

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 2, 1998

0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

Dear Dr. Gunaga:

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

Dr. Gunaga  
Page 2 of 2  
10/02/98

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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/M1

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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: 0240  
Document No. Final

Laboratory: Sparrow Health System

Location: Lansing, MI

Document Reviewed:     Application Form  
                               Inspection Report #M1                      Date: September 10, 1998  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                          Unacceptable                 Failure

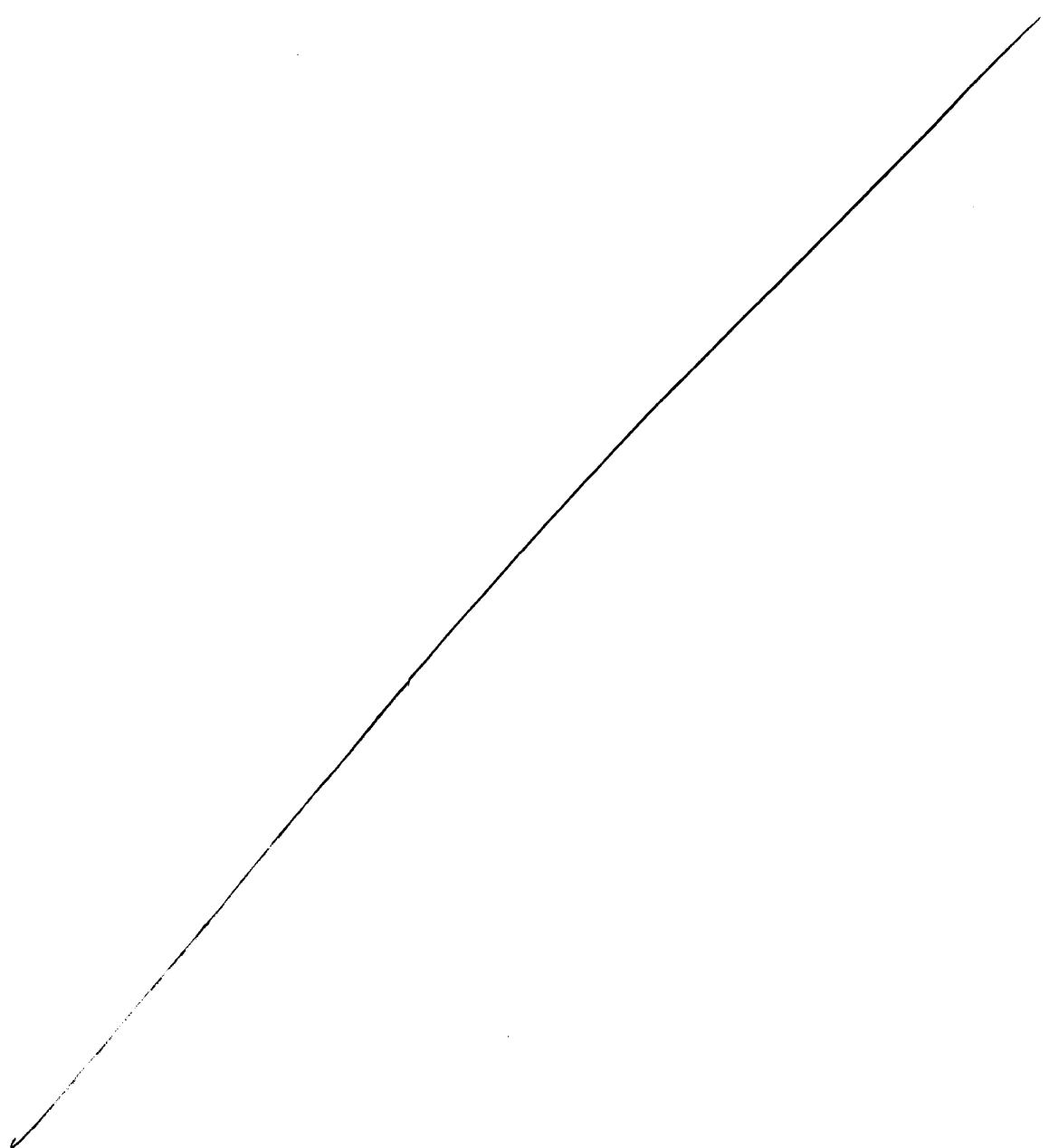
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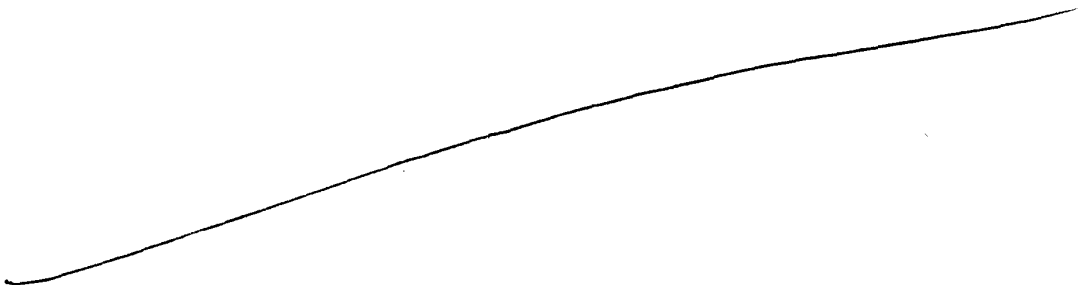
A review of the two independent National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

