

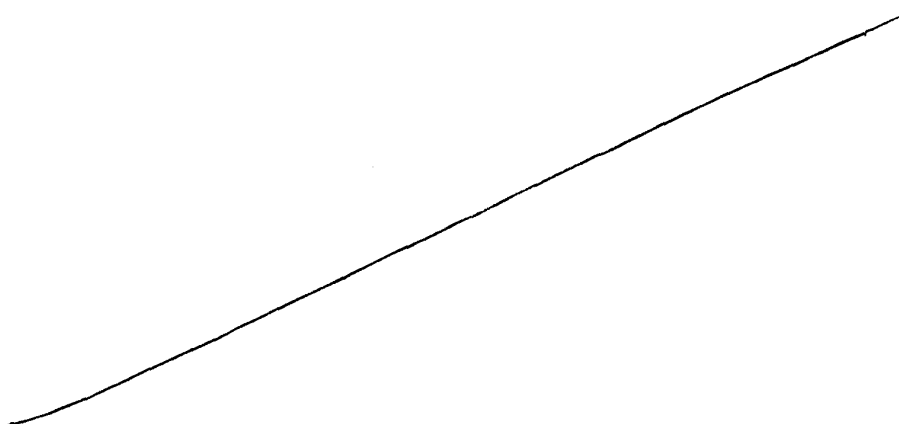
March 3, 1999

0160
Dr. Gary D. Carmack
Southwest Laboratories
2727 West Baseline Road
Suite 6
Tempe, AZ 85283

Dear Dr. Carmack:

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

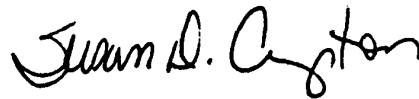




The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issue described in item 16b above. Once the issue has been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that your 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 of the 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 D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M11



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: Q160
Document No. Final

Laboratory: Southwest Laboratories

Location: Tempe, AZ

Document Reviewed: Application Form
 Inspection Report #M11 Date: 4 February 1999
 Other _____

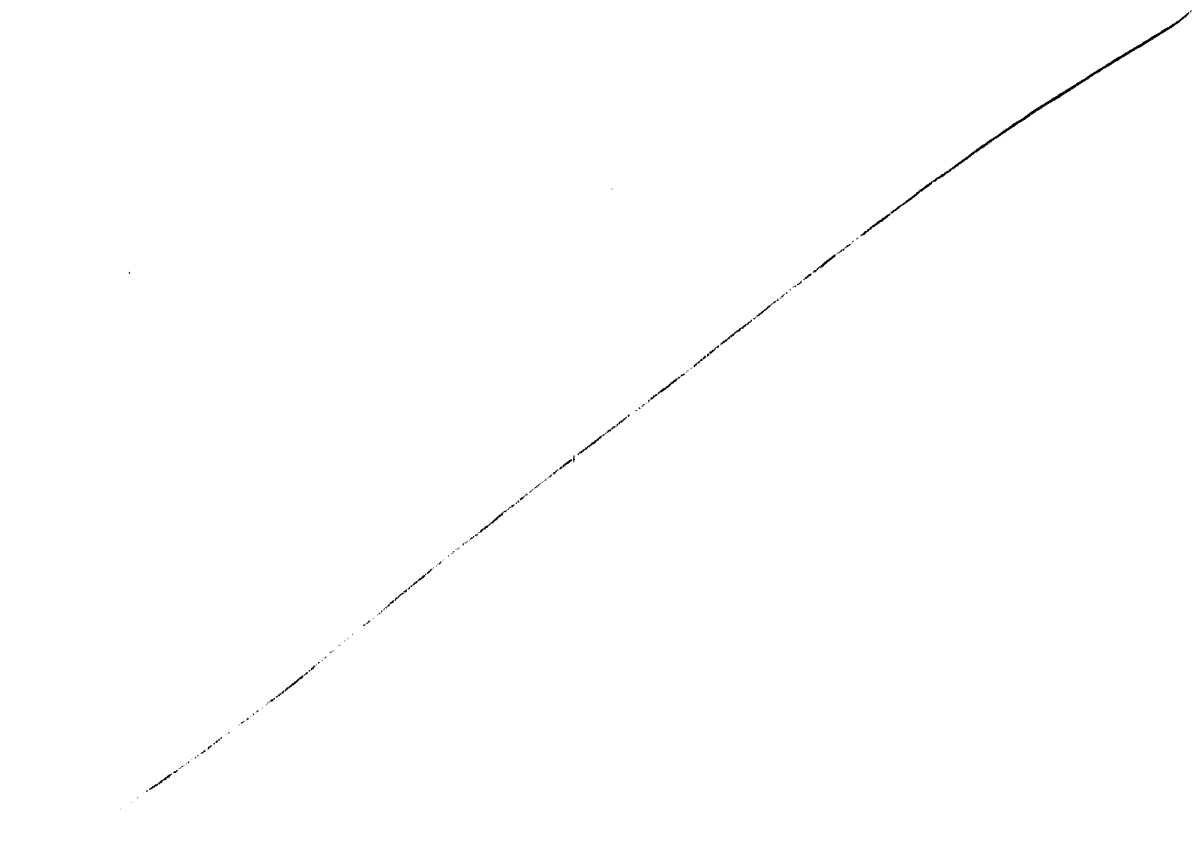
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



