RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

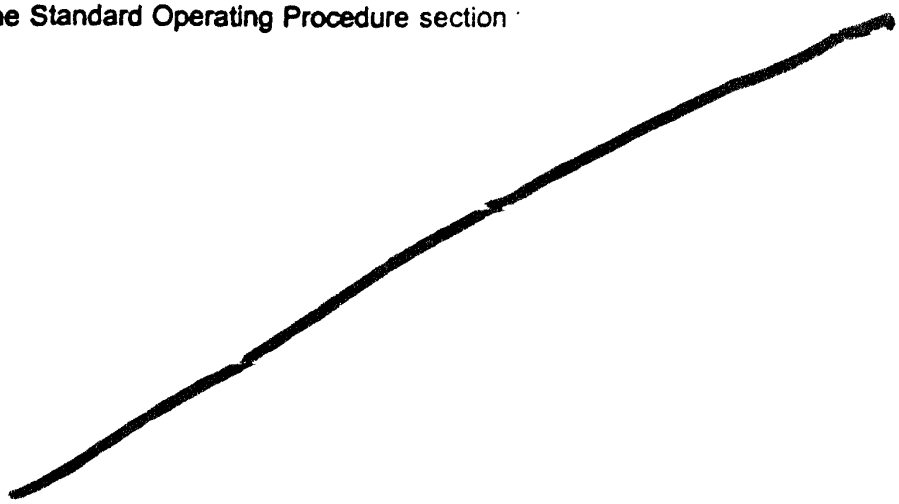
December 23, 1998

0108
Dr. David Armbruster
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

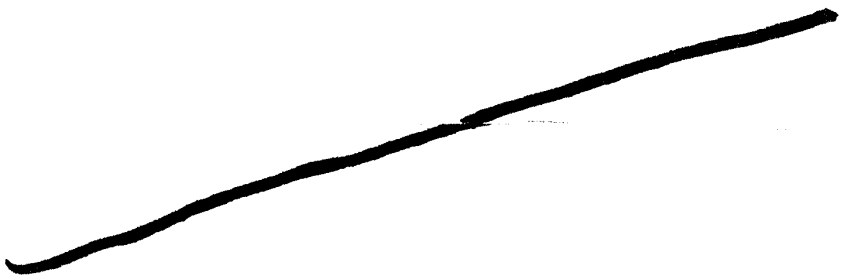
Dear Dr. Armbruster:

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

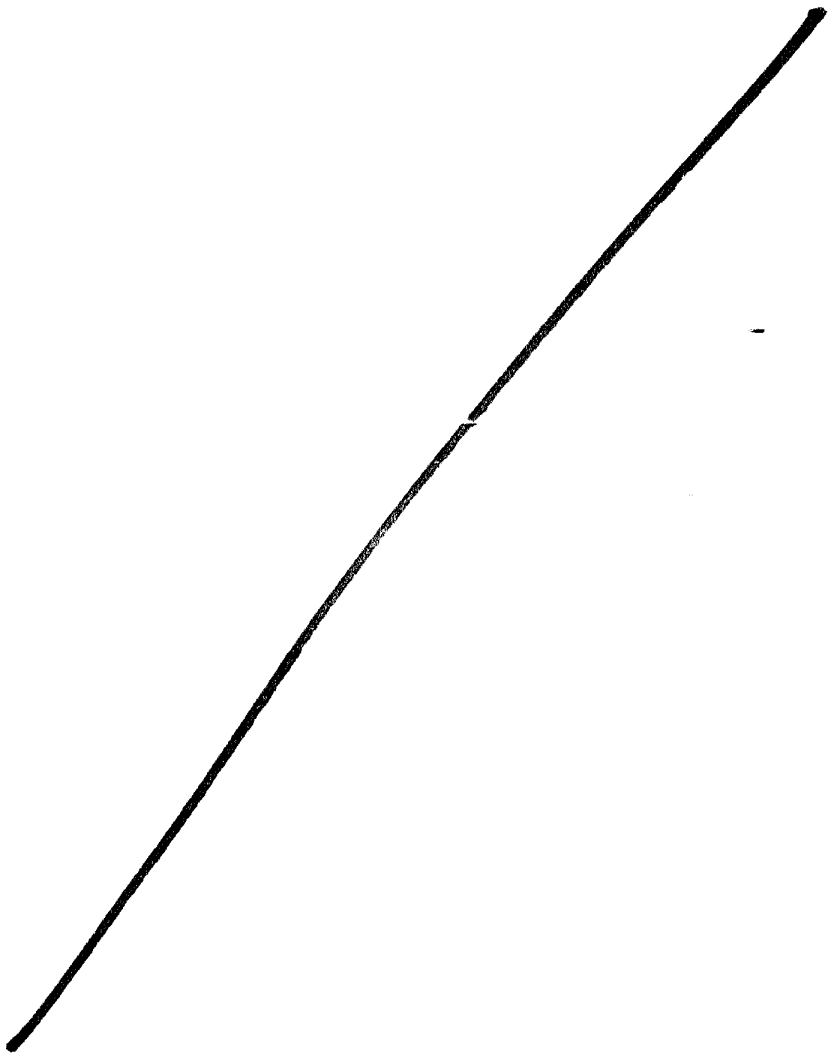
E. The Standard Operating Procedure section



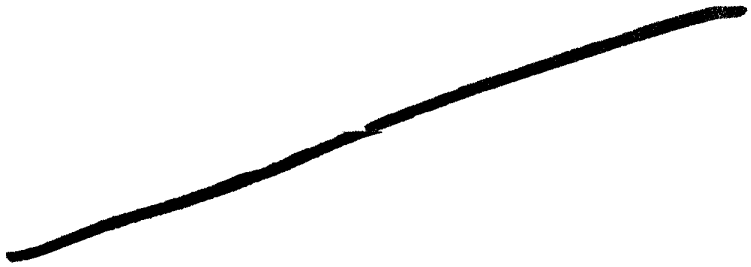
F. The Chain of Custody, Accessioning, and Security section



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194
Telephone 919 541-6709 • Fax 919 541-7042



G. The Records Audit section



J. The Quality Control and Standards section

L. The Equipment and Maintenance section

N. The Gas Chromatography/Mass Spectrometry section

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

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Fort Worth, TX

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M15 Date: 12 November 1998
[ ] Other _____

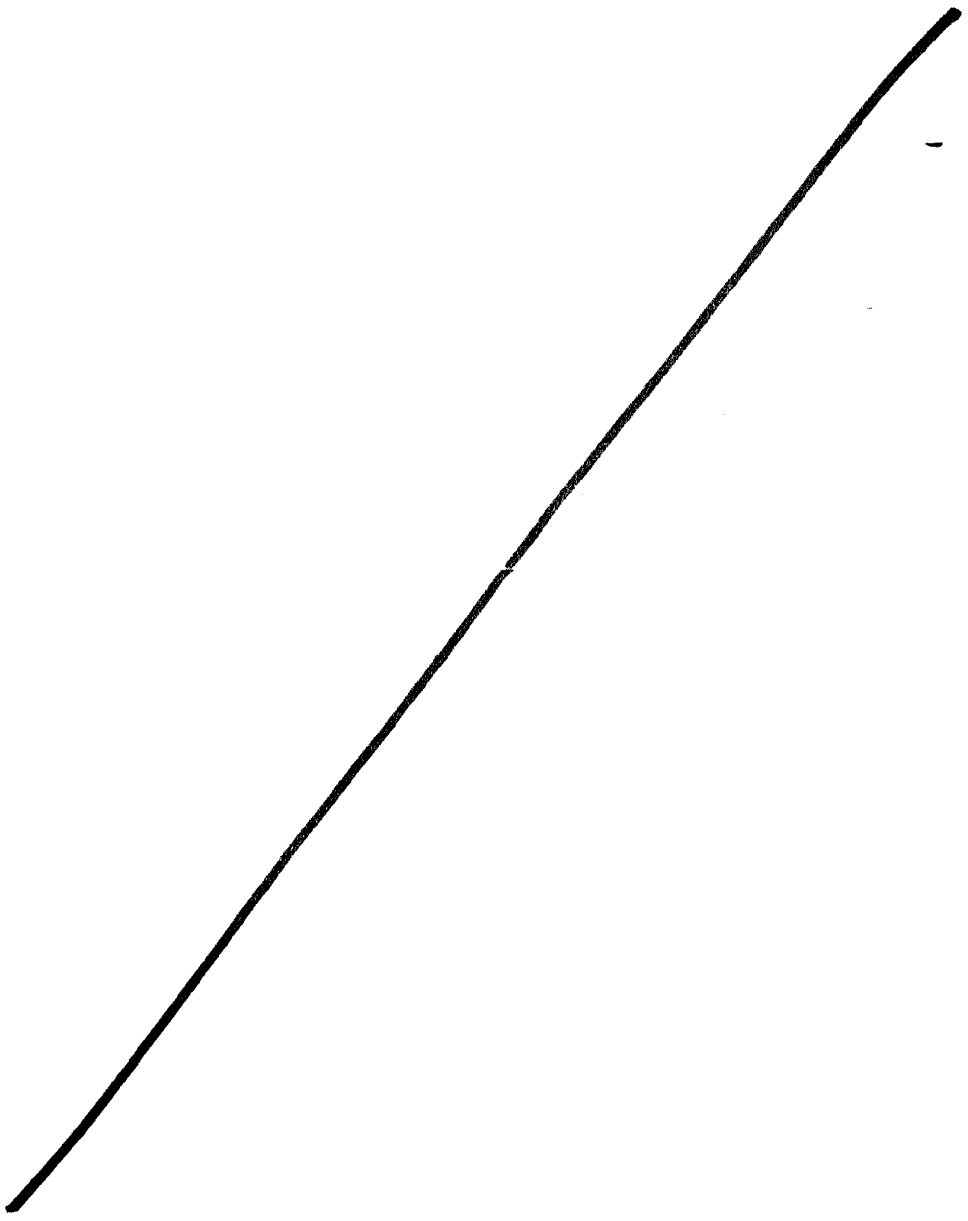
Status: [ ] Highly Acceptable [XX] Acceptable
[ ] Unacceptable [ ] Failure

