

October 1, 1998

0006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

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

E. The Standard Operating Procedures (SOP) section [

G. The Records Audit section:

N. The Gas Chromatography/Mass Spectrometry section:

Mr. Fortner  
October 1, 1998  
Page 2 of 2

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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.

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

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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: C006  
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Menlo Park, CA

Document Reviewed:     Application Form  
                               Inspection Report #M17                    Date: 10 September 1998  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

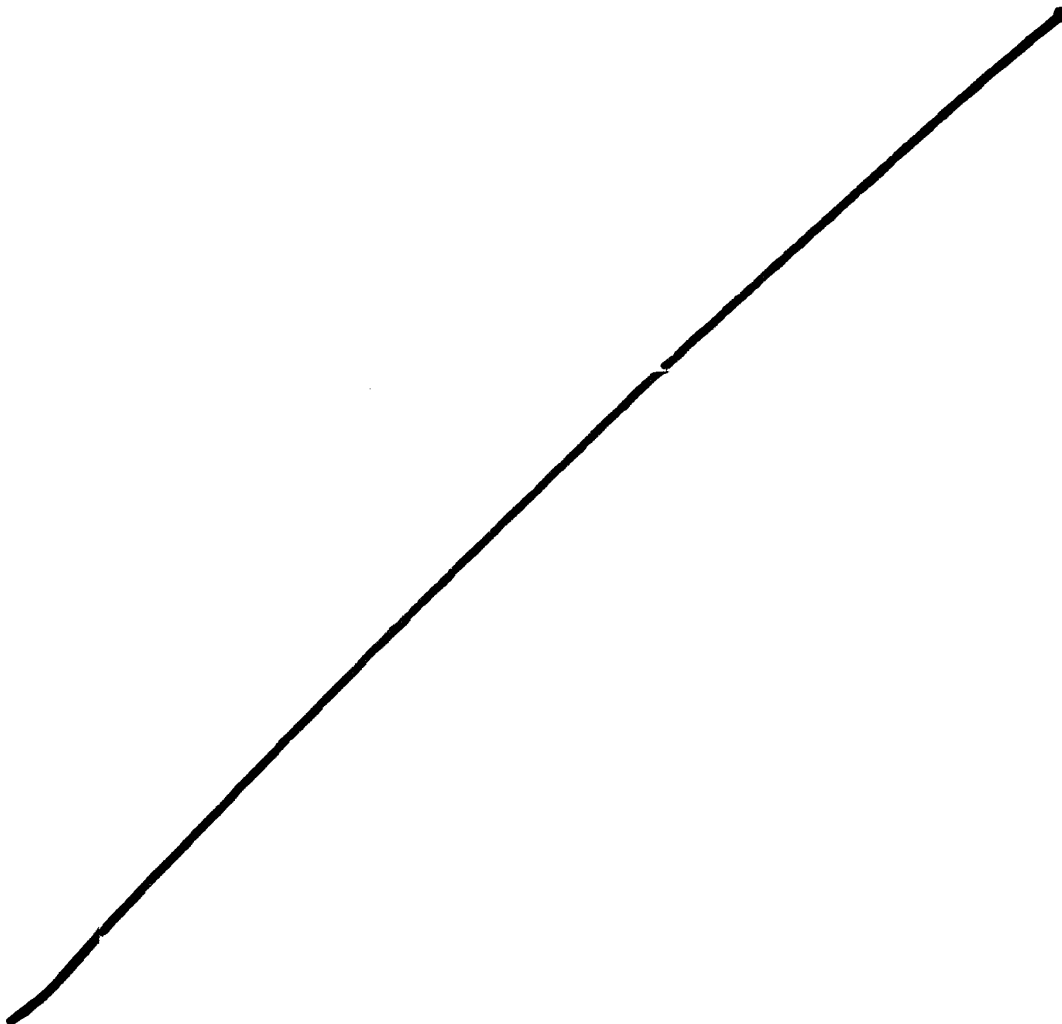
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Inspection reports, from the three inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards 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. Records Audit

[REDACTED]

Section H. Personnel

[REDACTED]

Section I. Reagents

[REDACTED]

Section J. Quality Control and Standards

[REDACTED]

Section K. Reporting

[REDACTED]

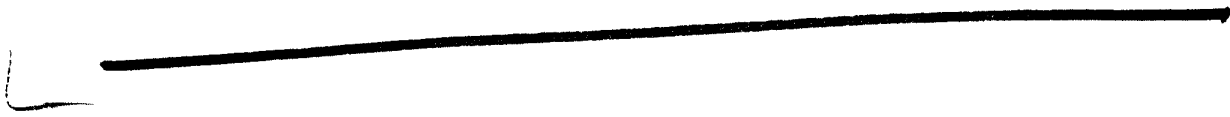
Section L. Equipment and Maintenance

[REDACTED]

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Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



**IPHILFRIN CHEM**  
**LABORATORIES, INC.**

Rec'd 11/3/98  
SDC

1505A O'Brien Drive  Menlo Park, California 94025-1435  (650) 328-6200  Fax: (650) 688-1122