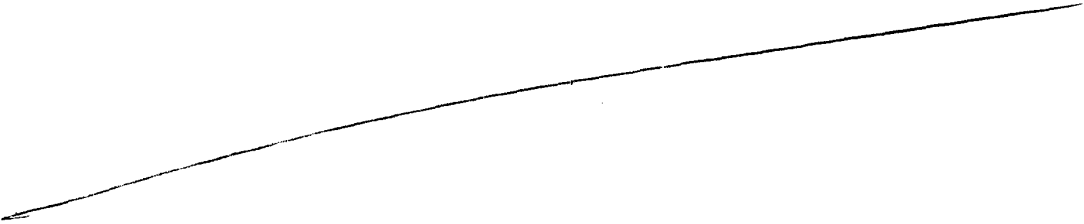
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





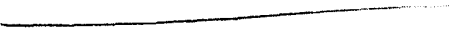
**Section F. Chain-of-Custody, Accessioning and Security**



**Section G. Records Audit**



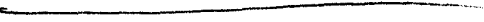
**Section H. Personnel**



**Section I. Reagents**



**Section J. Quality Control and Standards**



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**Section K. Reporting**

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**Section L. Equipment and Maintenance**

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**Section M. Immunoassay**

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**Section N. Gas Chromatography/Mass Spectrometry**

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 30, 1999

0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

Dear Dr. Gunaga:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the second 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/M2



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0240  
Document No. Final

Laboratory: Sparrow Health System, Toxicology Testing Center

Location: Lansing, MI

Document Reviewed:     Application Form  
                               Inspection Report #M2                      Date: 4 March 1999  
                               Other \_\_\_\_\_

Status:            Highly Acceptable            Acceptable  
                       Unacceptable                Failure

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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**

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**Section M. Equipment and Maintenance**

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**Section N. Personnel**

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0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

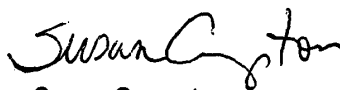
Dear Dr. Gunaga:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the third 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/M3



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0240  
Document No. Final

Laboratory: Sparrow Health System

Location: Lansing, MI

Document Reviewed:     Application Form  
                               Inspection Report #M3                    Date: 16 September 1999  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                          Unacceptable                 Failure

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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

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 30, 2000

0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

Dear Dr. Gunaga:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourth 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/or cover letter:

Dr. Gunaga  
March 30, 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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

Enclosure  
cc: Project Files/M4



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0240  
Document No. Final

Laboratory: Sparrow Health Systems

Location: Lansing, MI

Document Reviewed:      Application Form  
                               Inspection Report #M4     Date: 9 March 2000  
                               Other \_\_\_\_\_