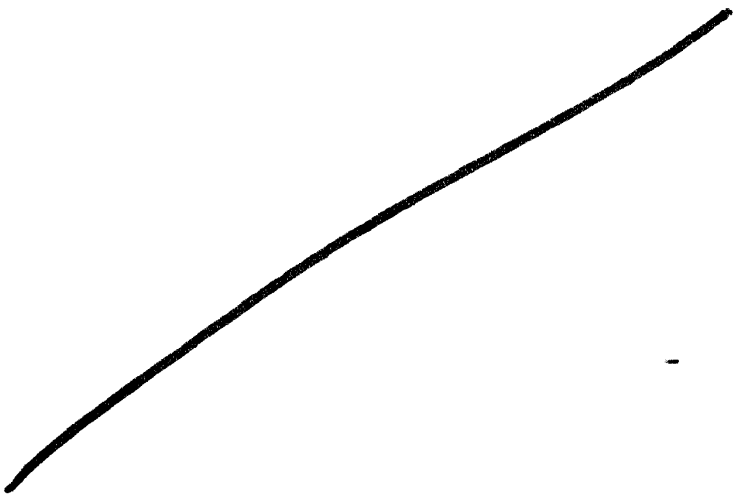
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

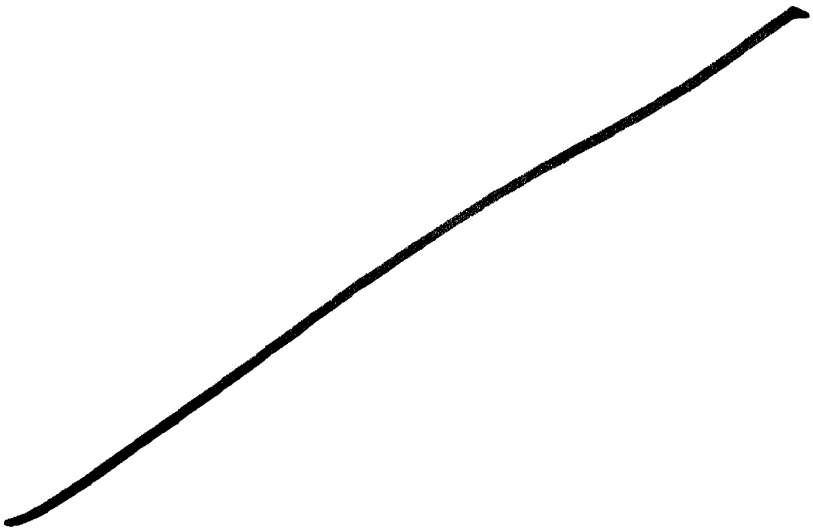
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

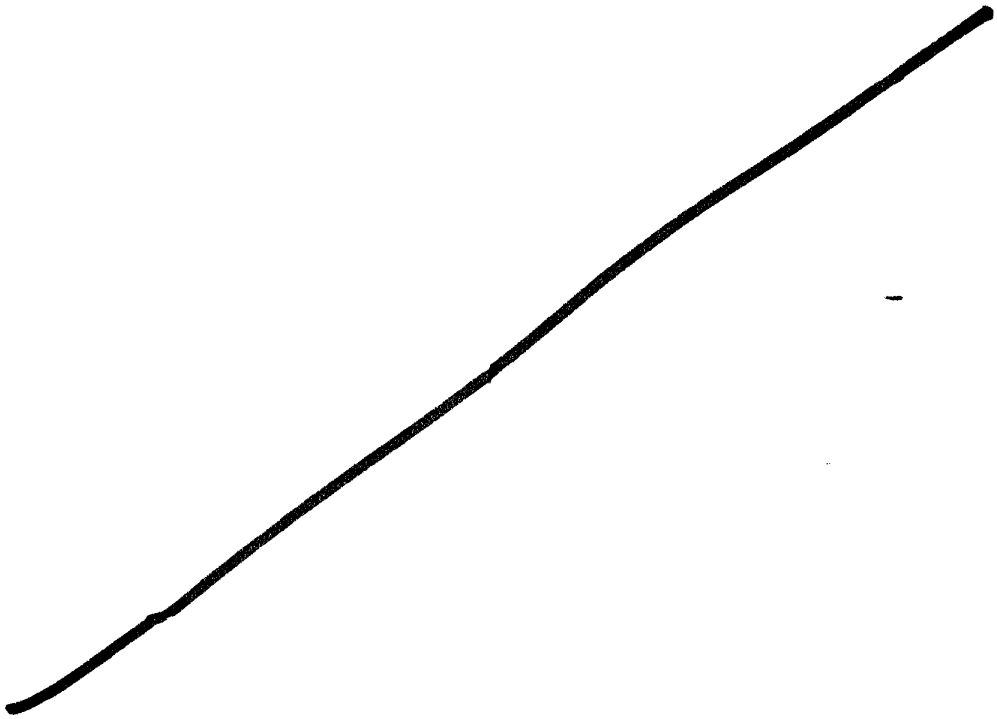
Section E. Standard Operating Procedures - Procedures Manual



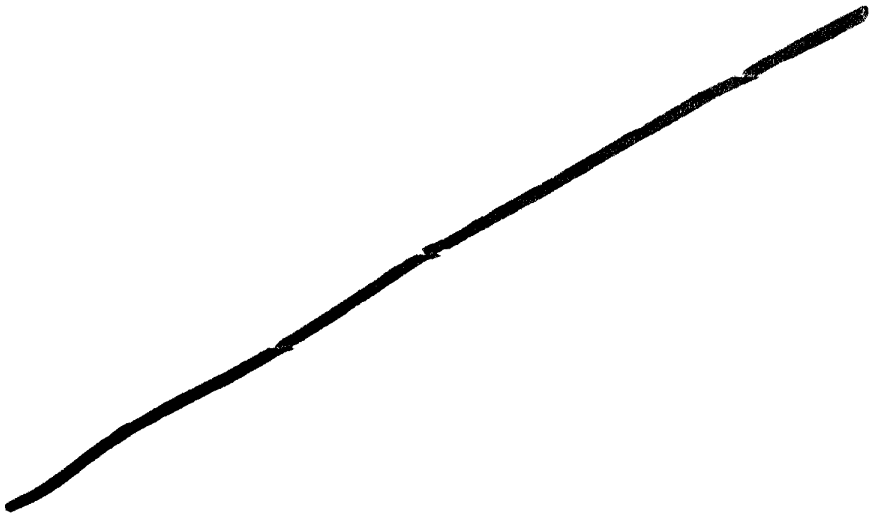


Section F, Chain-of-Custody, Accessioning and Security





Section G. Records Audit



Section H. Personnel

Section I. Reagents

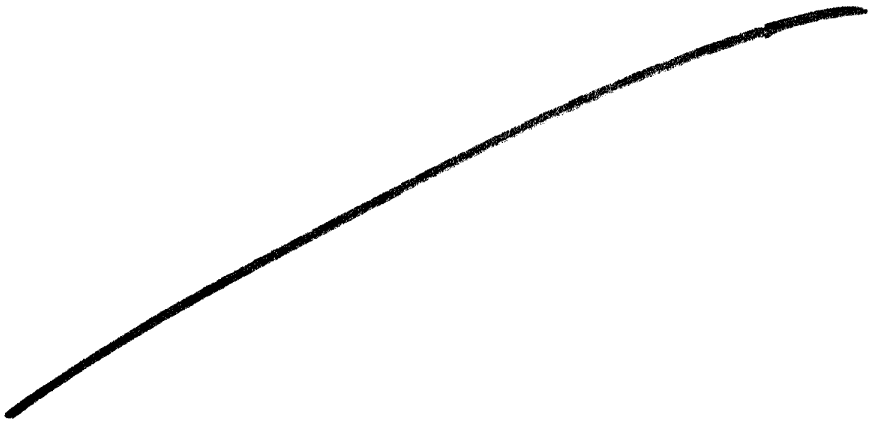
Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



PHARMCHEM
LABORATORIES, INC.

TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 817.215.8800 ☐ (800.367.8378 ☐ Fax 817.215.8801
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park, California 94025 ☐ (800)448-5177 ☐ Fax (650)688-1122