October 30, 1998

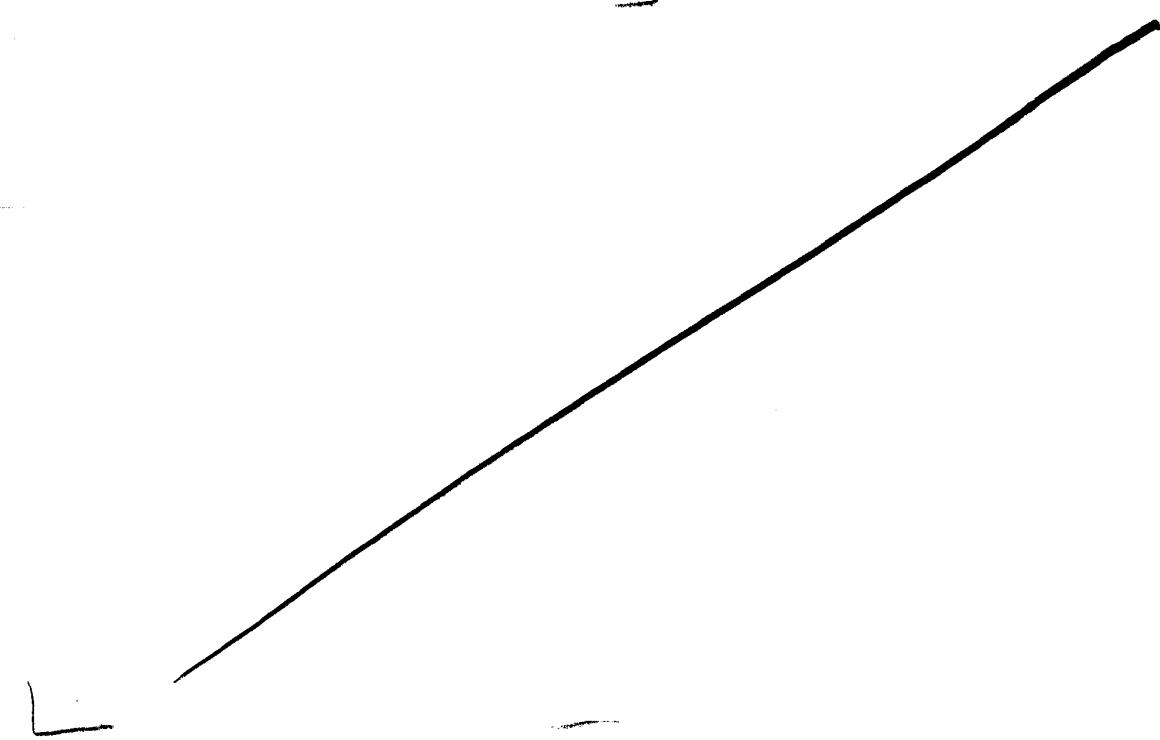
Susan Crumpton  
NLCP Inspection Analyst  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton,

In response to your letter dated October 1, 1998 regarding our seventeenth maintenance inspection, I am providing the following information.

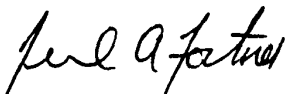
[Redacted content]





If I can be of further assistance, or should you have any questions, please call me at 1-800-446-5177, extension 217.

Sincerely,



Neil A. Fortner  
Vice President, Laboratory Operations  
Fax (650) 463-7517  
Email [neil\\_fortner@pharmchem.com](mailto:neil_fortner@pharmchem.com)



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 29, 1999

006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

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. However, the following issues were raised:

E. The Standard Operating Procedures (SOP) section ;

H. The Initial Test section  
issue was raised:

I. The Confirmatory Test section

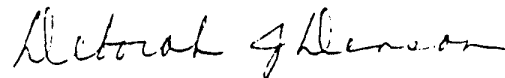
Mr. Fortner  
March 31, 1999  
Page 2 of 2

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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/M18

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0006  
Document No. Final

Laboratory: PharmChem Laboratories

Location: Menlo Park, CA

Document Reviewed:     Application Form  
                               Inspection Report # M18                      Date: March 4, 1999  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable                    Acceptable  
                               Unacceptable                        Failure