Status:            Highly Acceptable      Acceptable  
                      Unacceptable            Failure

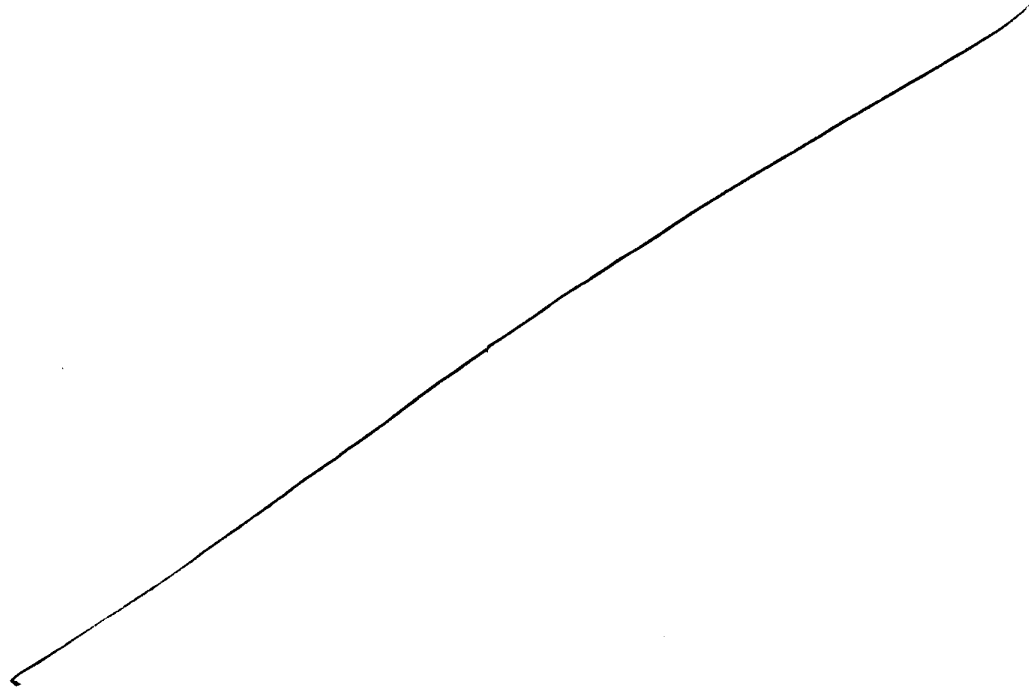
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Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

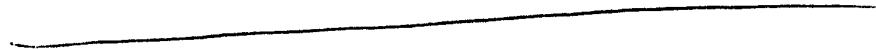
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



received  
5/3/00 DD

TOXICOLOGY  
TESTING CENTER

April 27, 2000

Deborah J. Denson  
NLCP Inspection Analyst  
3040 Cornwallis Road  
P.O. Box 12194  
Research Triangle Park, NC 27709-2194

RE: Lab #0240

Dear Ms. Denson:

Enclosed please find our response to the deficiencies cited during our fourth maintenance inspection under the National Laboratory Certification Program.