SOUTHWEST LABORATORIES



March 30, 1999

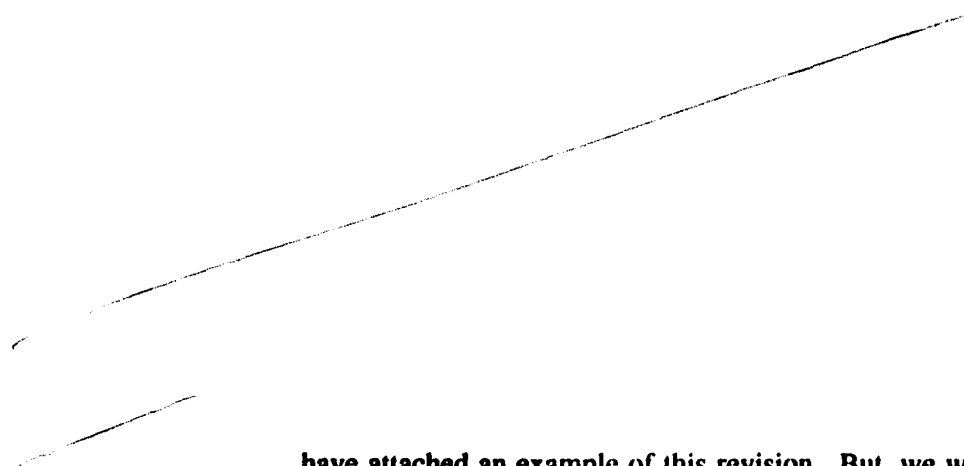
Ms. Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 37709

Main Office
2727 W. Baseline Road
Suite 1
Tempe, Arizona 85283
(602) 438-8507

Las Vegas
1973 N. Nellis Boulevard
Suite 233
Las Vegas, Nevada 89111

Dear Ms. Crumpton:

With regard to your last inspection critique (March 3, 1999) we are aware of the guidance


have attached an example of this revision. But, we would like to discuss this issue further with the RTI staff at a later date.

Sincerely,

Gary D. Carmack
Laboratory Director



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 6, 1999

0160
Dr. Gary D. Carmack
Southwest Laboratories
2727 West Baseline Road
Suite 6
Tempe, AZ 85283

Dear Dr. Carmack:

We have reviewed the material provided in your correspondence of March 30, 1999, submitted in response to an issue raised during the eleventh maintenance inspection of your laboratory as outlined in our correspondence of March 3, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issue.

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. The implementation of 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 Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M11



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

September 9, 1999

0160
Dr. Gary D. Carmack
Southwest Laboratories
2727 West Baseline Road
Suite 6
Tempe, AZ 85283

Dear Dr. Carmack:

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.