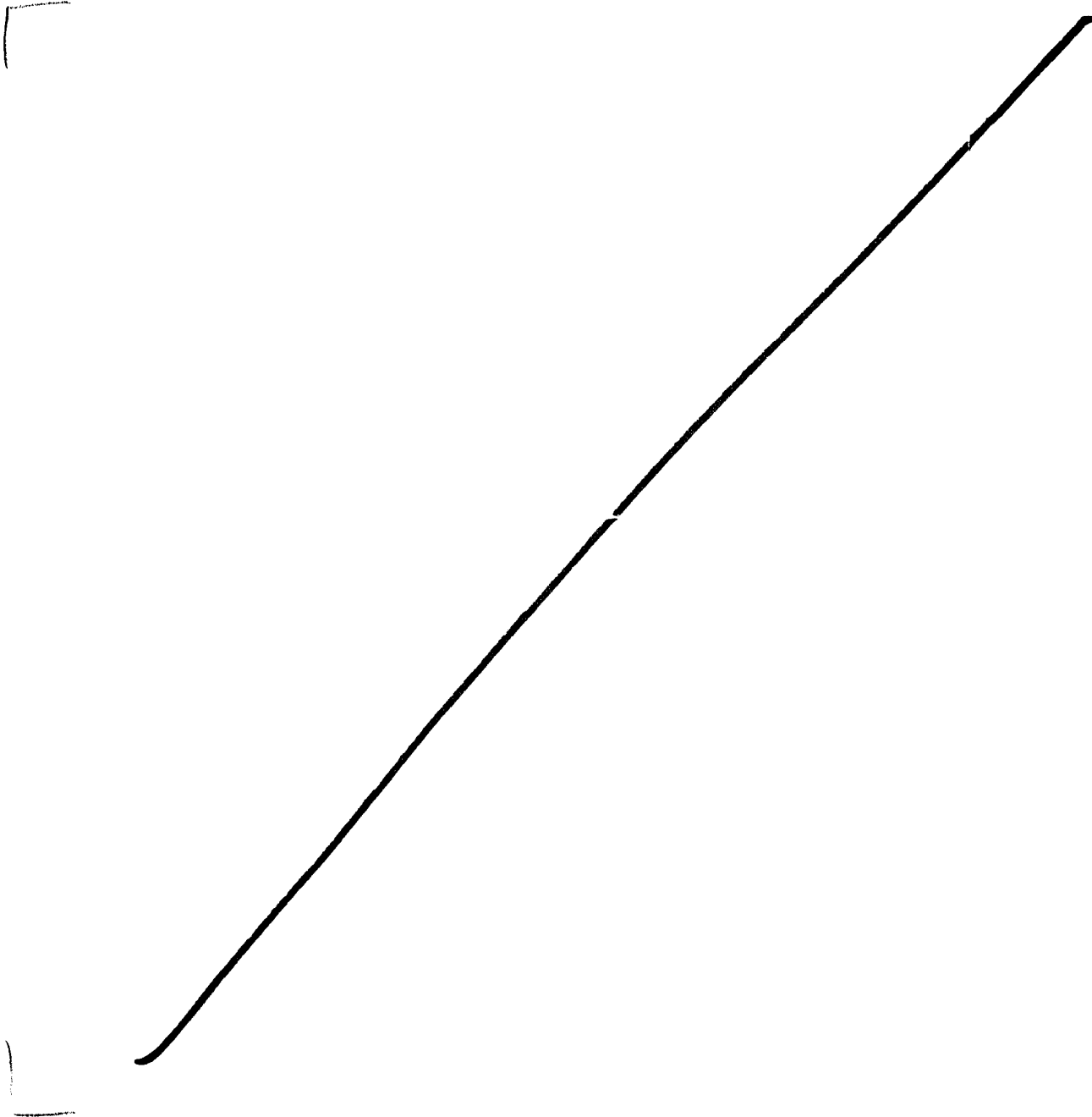
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

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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

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 12, 1999

0006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

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

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





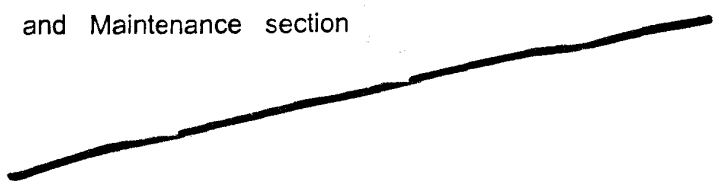
G. The Quality Control section



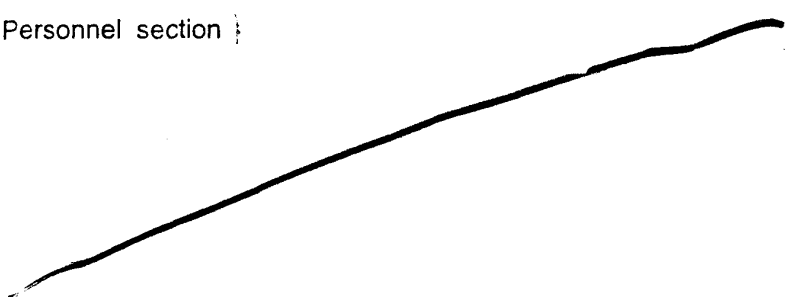
J. The Records section



M. The Equipment and Maintenance section



N. The Personnel 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

Mr. Fortner  
Page 3 of 3  
11/12/99

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/M19



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0006  
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Menlo Park, CA

Document Reviewed:      Application Form  
                               Inspection Report #M19     Date: 30 September 1999  
                               Other \_\_\_\_\_

Status:            Highly Acceptable      Acceptable  
                      Unacceptable            Failure

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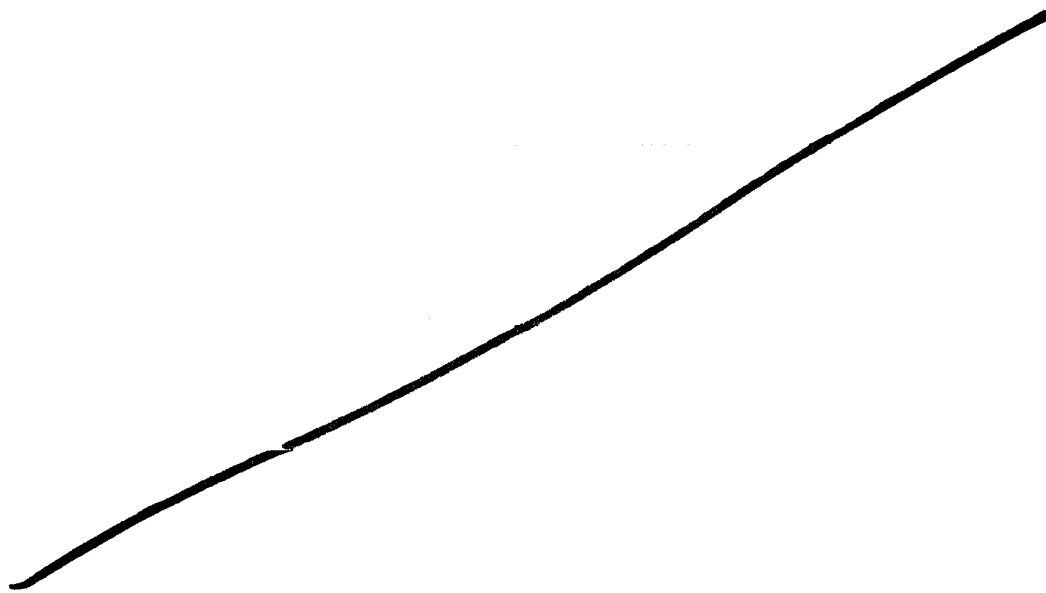
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