received
2/1/99 DD

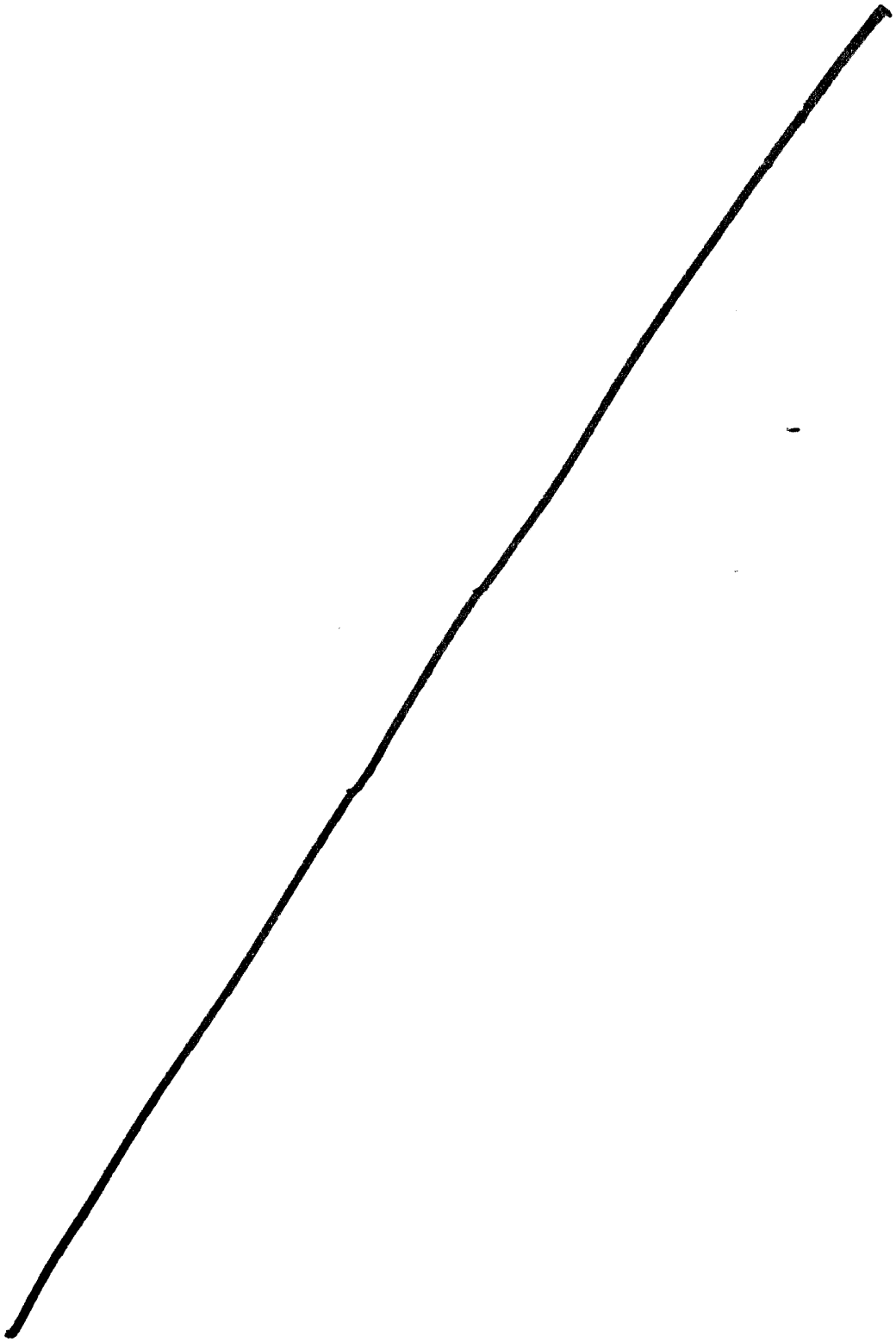
January 28, 1999

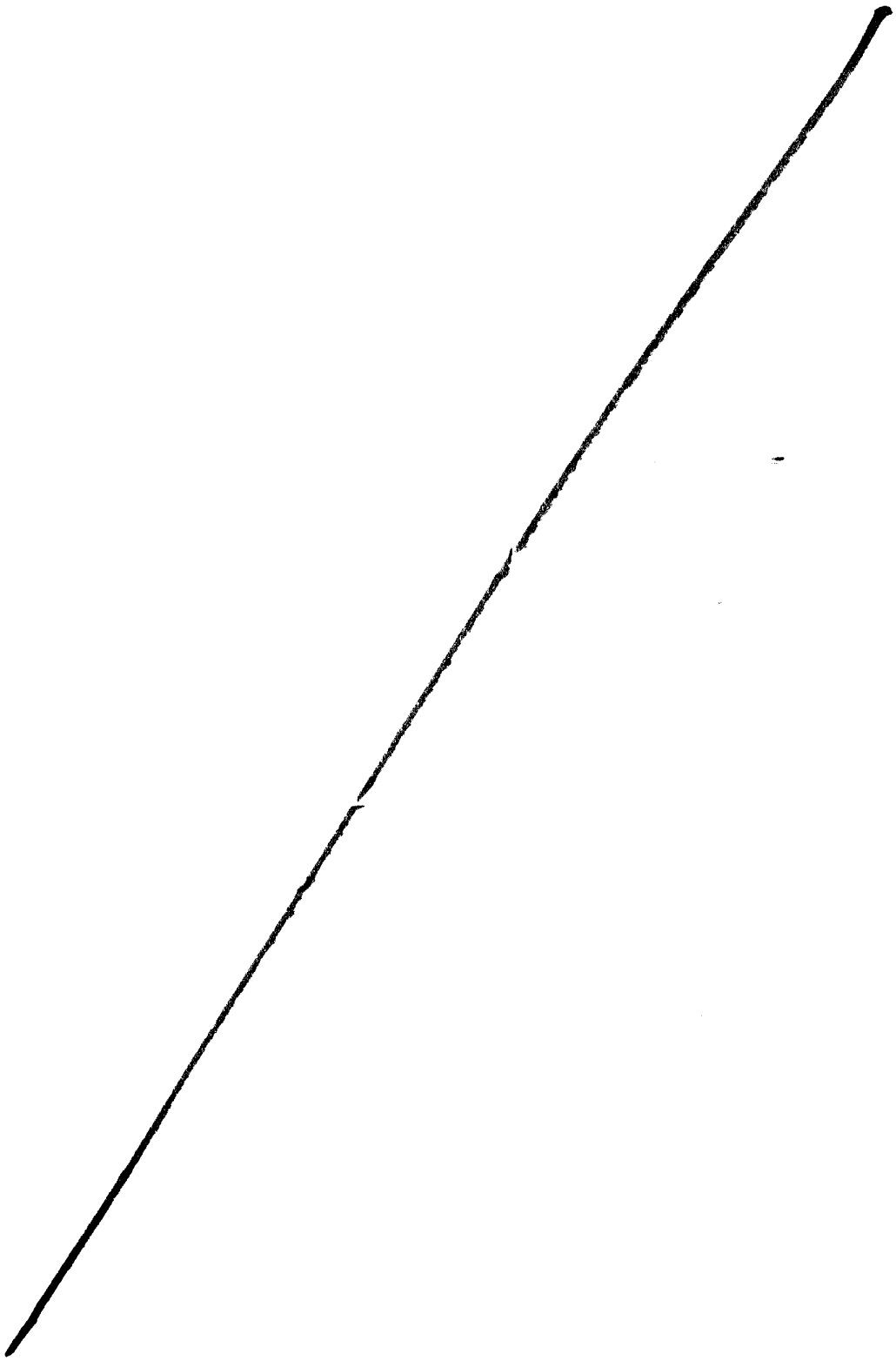
Ms. Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, North Carolina 27709-2194

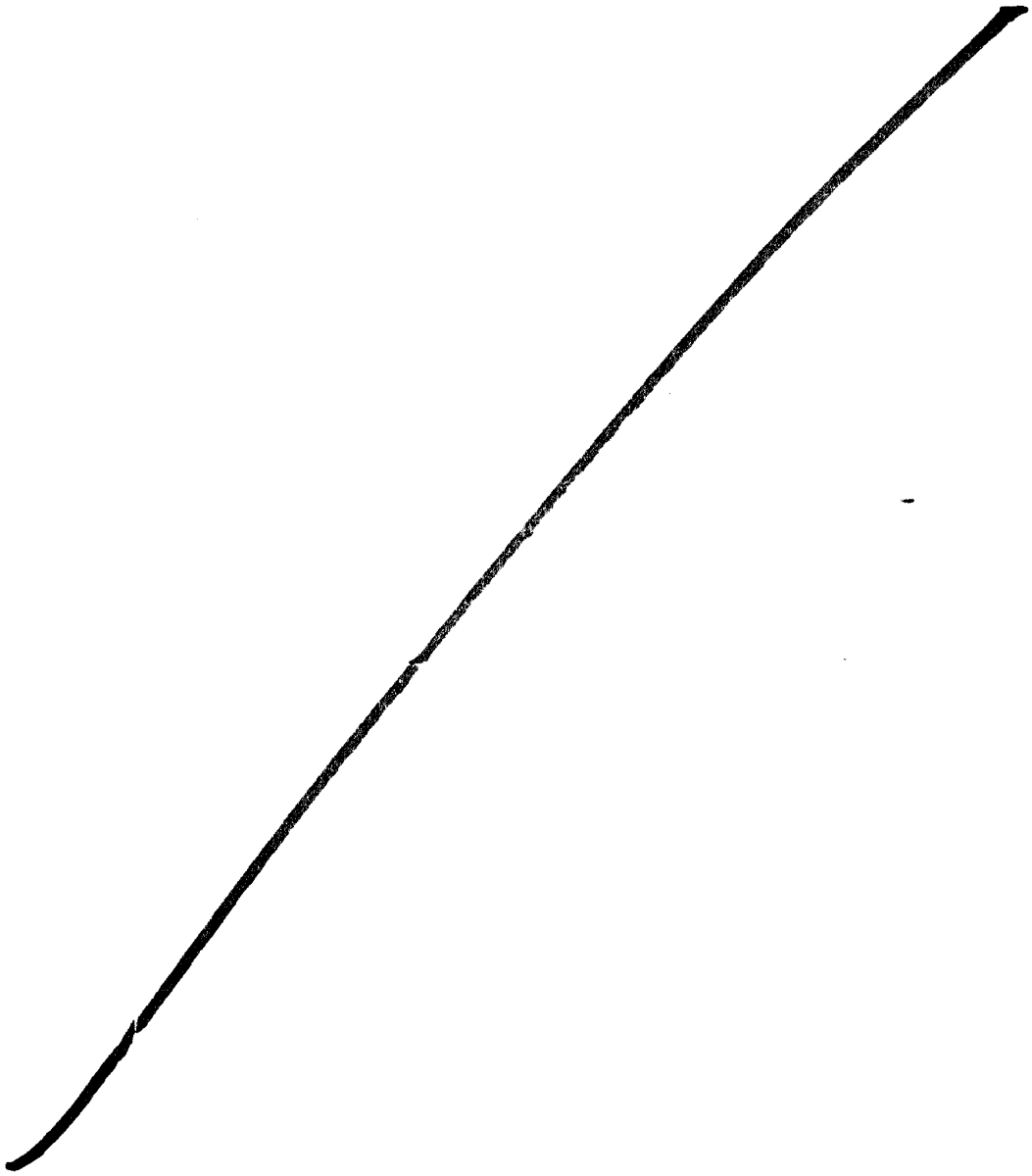
Dear Ms. Denson:

In response to the inspection critique from the fifteenth maintenance inspection of PharmChem Laboratories-Texas Division, the following documentation and corrective actions are submitted.

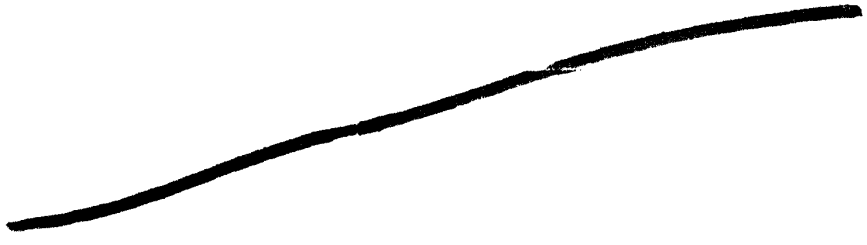
Section E. Standard Operating Procedures - Procedures Manual