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,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M12



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0160
Document No. Final

Laboratory: Southwest Laboratories

Location: Tempe, AZ

Document Reviewed: Application Form
 Inspection Report #M12 Date: 5 August 1999
 Other _____

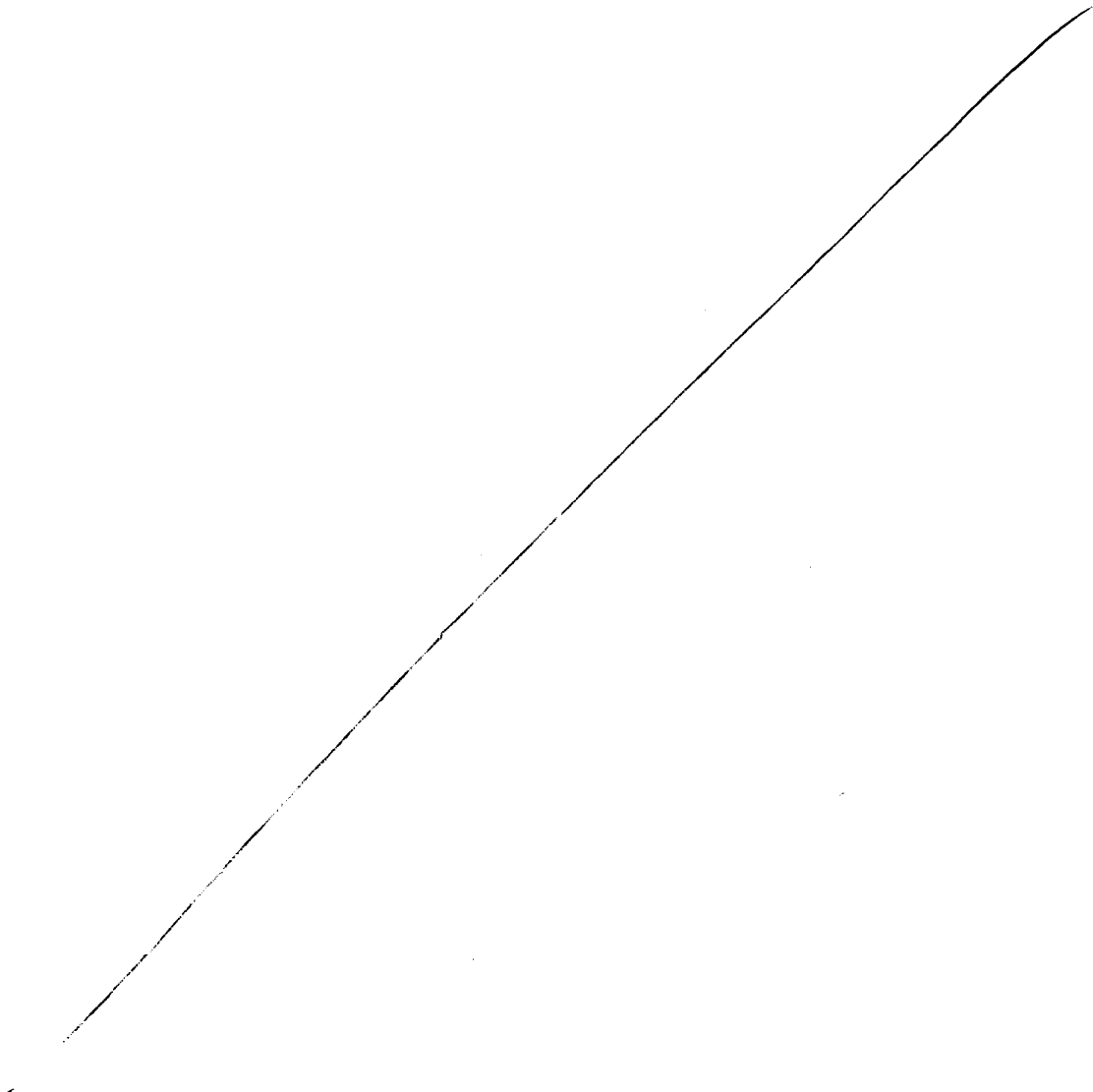
Status: Highly Acceptable Acceptable
 Unacceptable Failure