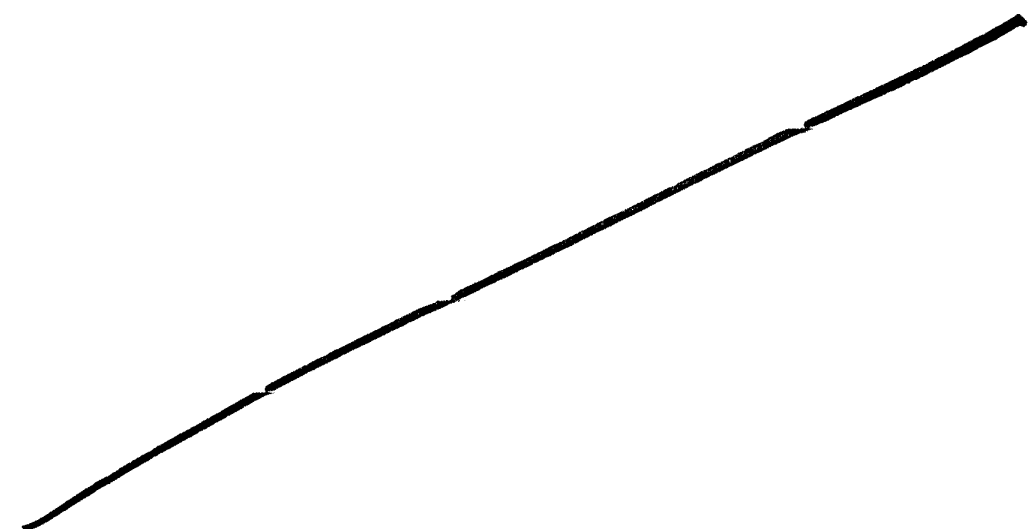
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



Ver. Final

[Redacted content]

Section G. Quality Control

[Redacted content]

Section H. Initial Tests

[Redacted content]


Section I. Confirmatory Tests

[Redacted content]


Section J. Records Audit

[Redacted content]

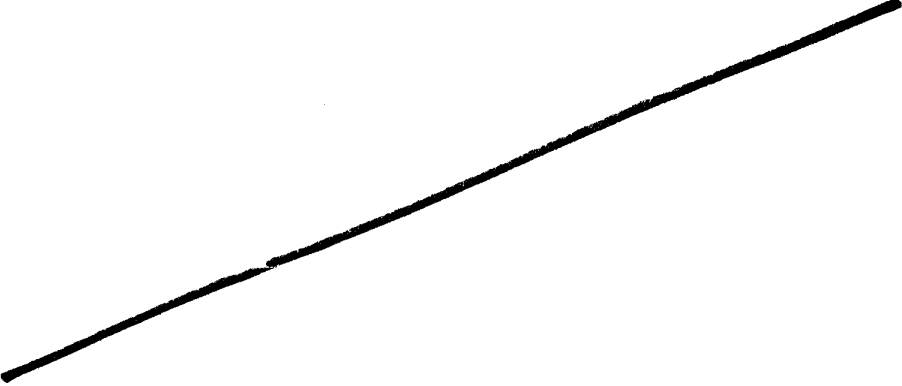
Section K. Reporting




Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



May 11, 2000

0006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth 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.

E. The Standard Operating Procedures (SOP) section :



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



[Redacted]

H. The Initial Tests section:

[Redacted]

I. The Confirmatory Tests section  
were raised:

[Redacted]

J. The Records Audit section:

[Redacted]



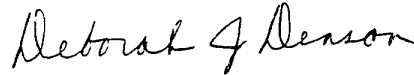
Mr. Ffortner  
May 11, 2000  
Page 3 of 3

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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.

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 Technical Analyst

Enclosure

cc: Project Files/M20

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0006  
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Menlo Park, CA