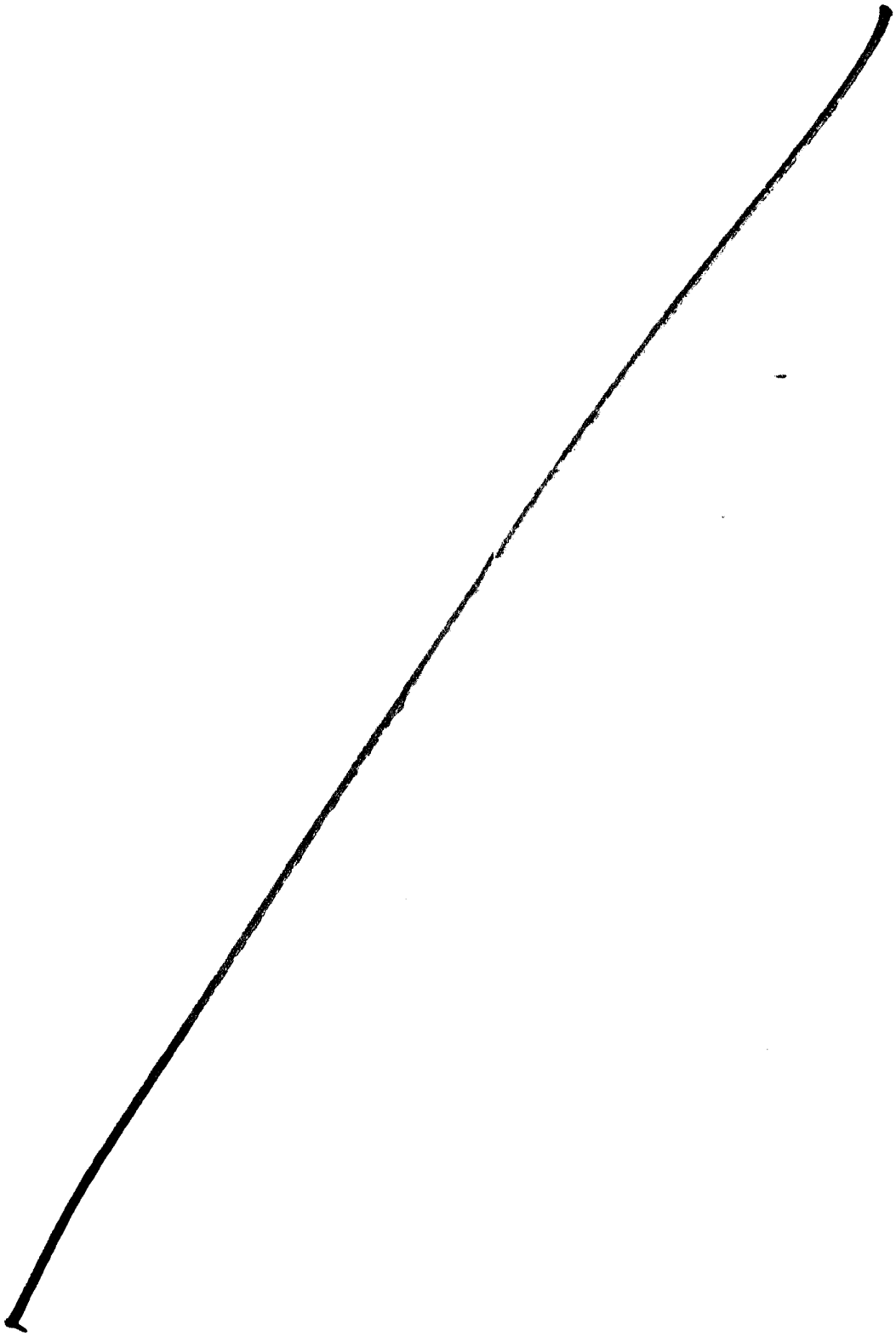


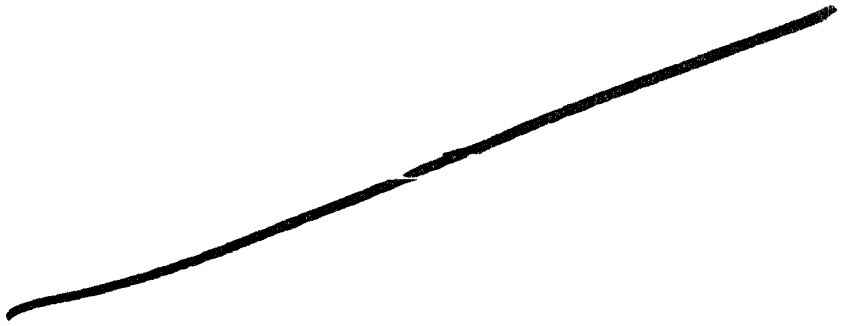




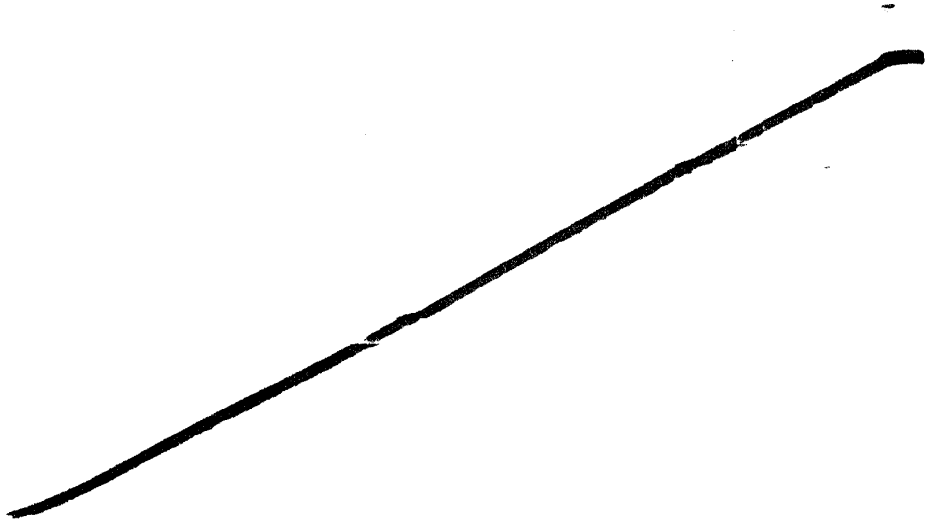
Section F. Chain-of-Custody, Accessioning and Security



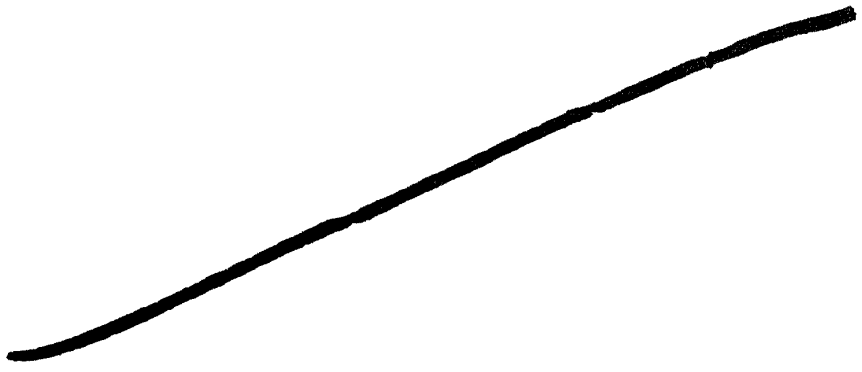




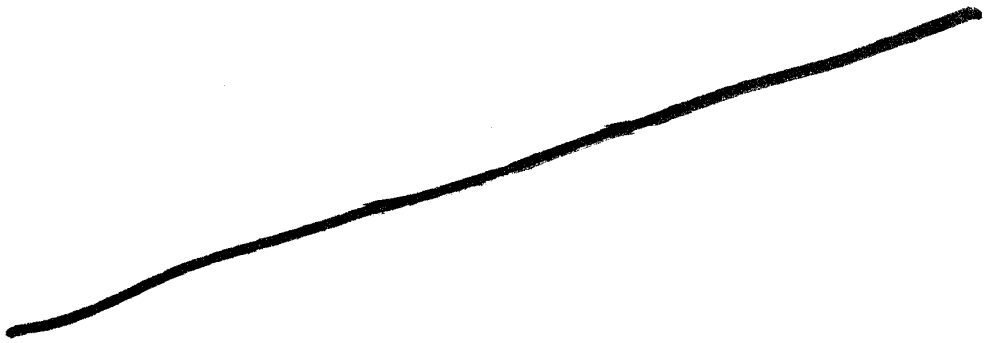
Section G. Records Audit



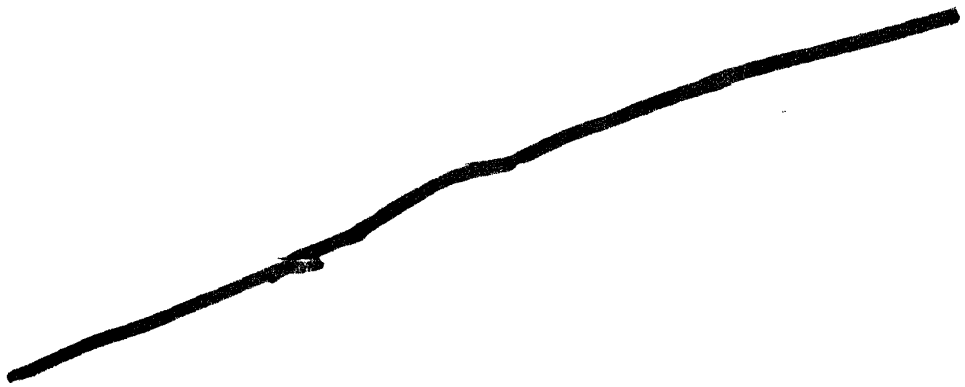
Section J. Quality Control and Standards



Section L. Equipment and Maintenance



Section N. Gas Chromatography/Mass Spectrometry



Respectfully,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D., DABFT
Laboratory Director/Responsible Person

RESEARCH TRIANGLE INSTITUTE

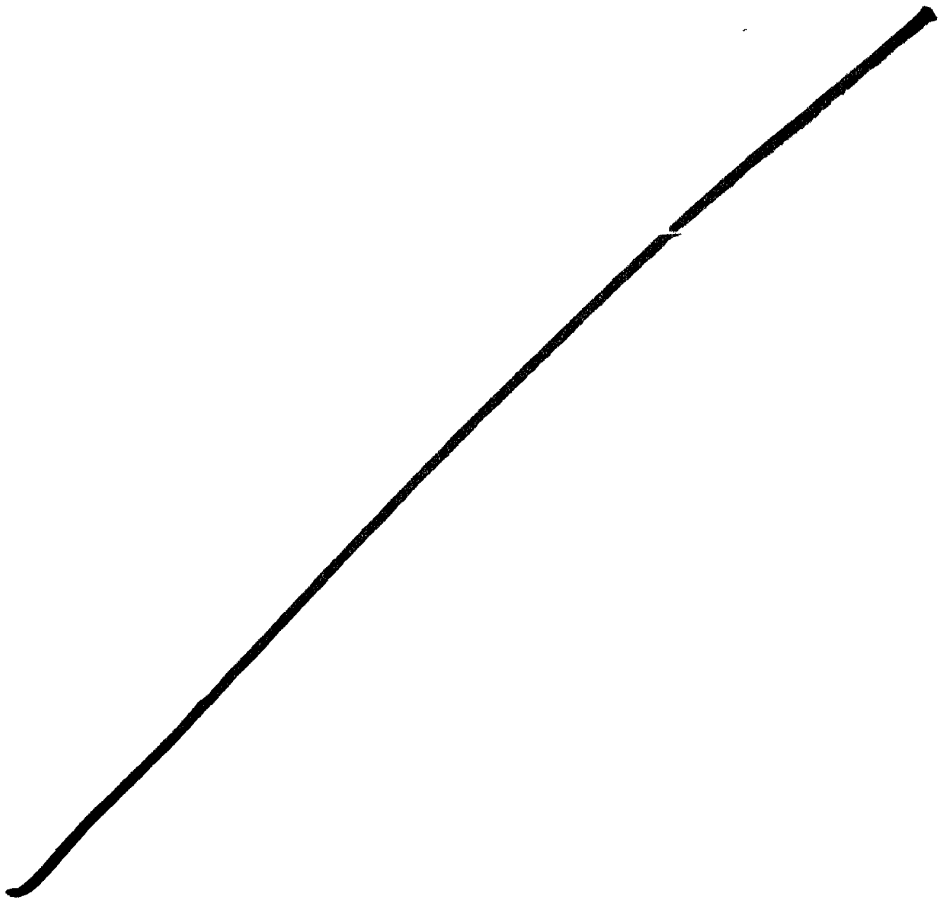
National Laboratory Certification Program