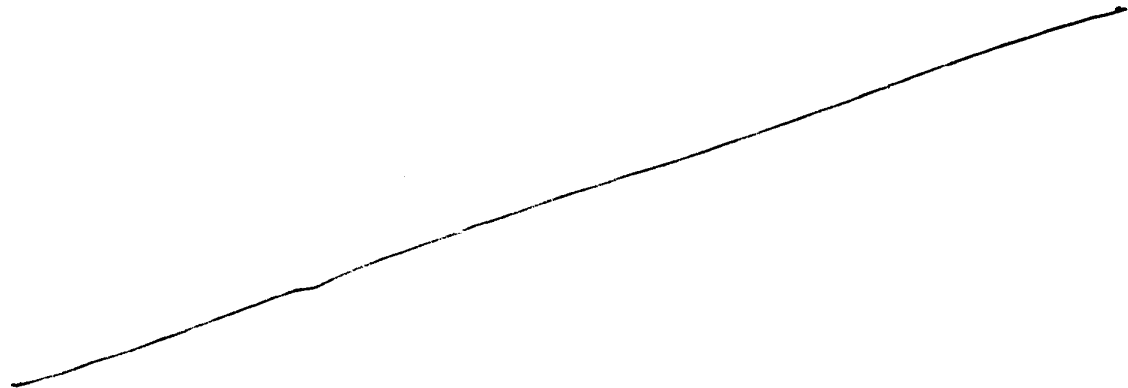
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

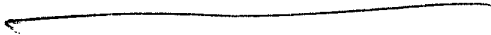




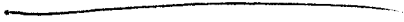
Section F. Chain-of-Custody, Accessioning, and Security



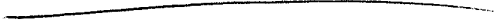
Section G. Quality Control



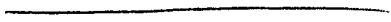
Section H. Initial Tests



Section I. Confirmatory Tests



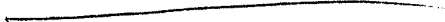
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 1, 2000

0160
Dr. Gary D. Carmack
Southwest Laboratories
2727 West Baseline Road
Suite 6
Tempe, AZ 85283

Dear Dr. Carmack:

The enclosed critique was developed from the inspection reports of the 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. 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.



Dr. Carmack
March 1, 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/M13

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0160
Document No. Final

Laboratory: Southwest Laboratories

Location: Tempe, AZ

Document Reviewed: Application Form
 Inspection Report #M13 Date: 3 February 2000
 Other _____

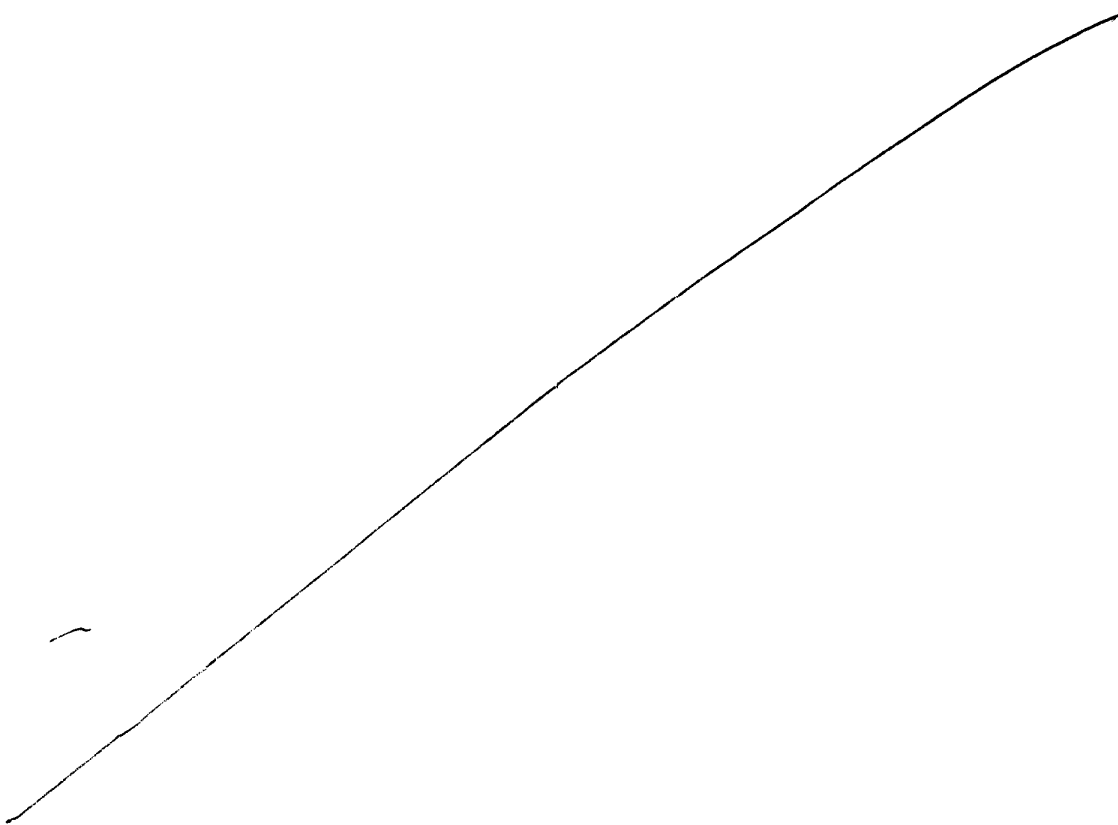
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

