

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 9, 1999

0396
Dr. Robert Fomey
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Fomey and Mr. Darling:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the ninth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is 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 D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M9



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0396
Document No. Final

Laboratory: Medical College Hospitals Toxicology Laboratory

Location: Toledo, OH

Document Reviewed: Application Form
 Inspection Report #M9 Date: 21 January 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

August 16, 1999

0396

Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Forney and Mr. Darling:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the tenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

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/M10



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0396
Document No. Final

Laboratory: Medical College Hospitals Toxicology Laboratory

Location: Toledo, OH

Document Reviewed: Application Form
 Inspection Report #M10 Date: 22 July 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

0396
Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43614

Dear Dr. Forney and Mr. Darling:

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



Dr. Forney
Mr. Darling
Page 2 of 2
02/21/00

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/M11

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0396
Document No. Final

Laboratory: Medical College Hospitals Toxicology Laboratory

Location: Toledo, OH

Document Reviewed: Application Form
 Inspection Report #M11 Date: 20 January 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

3.

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

September 15, 2000

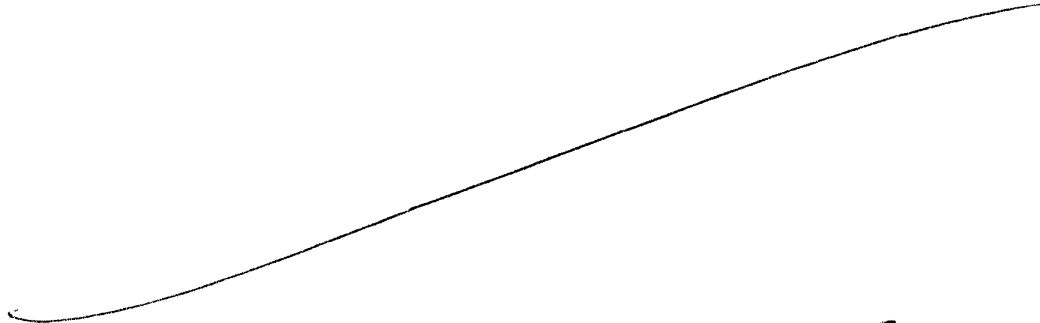
0396
Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Forney and Mr. Darling:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twelfth 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 take steps to correct the following issues raised:



Dr. Forney
Mr. Darling
Page 2 of 2
09/15/00



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

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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M12

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0396
Document No. Final

Laboratory: Medical College Hospitals Toxicology Laboratory

Location: Toledo, OH

Document Reviewed: Application Form
 Inspection Report #M12 Date: 27 July 2000
 Other _____

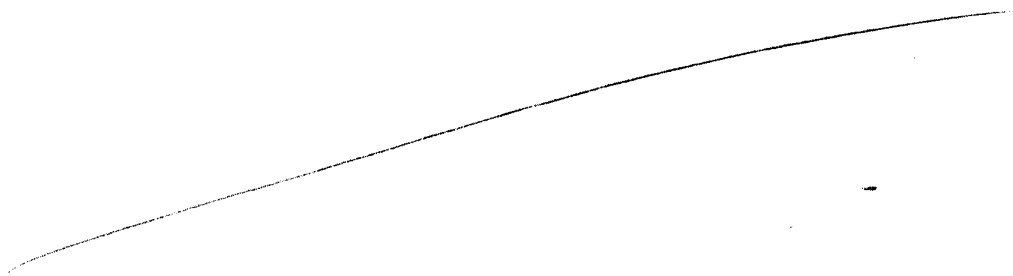
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

Department of Pathology

Medical College of Ohio
Hospital, Room 0102
3000 Arlington Avenue
Toledo, Ohio 43614-2598

Medical College of Ohio



Hospitals
Healing Begins with Knowledge

Toxicology
(419) 383-5213

received
SDC 10/16/00

October 12, 2000

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Re: Responses to Document Review and Critique
Laboratory Identification No. 0396

Dear Ms. Crumpton:

Attached are our responses to the NLCP Document Review and Critique report dated September 15, 2000, from the 12th maintenance inspection of our laboratory.

Thank you for your attention.

Very truly yours,

Robert B. Forney, Jr., Ph.D.

Encl.
RBF:jhs

S. Crumpton, NLCP Inspection Analyst

NIDA RESPONSES
OCTOBER 12, 2000

SECTION E STANDARD OPERATING PROCEDURES - PROCEDURE MANUAL

SECTION G QUALITY CONTROL

SECTION I CONFIRMATORY TESTS

SECTION J RECORDS AUDIT



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 23, 2000

0396
Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Forney and Mr. Darling:

We have reviewed the material provided in your correspondence of October 12, 2000, submitted in response to issues raised during the twelfth maintenance inspection of your laboratory as outlined in our correspondence of September 15, 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 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.



Dr. Forney
Mr. Darling
Page 2 of 2
10/23/00

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,

A handwritten signature in cursive script, appearing to read "Susan Crumpton".

Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M12