Document Reviewed:     Application Form  
                               Inspection Report #M20                      Date: 23 March 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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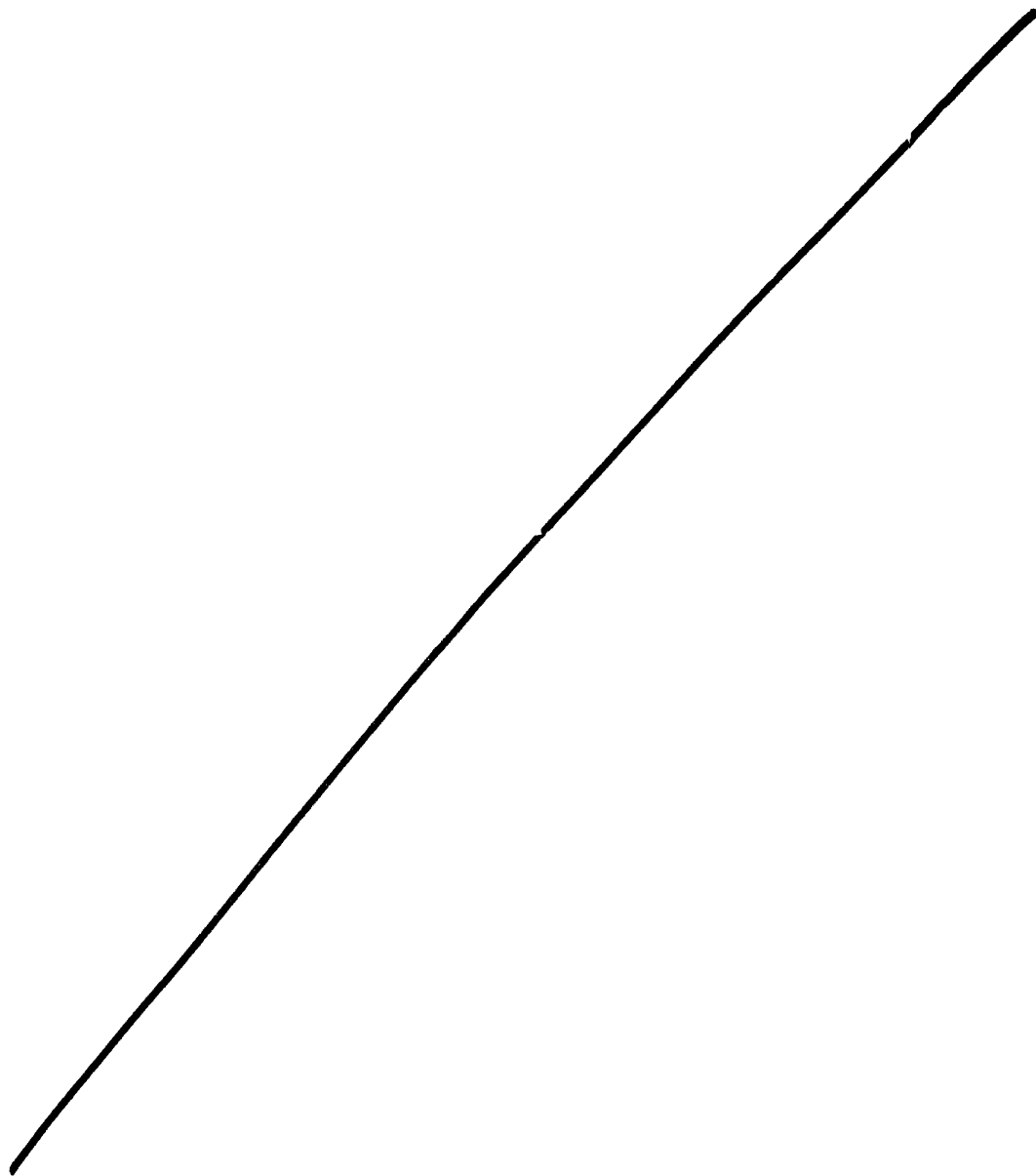
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

1



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

Section G. Quality Control

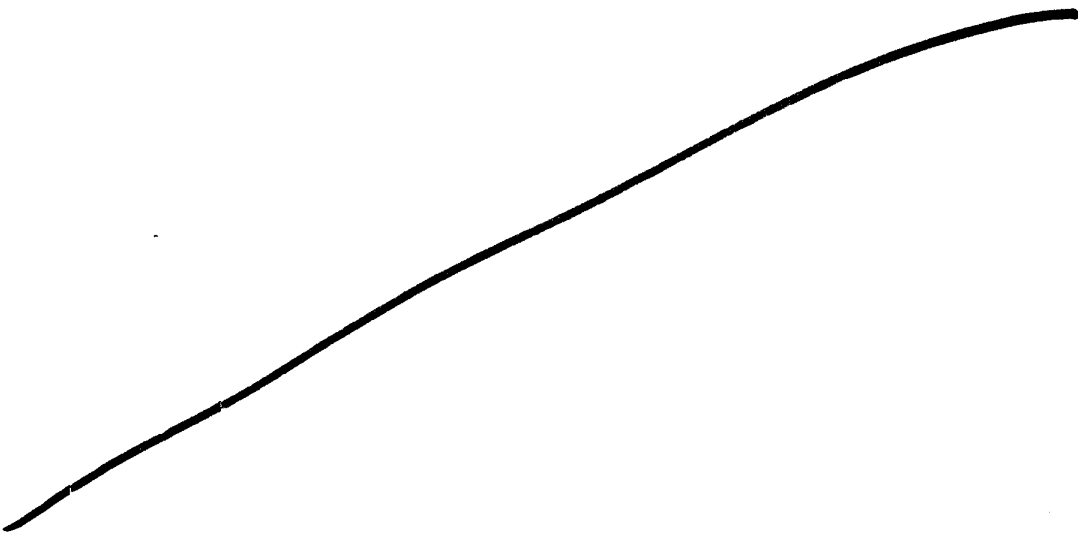
Section H. Initial Tests



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





LABORATORIES, INC.