Section E. Standard Operating Procedures (SOP) Section

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

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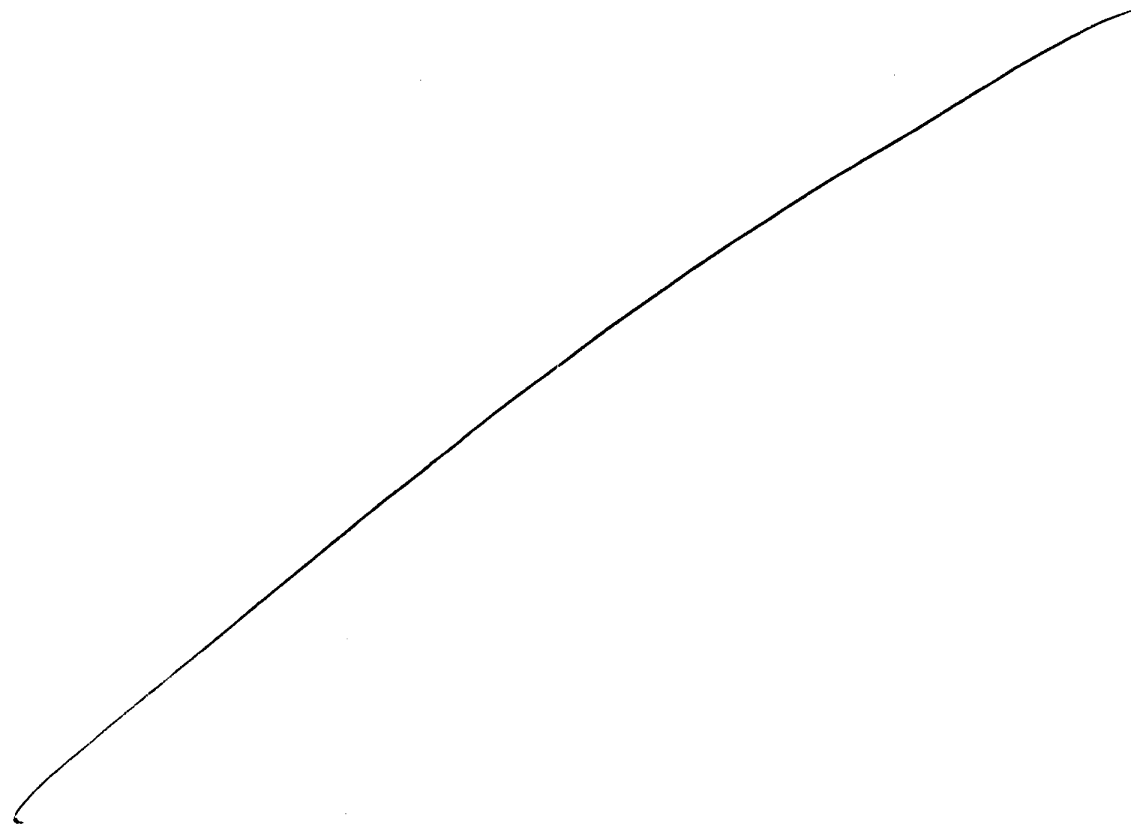
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St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915 • (517) 377-0520 Fax: (517) 377-0521

"A SAMHSA/CAP-FUDT Certified Laboratory"

Deborah J. Denson  
April 27, 2000  
Page 2 of 3



Section I. Confirmatory Tests Section



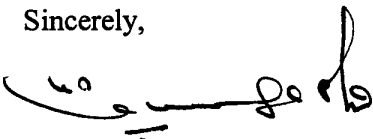
Deborah J. Denson  
April 27, 2000  
Page 3 of 3

J. Records Audit Section

We also reviewed all of the other enclosed critique and implemented the necessary corrective action.

If you have any questions please call me or Dale Dummer (ARP) at 517-377-0520.