February 9, 1999

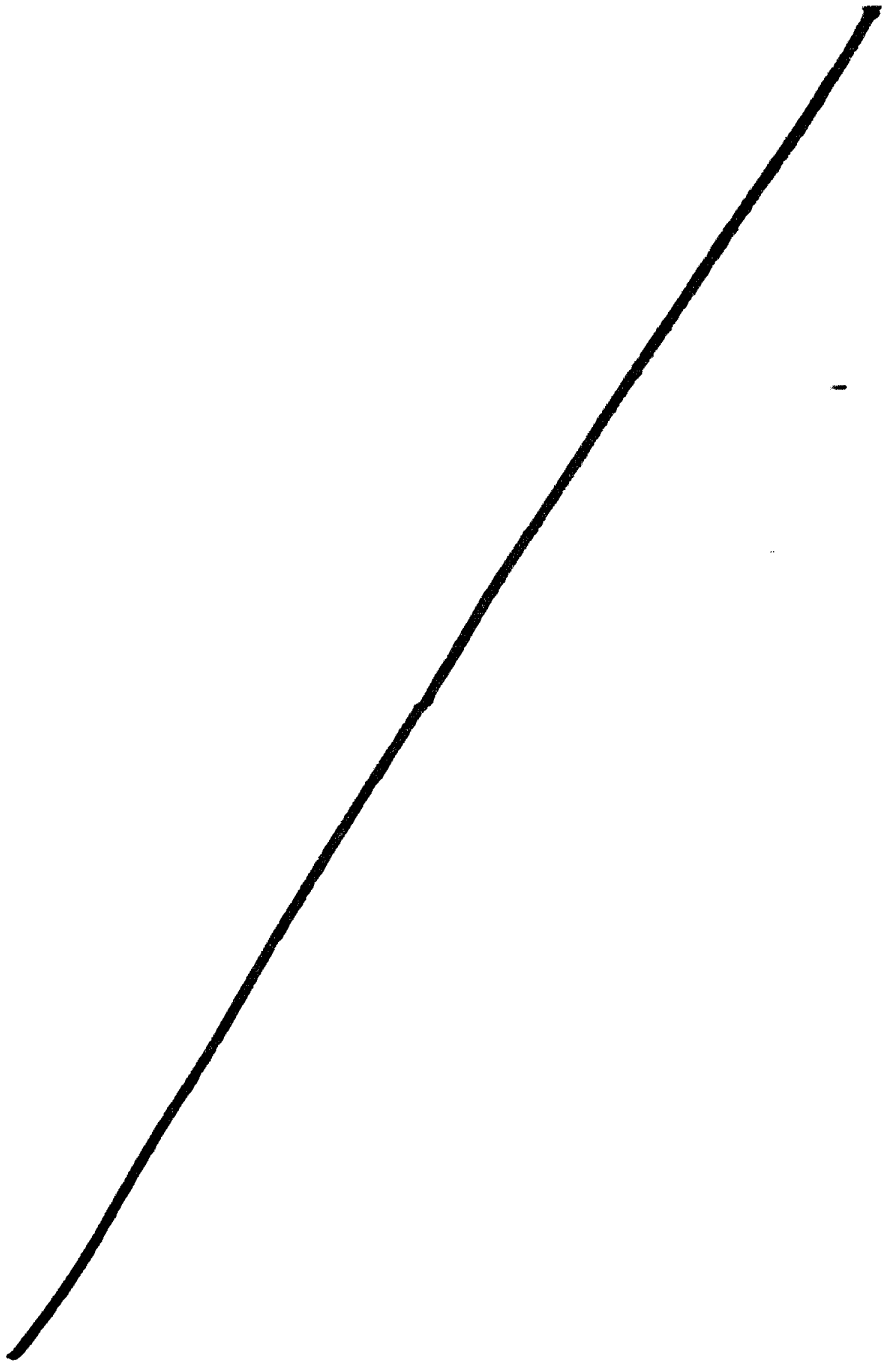
0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

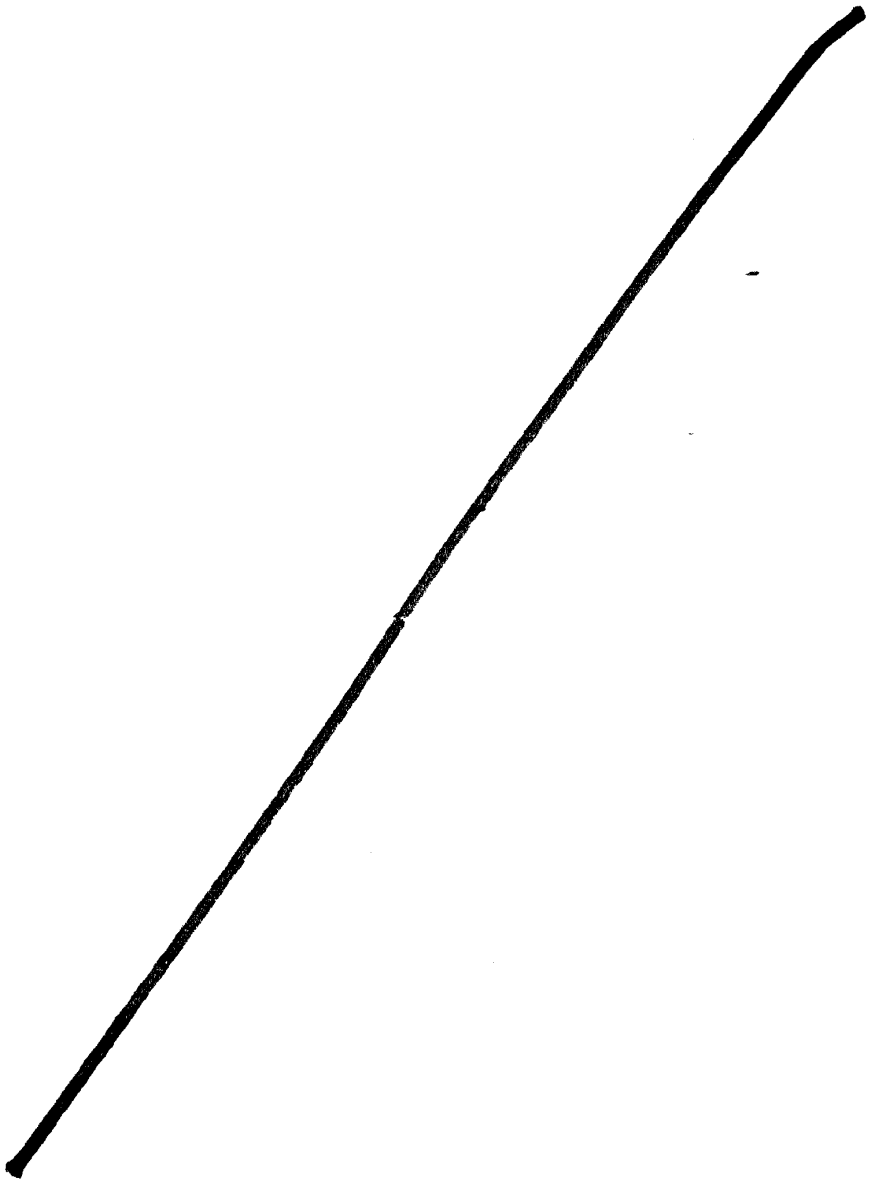
Dear Dr. Bost:

We have reviewed the material provided in your correspondence of January 28, 1999, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of December 23, 1998. 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.



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042





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.

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

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M15

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

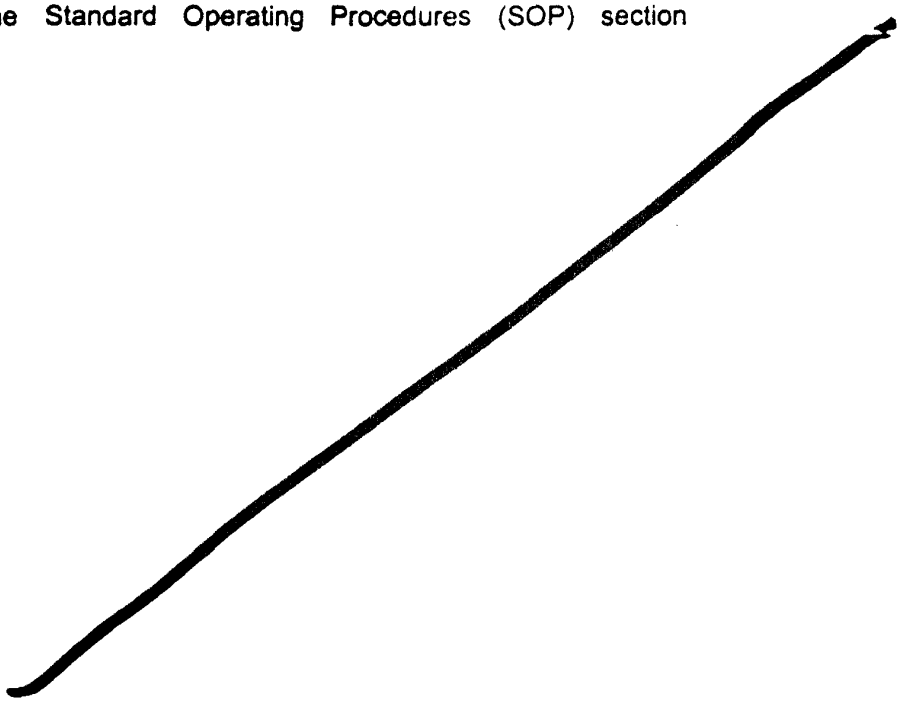
June 23, 1999

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth 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 clarify/correct the following issues raised:

