



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 13, 1998

0118
Dr. Kenneth K. Sun
Methodist Hospital Toxicology Services
Clarian Health Partners, Inc.
1701 North Senate Blvd. Room AG007F
Indianapolis, IN 46202

Dear Dr. Sun:

The enclosed critique was developed from the inspection reports of the two inspectors who conducted the thirteenth 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 issue raised:

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



Dr. Sun
Page 2 of 2
11/13/98

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/M13

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0118
Document No. Final

Laboratory: Methodist Hospital Toxicology Services of Clarian Health Partners, Inc.

Location: Indianapolis, IN

Document Reviewed: Application Form
 Inspection Report #M13 Date: 29 October 1998
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the two independent 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

[Redacted]

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

[Redacted]

Section G. Records Audit

[Redacted]

Section H. Personnel

[Redacted]

Section I. Reagents

[Redacted]

Section J. Quality Control and Standards

[Redacted]

Section K. Reporting

[Redacted]

Section L. Equipment and Maintenance

[Redacted]

Section M. Immunoassay

[Redacted]

Section N. Gas Chromatography/Mass Spectrometry

[Redacted]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

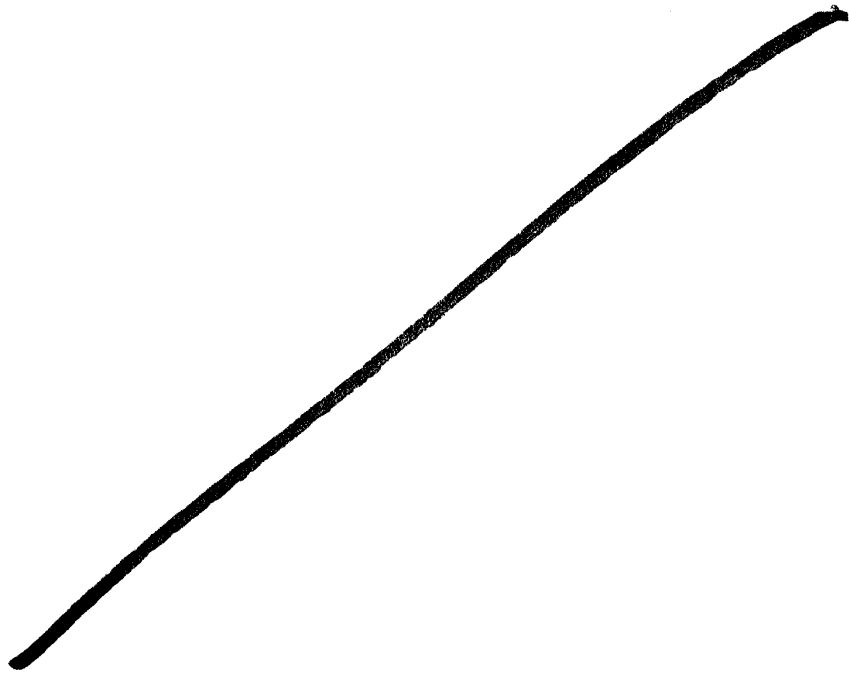
May 24, 1999

0118
Dr. Kenneth K. Sun
Methodist Hospital Toxicology Services
Clarian Health Partners, Inc.
1701 North Senate Blvd. Room AG007F
Indianapolis, IN 46202

Dear Dr. Sun:

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

G. The Quality Control section



Dr. Sun
Page 2 of 2
05/24/99

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.

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M14


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 01
Document No. Fin

Laboratory: Methodist Hospital Toxicology Services

Location: Indianapolis, IN

Document Reviewed: Application Form
 Inspection Report #M14 Date: 8 April 1999
 Other _____

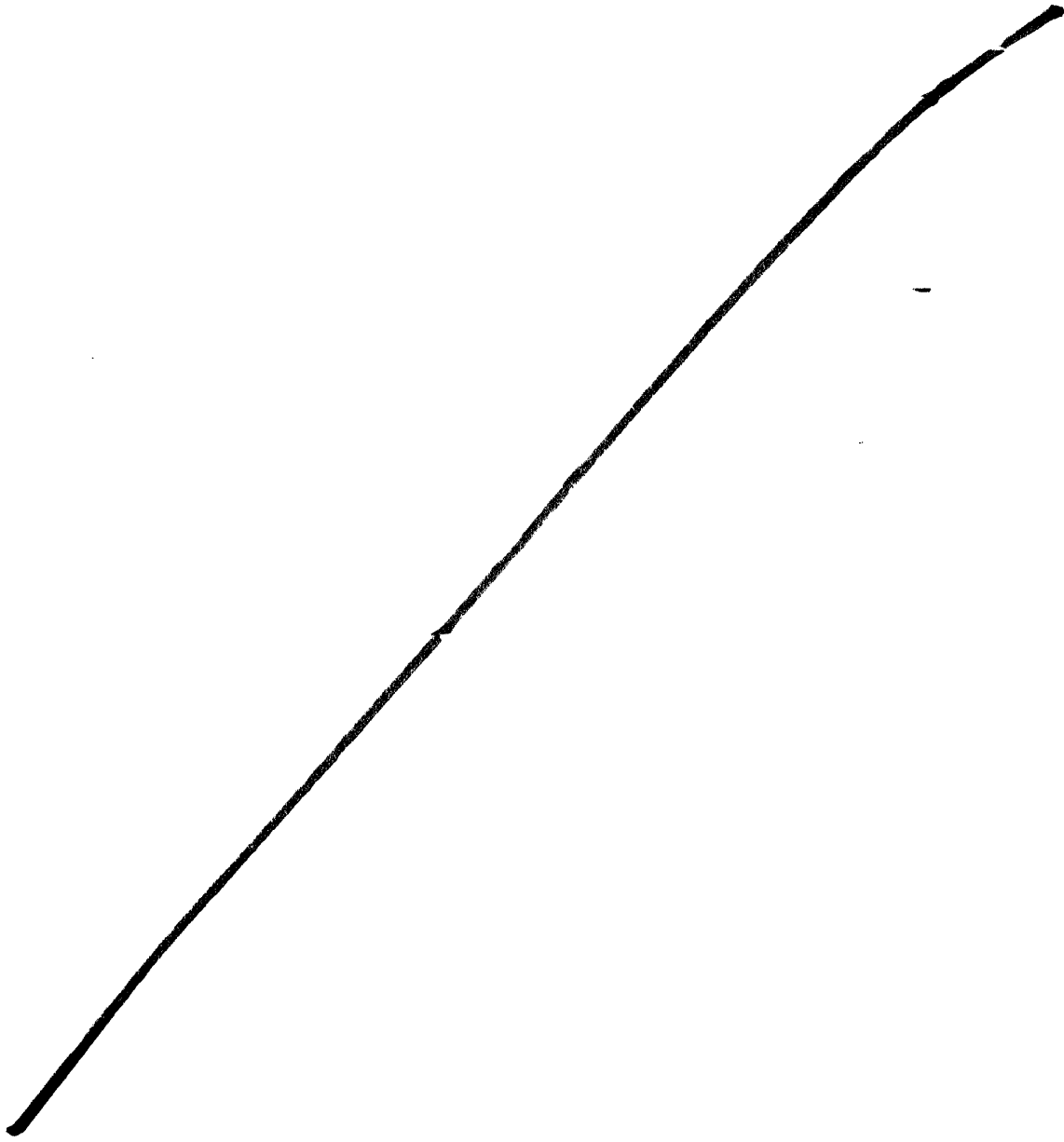
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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