1505A O'Brien Drive □ Mento Park, California 94025-1435 □ (650) 328-6200 □ Fax: (650) 463-7500

received  
6/13/00 DD

June 12, 2000

Deborah J. Denson  
NLCP Technical Analyst  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Denson,

As a follow up to your letter dated May 11, 2000 regarding our twentieth maintenance inspection under the National Laboratory Certification Program (NLCP) I am providing you with the following information.

If I can be of further assistance, or should you have any questions, I can be reached at 1-800-446-5177, extension 217.

Sincerely

Neil Fortner, M.S., TC (NRCC)  
Vice President Laboratory Operations  
SAMHSA Responsible Person



RESEARCH TRIANGLE INSTITUTE

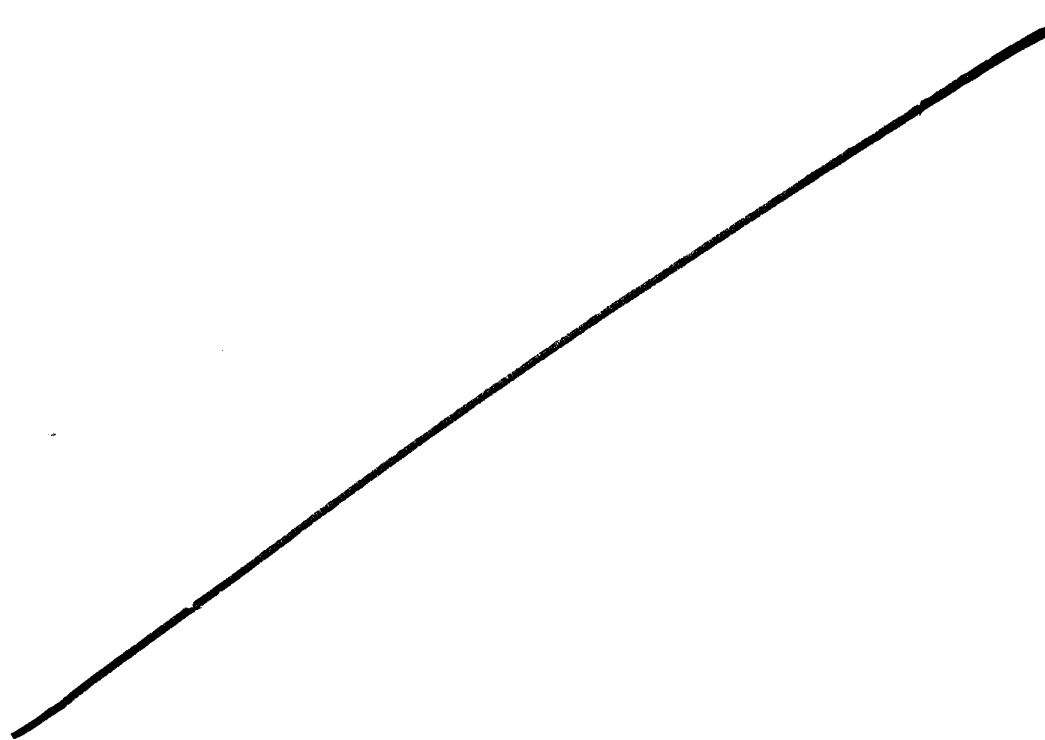
National Laboratory Certification Program

June 19, 2000

0006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

We have reviewed the material provided in your correspondence of June 12, 2000 submitted in response to issues raised during the twentieth maintenance inspection of your laboratory as outlined in our correspondence of May 11, 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 review of the material submitted:





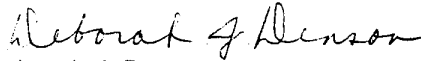
Mr. Fortner  
June 19, 2000  
Page 2 of 2

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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 R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M20



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 11, 2000

0006  
Mr. Neil Fortner  
PharmChem Laboratories, Inc.  
1505-A O'Brien Drive  
Menlo Park, CA 94025

Dear Mr. Fortner:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-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. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

E. The Standard Operating Procedures (SOP) section |

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F. The Chain-of-Custody, Accessioning, and Security section |

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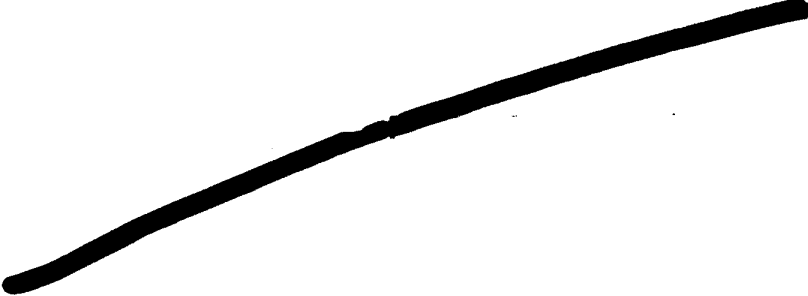
H. The Initial Tests section



I. The Confirmatory Tests section



J. The Records Audit section  
was raised:

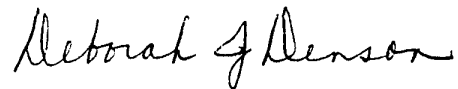
  


RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the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

Mr. Fortner  
December 11, 2000  
Page 3 of 3

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,



Deborah J. Denson  
NLCP Technical Analyst

Enclosure  
cc: Project Files/M21



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0006  
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Menlo Park, CA

Document Reviewed:     Application Form  
                               Inspection Report # M21  
                               Other \_\_\_\_\_