Sincerely,



K.P. Gunaga, Ph.D.  
Director of Toxicology Testing Center

Enclosures



# RESEARCH TRIANGLE INSTITUTE

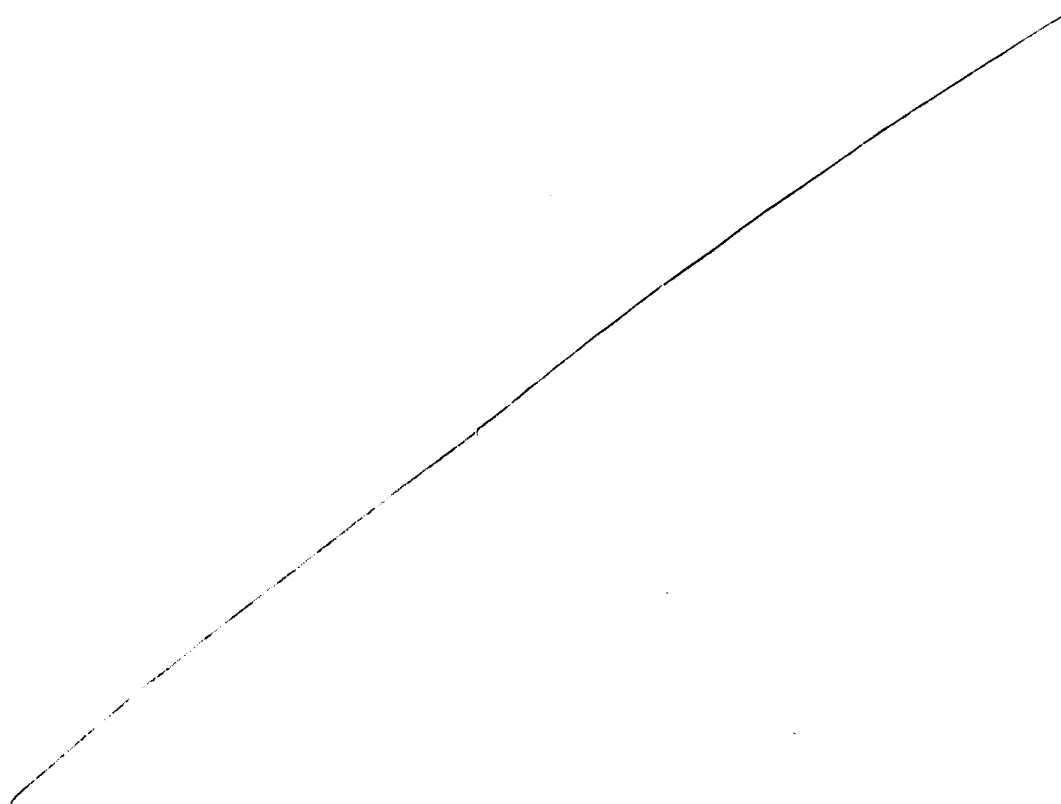
National Laboratory Certification Program

May 12, 2000

0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

Dear Dr. Gunaga:

We have reviewed the material provided in your correspondence of April 27, 2000, submitted in response to issues raised during the fourth maintenance inspection of your laboratory as outlined in our correspondence of March 30, 2000. The information submitted by the laboratory appears to demonstrate that appropriate actions have been completed to address the issues raised. The following is a summary of our review:





Dr. Gunaga  
May 12, 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 Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M4



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

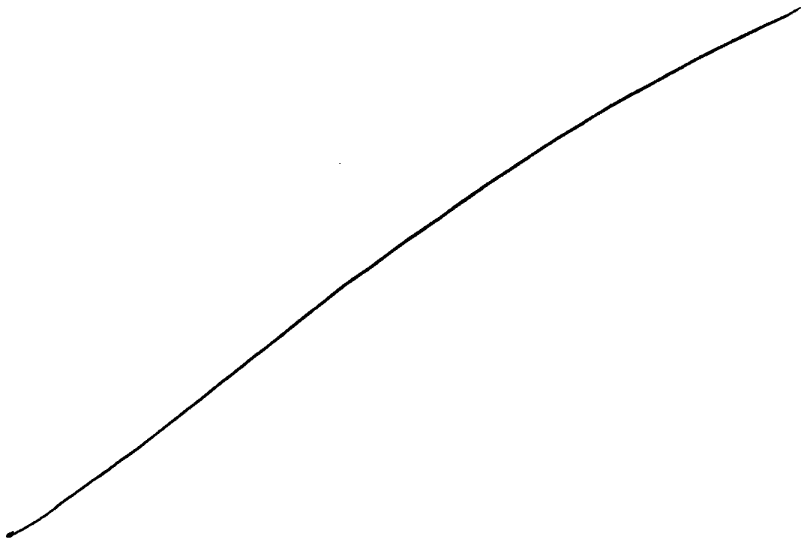
October 17, 2000

0240  
Dr. K.P. Gunaga  
Sparrow Health System  
Toxicology Testing Center  
1210 W. Saginaw  
Lansing, MI 48915

Dear Dr. Gunaga:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifth 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 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/M5

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0240  
Document No. Final

Laboratory: Sparrow Health System

Location: Lansing, MI

Document Reviewed:     Application Form  
                               Inspection Report #M5                    Date: 07 September 2000  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

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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

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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