E. The Standard Operating Procedures (SOP) section



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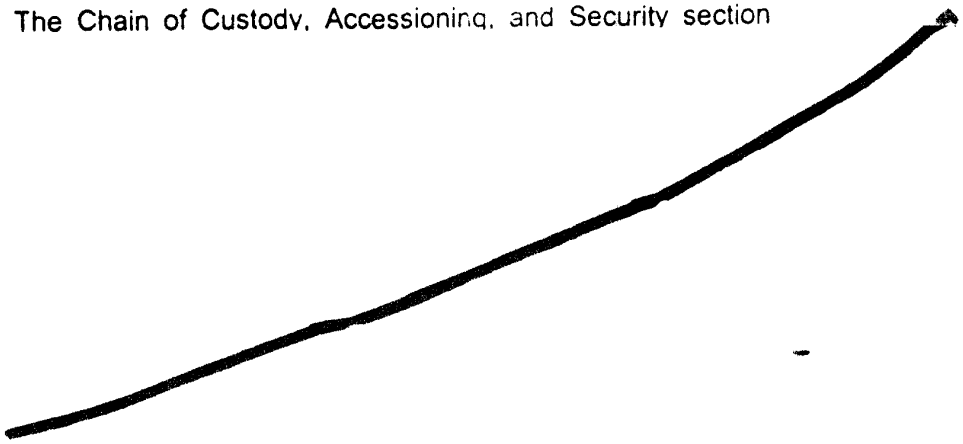
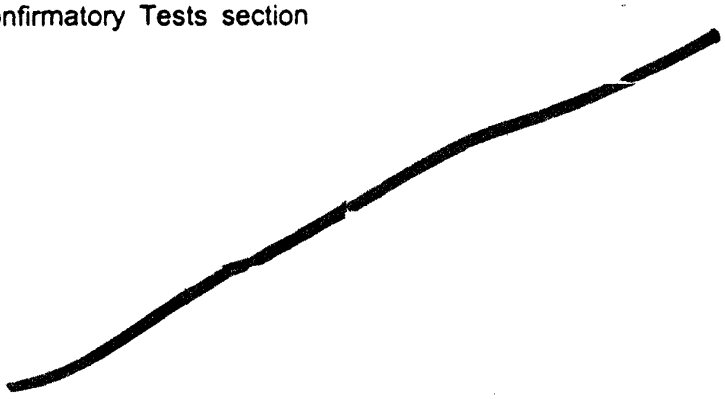
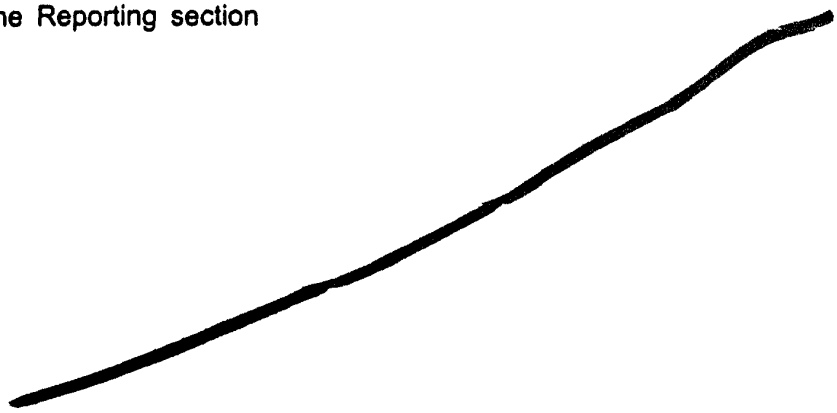
F. The Chain of Custody, Accessioning, and Security section



I. The Confirmatory Tests section



K. The Reporting section



N. The Personnel section

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 Inspection Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Inc., Texas Division

Location: Fort Worth, TX

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M16 Date: 6 May 1999
[ ] Other _____

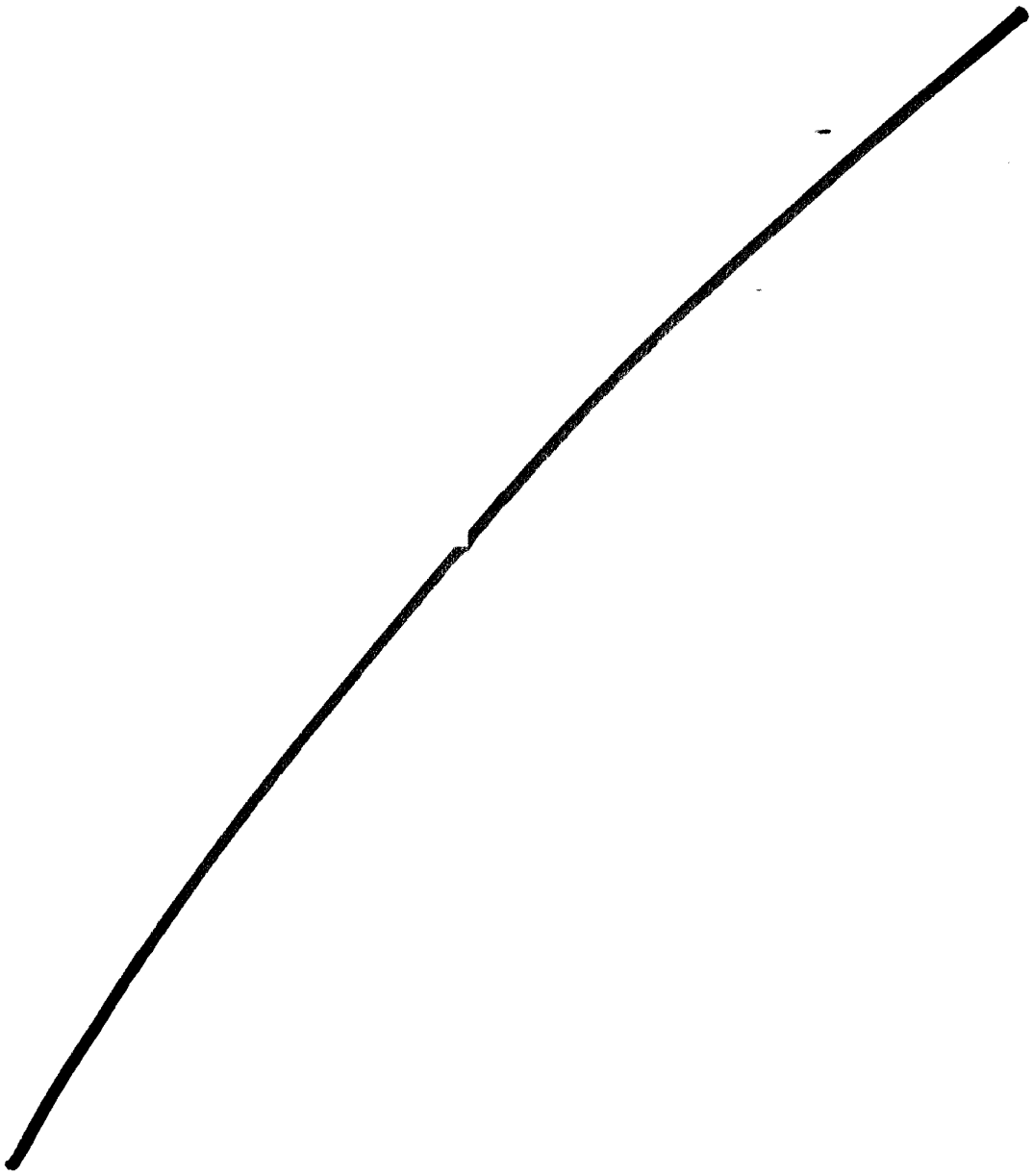
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

[redacted]

Section J. Records Audit

[redacted]

Section K. Reporting

[redacted]

Section L. Computers, Software, and LIMS

[redacted]

Section M. Equipment and Maintenance

[redacted]

Section N. Personnel

[redacted]

PHARMCHEM
LABORATORIES, INC.
1505A O'Brien Drive ☐ Menlo Park, California 94025-1435 (650) 328-6200 Fax (650) 463-7500

July 16, 1999

Mr. Ken Davis
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Mr. Davis,

This letter is in response to the issues raised in the sixteenth maintenance inspection of our Texas Laboratory

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

Sincerely,

Neil A. Fortner
Vice President, Laboratory Operations

PHARMCHEM
LABORATORIES, INC
TEXAS DIVISION 1906 Prospect Drive Fort Worth, Texas
CORPORATE HEADQUARTERS 1505A O'Brien Drive Menlo Park, California