Date: 21 September 2000

Status:            Highly Acceptable        Acceptable  
                       Unacceptable            Failure

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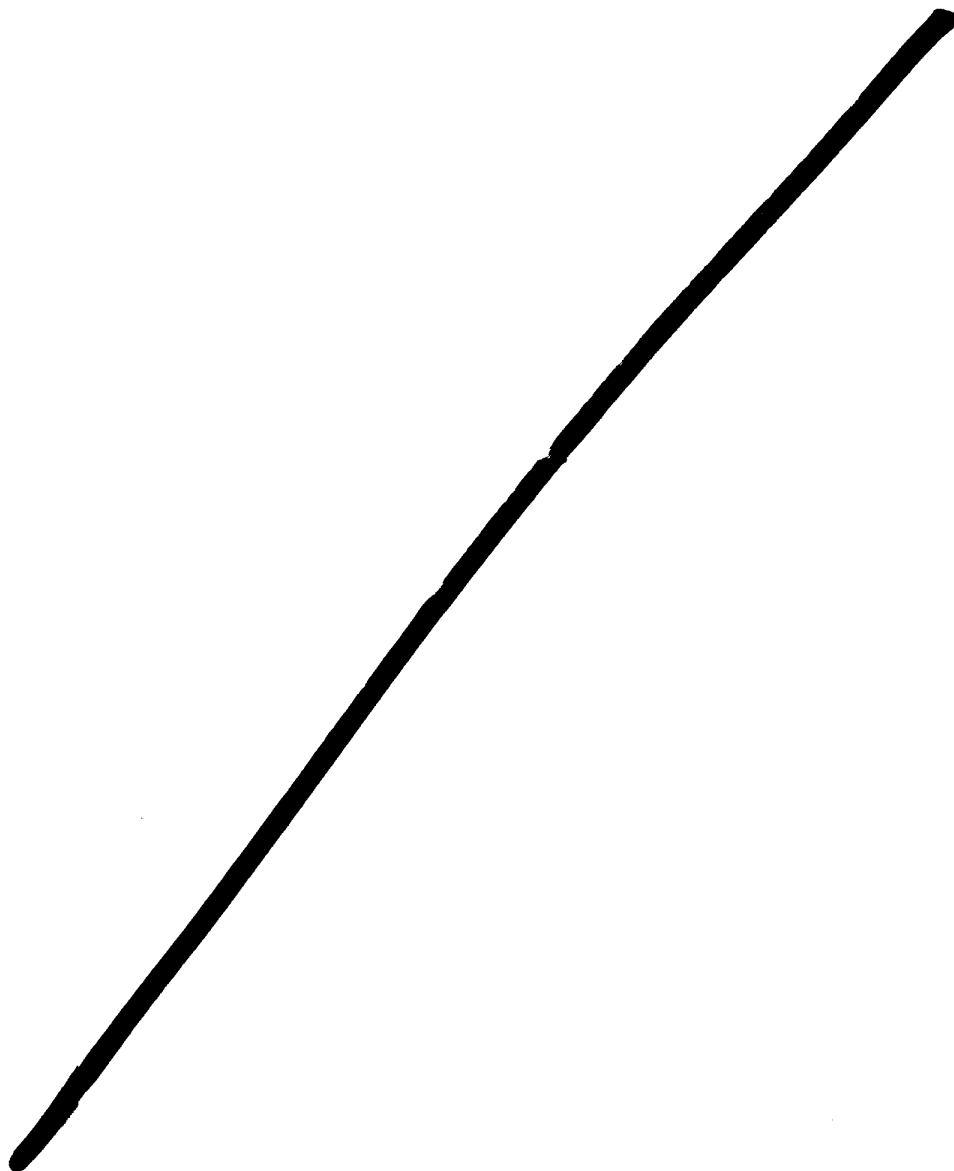
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

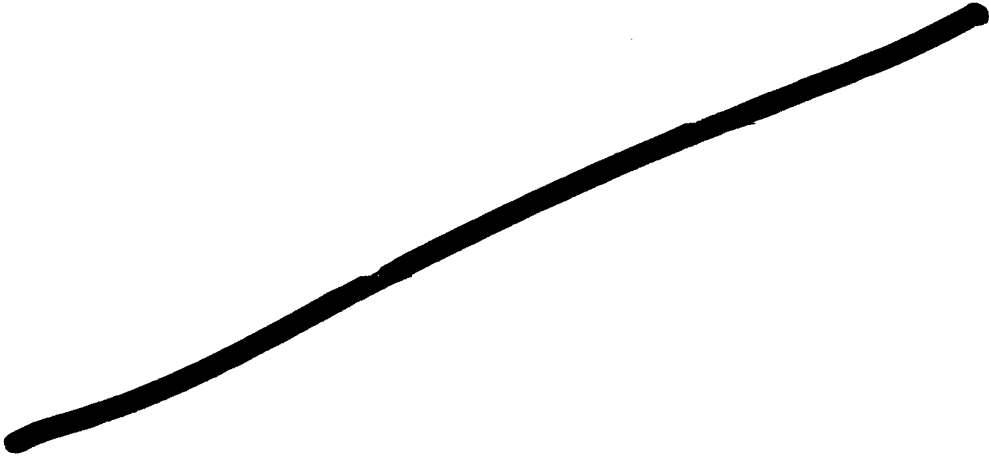
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