September 25, 2000

0160
Dr. Gary D. Carmack
Southwest Laboratories
2727 West Baseline Road
Suite 6
Tempe, AZ 85283

Dear Dr. Carmack:

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. 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

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

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M14



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0160
Document No. Final

Laboratory: Southwest Laboratories

Location: Tempe, AZ

Document Reviewed: Application Form
 Inspection Report #M14 Date: 3 August 2000
 Other _____

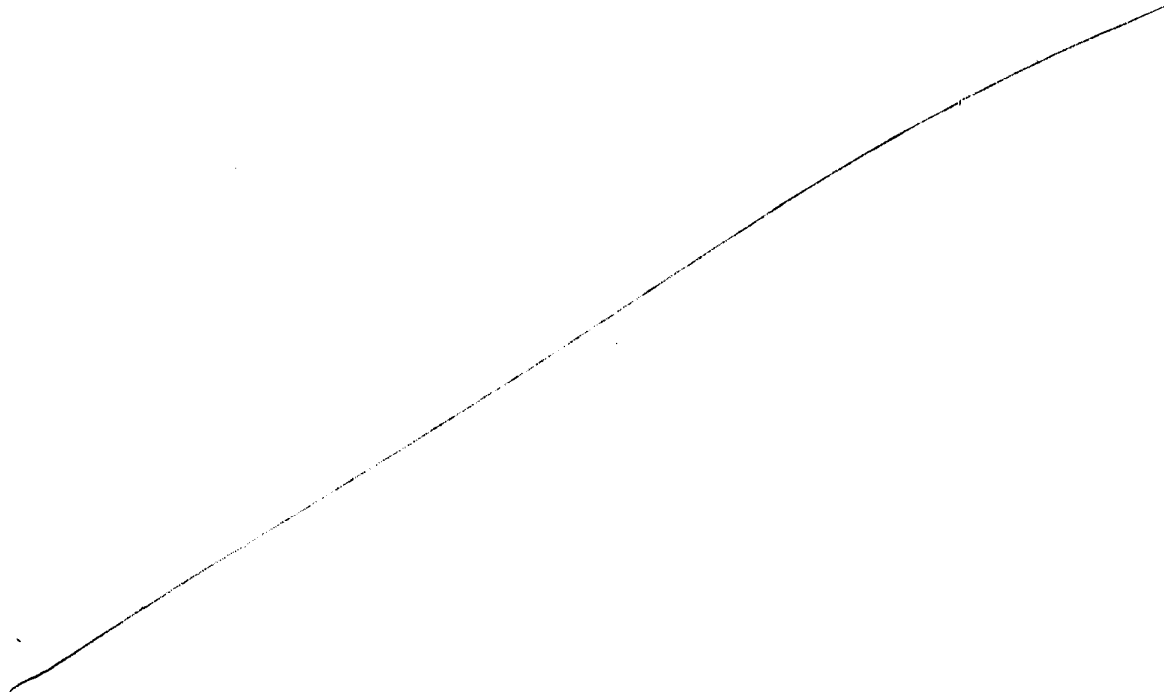
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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