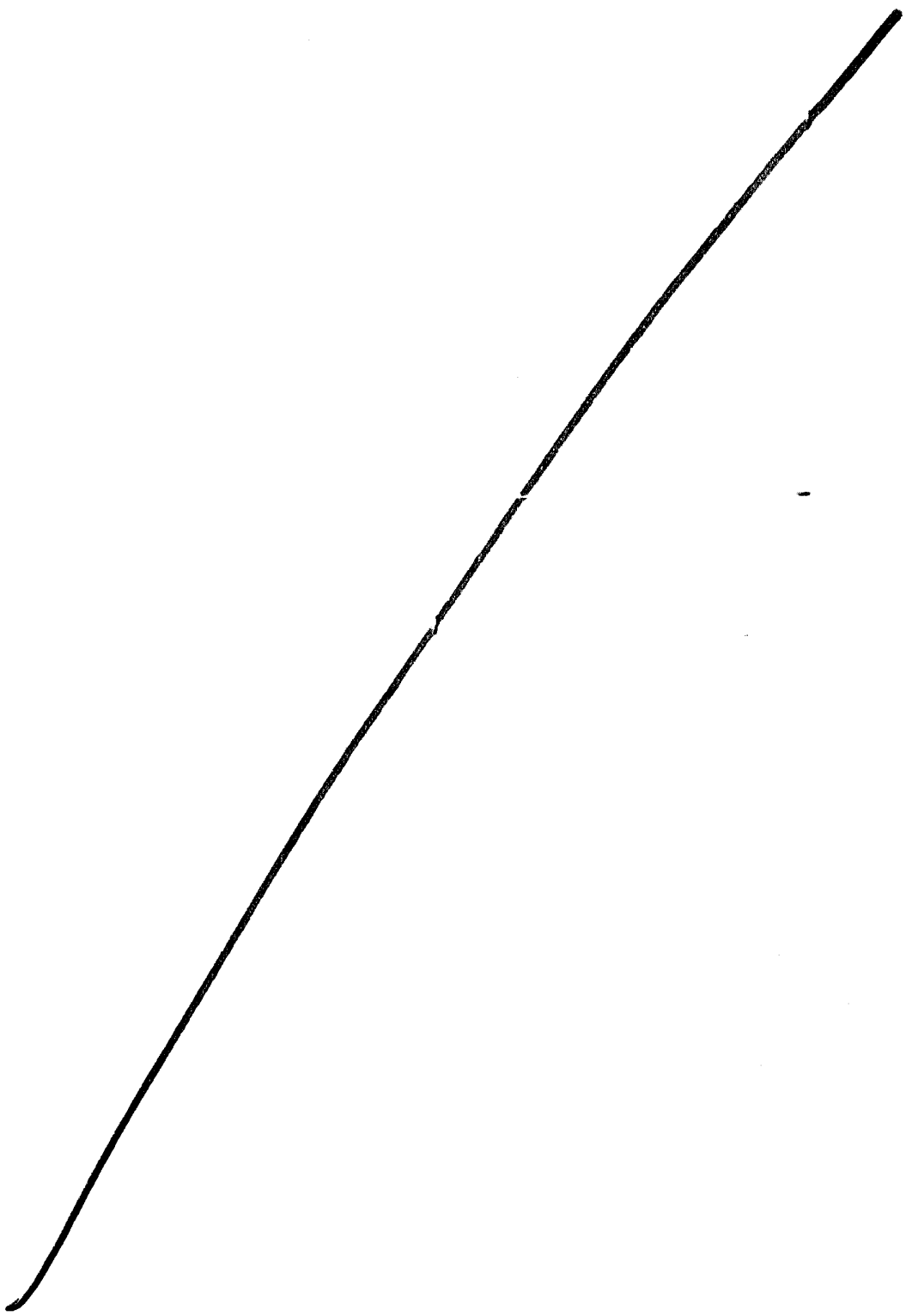
July 16, 1999

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, North Carolina 27709-2194

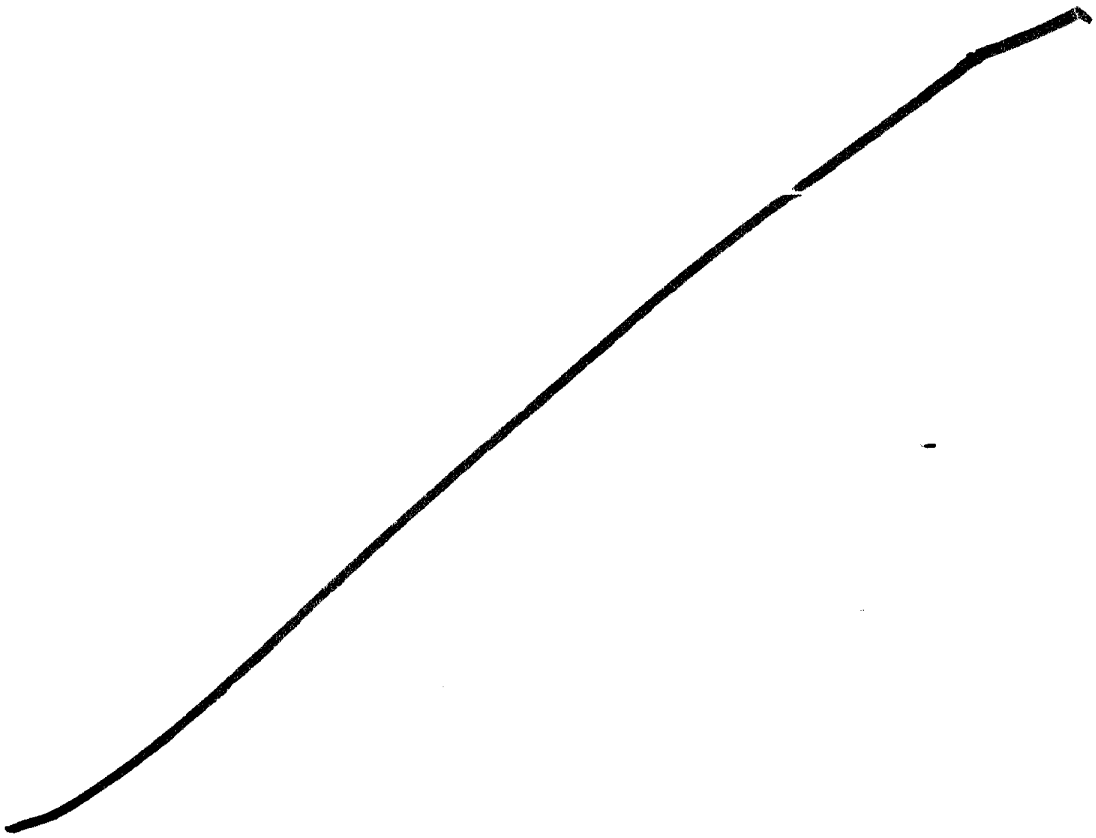
Dear Ms. Crumpton:

In response to the inspection critique from the sixteenth maintenance inspection of PharmChem Laboratories-Texas Division, the following documentation and corrective actions are submitted. The information submitted is organized and identified according to the sections and item numbers as listed in the inspection critique. In some of the attachments, the portion applicable to the specific critique item has been highlighted.

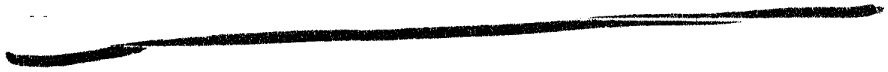
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section I. Confirmatory Tests

Section K. Reporting

Section L. Computers, Software, and LIMS

Section N. Personnel

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

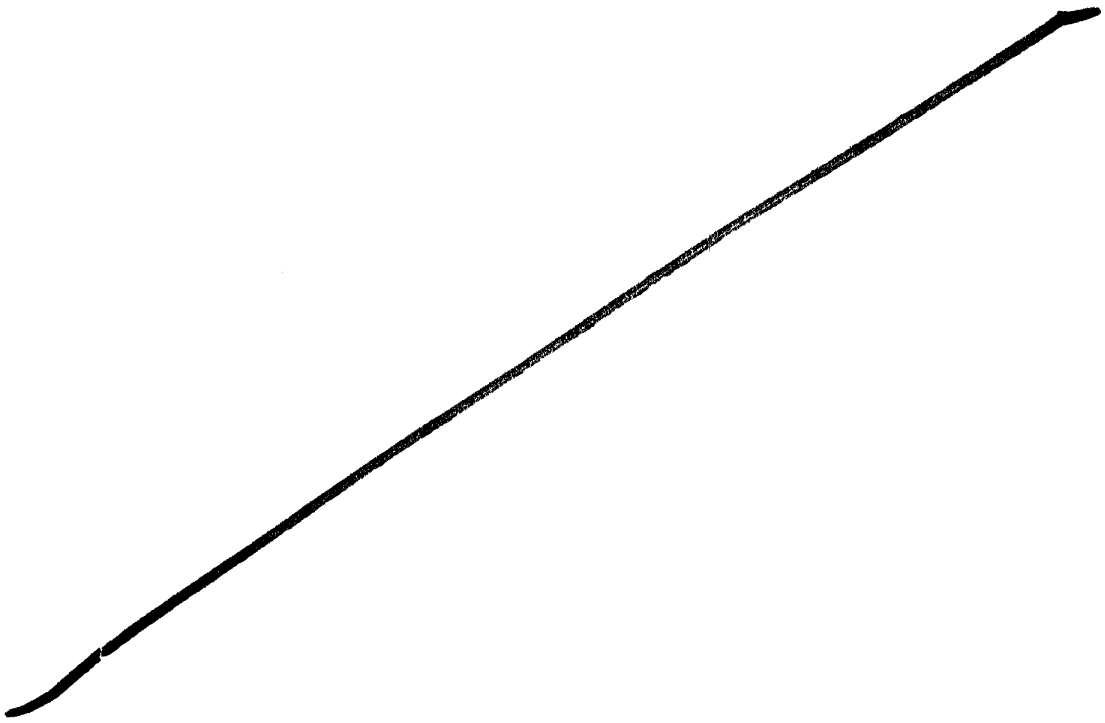
National Laboratory Certification Program

July 30, 1999

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of July 16, 1999, submitted in response to deficiencies cited during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of June 23, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most issues. However, the following issues remain or were raised during our review of the submitted material:



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The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP) upon receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to correct deficiencies may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the HHS Guidelines.

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,

Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor

PHARMACHEM
LABORATORIES, INC
TEXAS DIVISION 7606 Pebble Drive Fort Worth, Texas
CORPORATE HEADQUARTERS 7005A Corporate Blvd.

August 12, 1999

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, North Carolina 27709

Dear Ms. Crumpton:

The following information is submitted in response to your letter dated July 30, 1999.

Your letter of July 30, 1999 makes the statement that "Staff at RTI were, however, unable to contact the RP by telephone (July 22, 1999 through July 29, 1999) to clarify issues raised above." Please be advised that during the indicated dates, I was out of state on a previously-scheduled vacation.

Sincerely,

Robert O. Bost, Ph.D.

Robert O. Bost, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 16, 1999

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of August 12, 1999, submitted in response to remaining issues from the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of July 30, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

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. 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/M16

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194
Telephone 919 541-6709 • Fax 919 541-7042