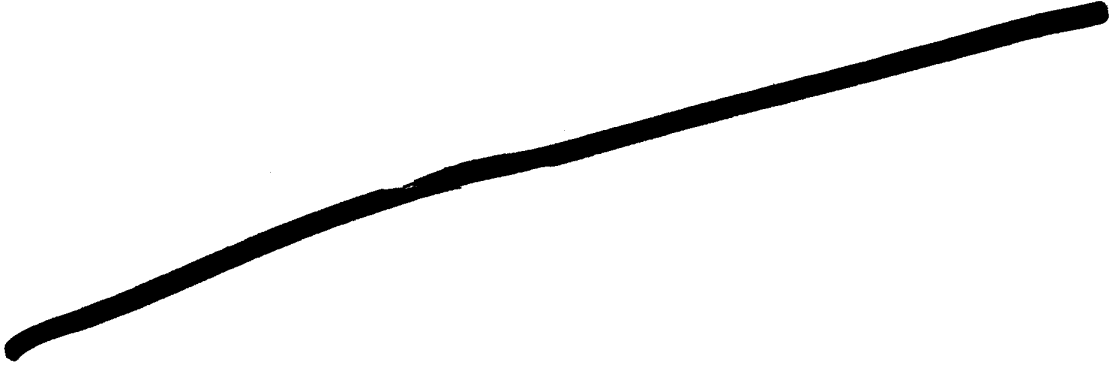
Section E. Standard Operating Procedures - Procedures Manual



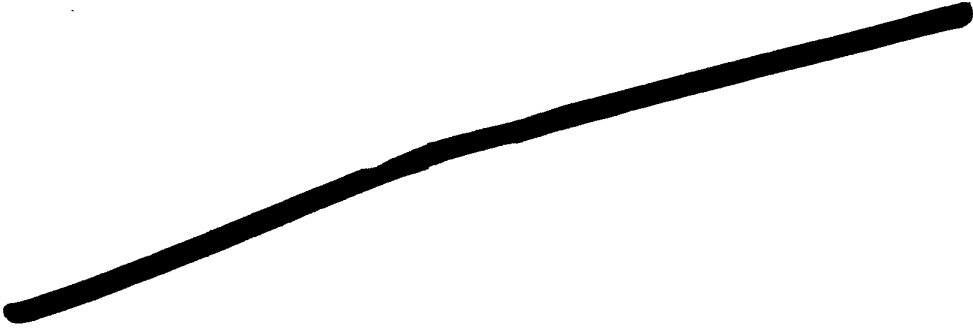
Section F. Chain-of-Custody, Accessioning, and Security



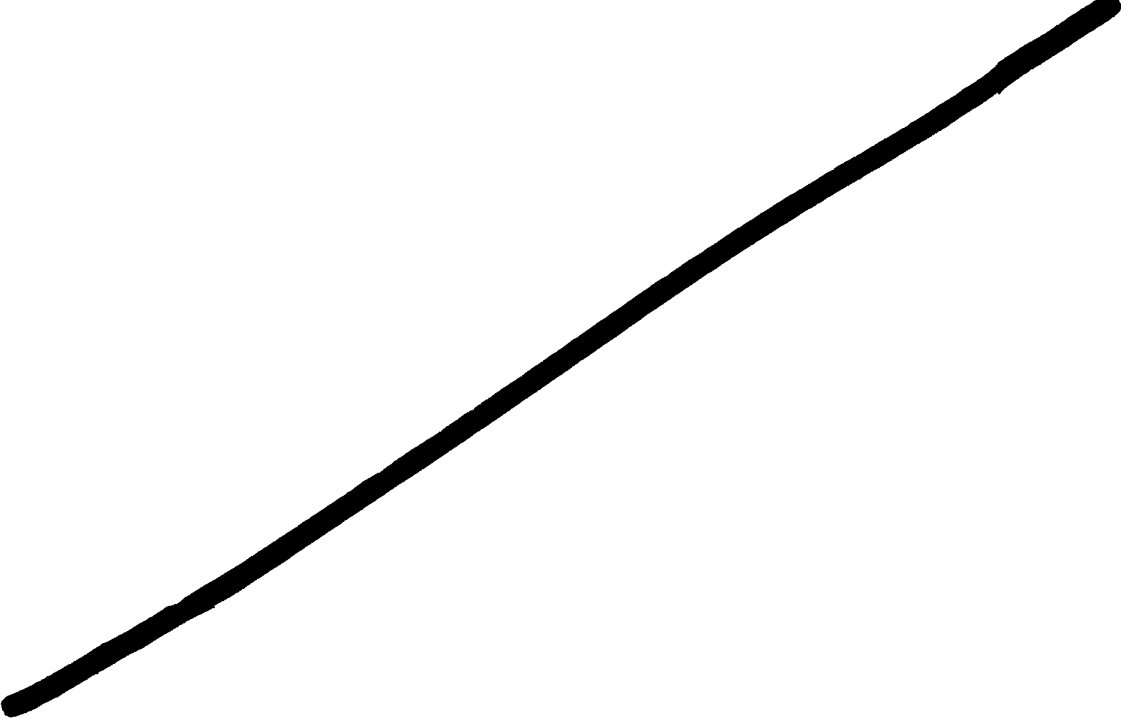
Section G. Quality Control




Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



Section K. Reporting





Section L. Computers, Software, and LIMS

[REDACTED]

Section M. Equipment and Maintenance

[REDACTED]

Section N. Personnel

[REDACTED]