ of MO Hosp & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

Dear Mr. Cary:

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.

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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 Inspection Analyst

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M17 Date: 9 December 1999
[ ] Other _____

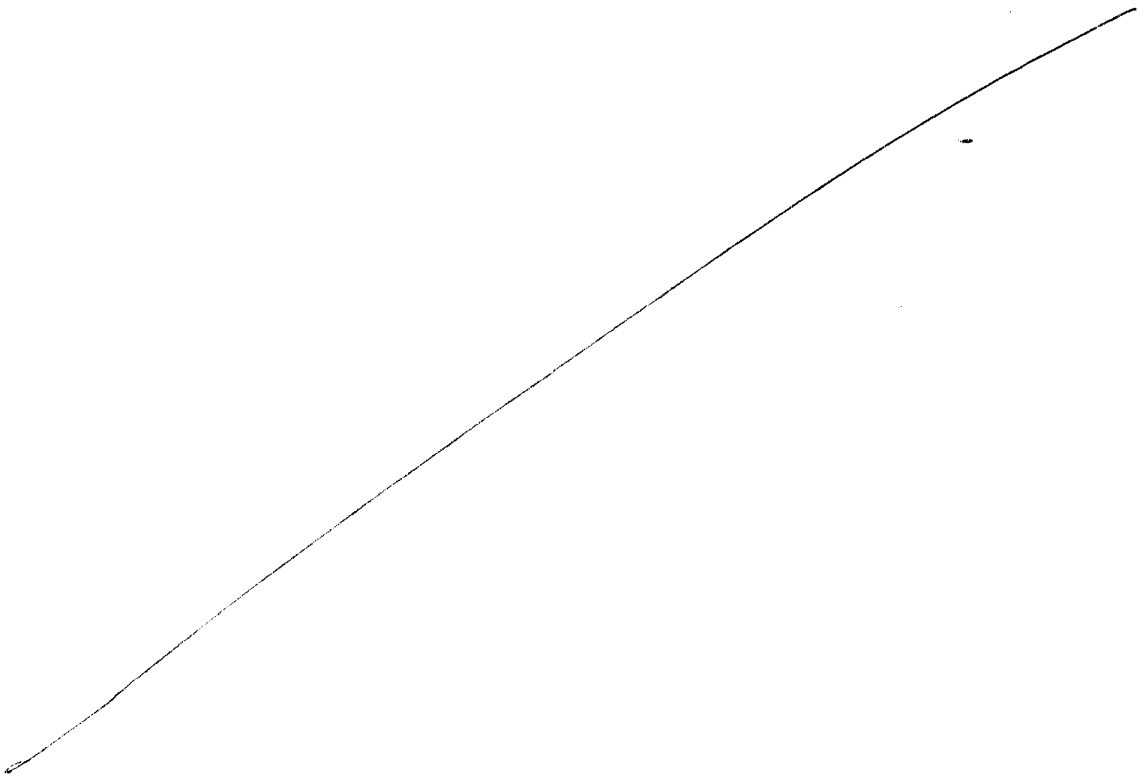
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

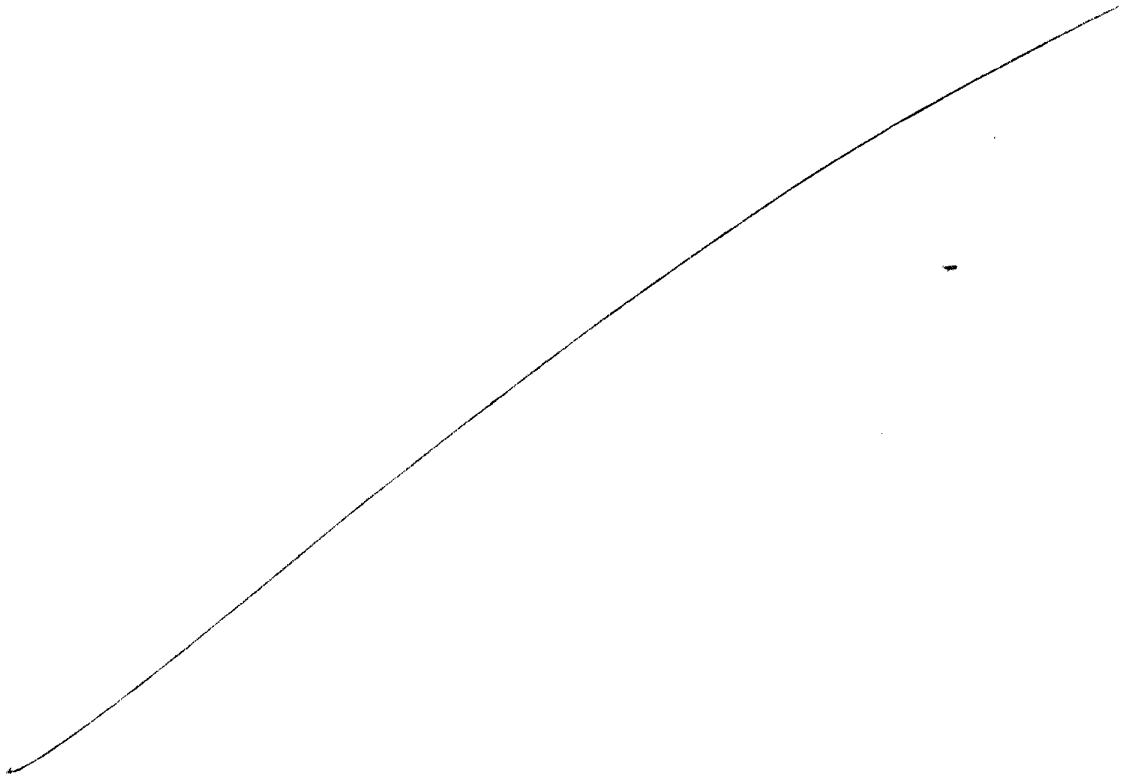


Section F. Chain-of-Custody, Accessioning, and Security

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 13, 2000

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
University of MO Hospital & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

Dear Mr. Cary:

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 this cover letter and attached critique.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the

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

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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M18

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M18 Date: 8 June 2000
[ ] Other _____

Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 5, 2001

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
University of Missouri Hospital & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

Dear Mr. Cary:

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 appeared to meet most of the minimum technical criteria. However, the laboratory must take steps to correct the following issues raised:

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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. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.***

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/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

Status:
[XX] 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