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

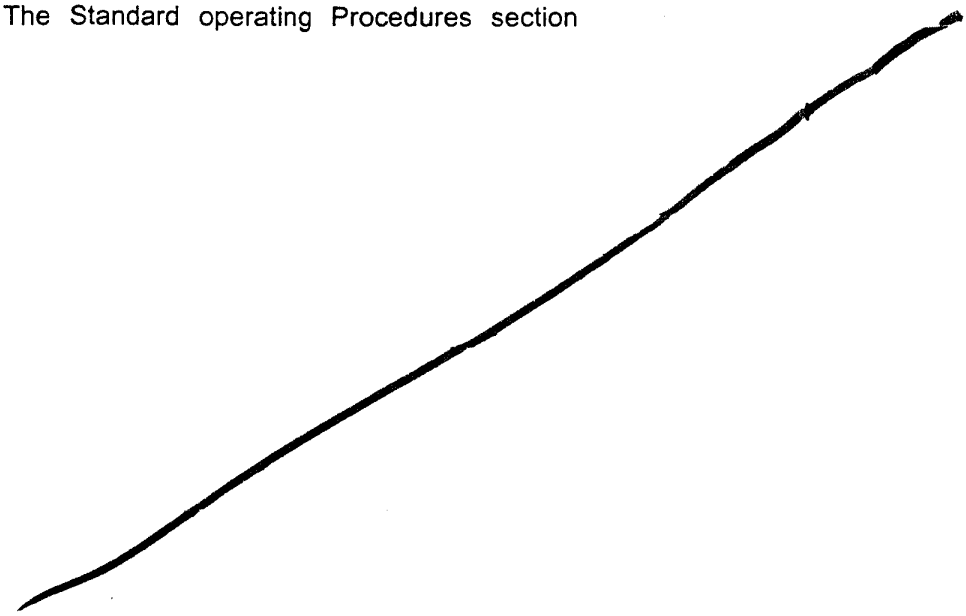
January 12, 2000

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

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

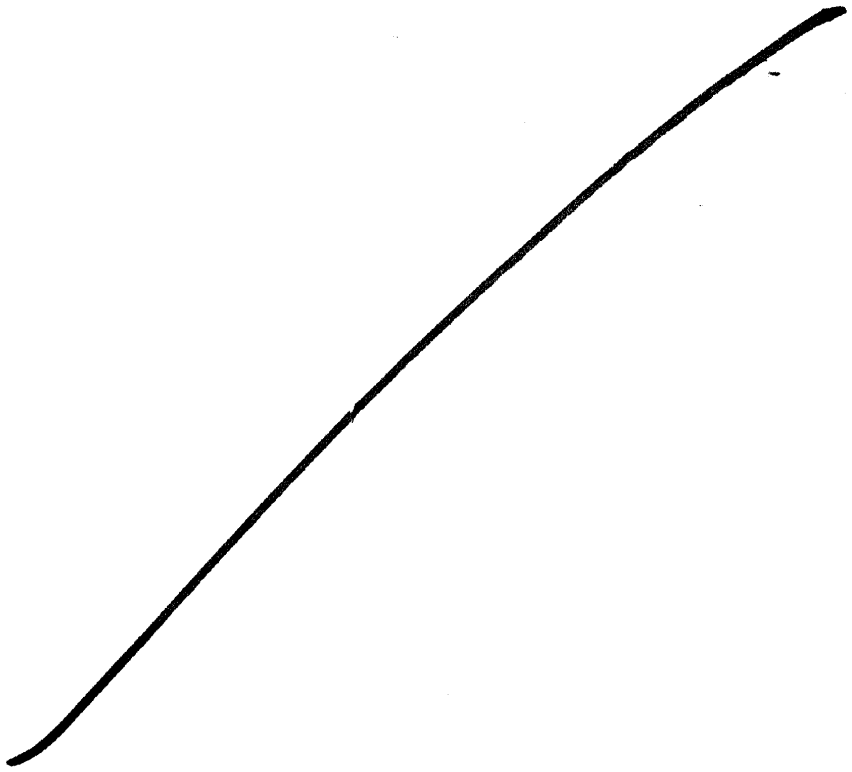
E. The Standard operating Procedures section



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

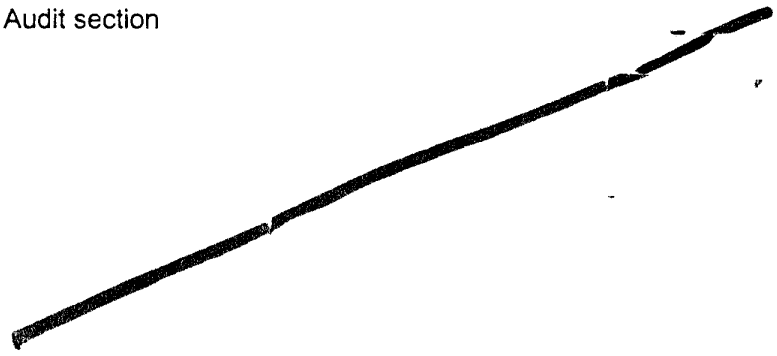
3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

G. The Quality Control Section



H. The Initial Tests section

I. The Records Audit section



K. The Reporting section

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

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Fort Worth, TX

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M17 Date: 4 November 1999
[ ] Other _____

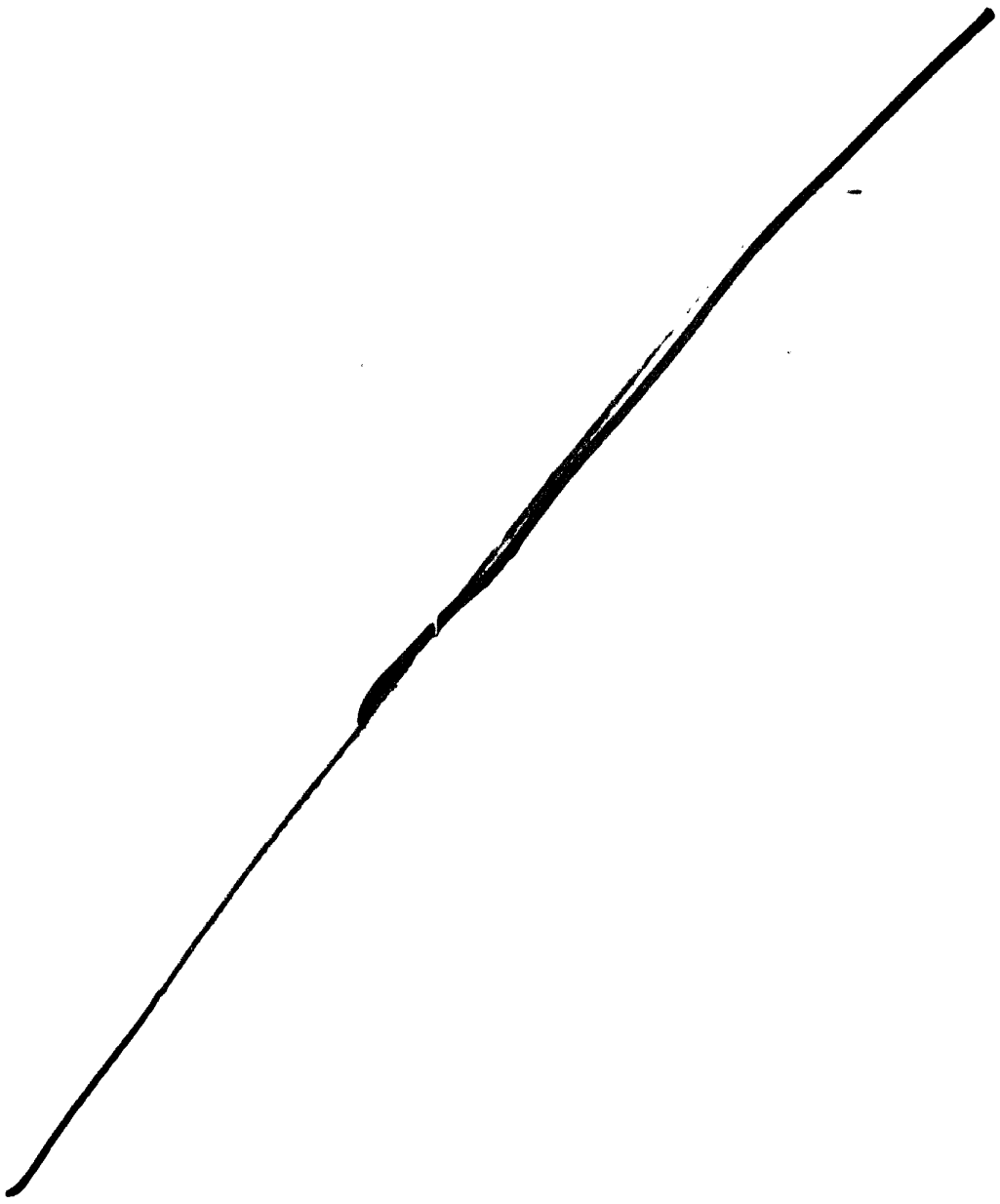
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

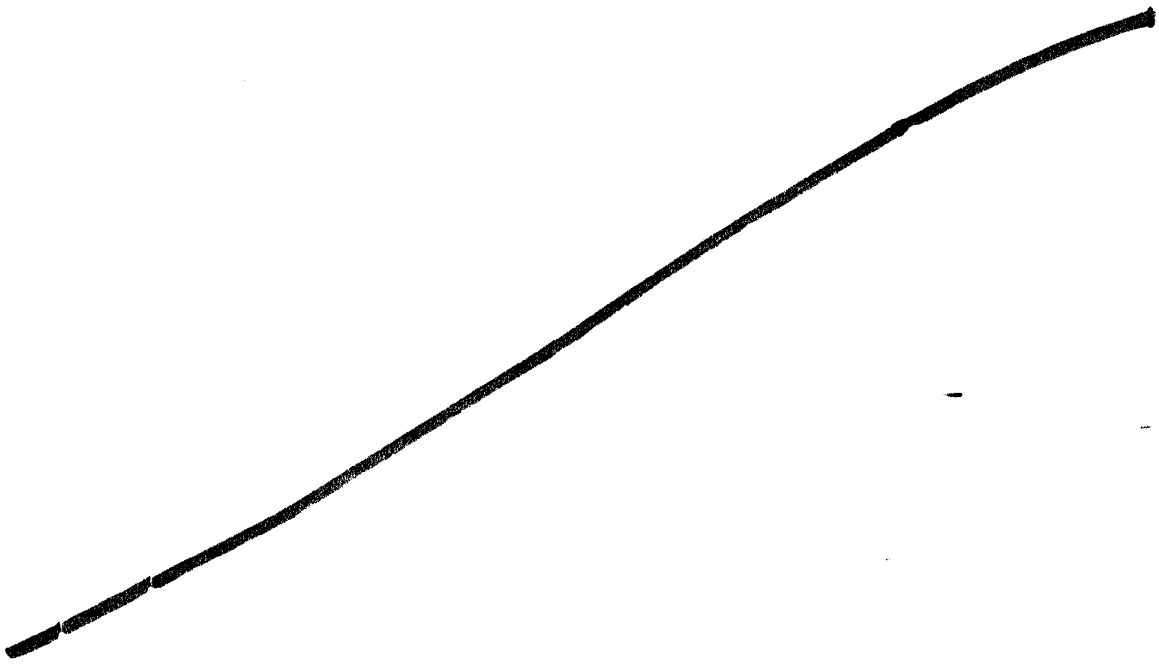
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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:

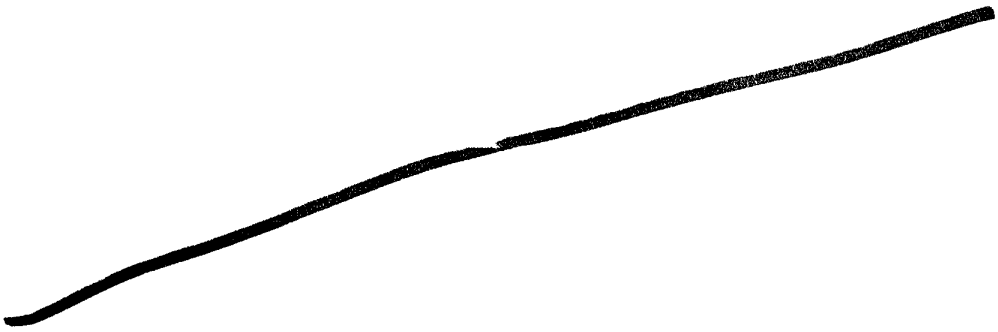
Section E. Standard Operating Procedures - Procedures Manual

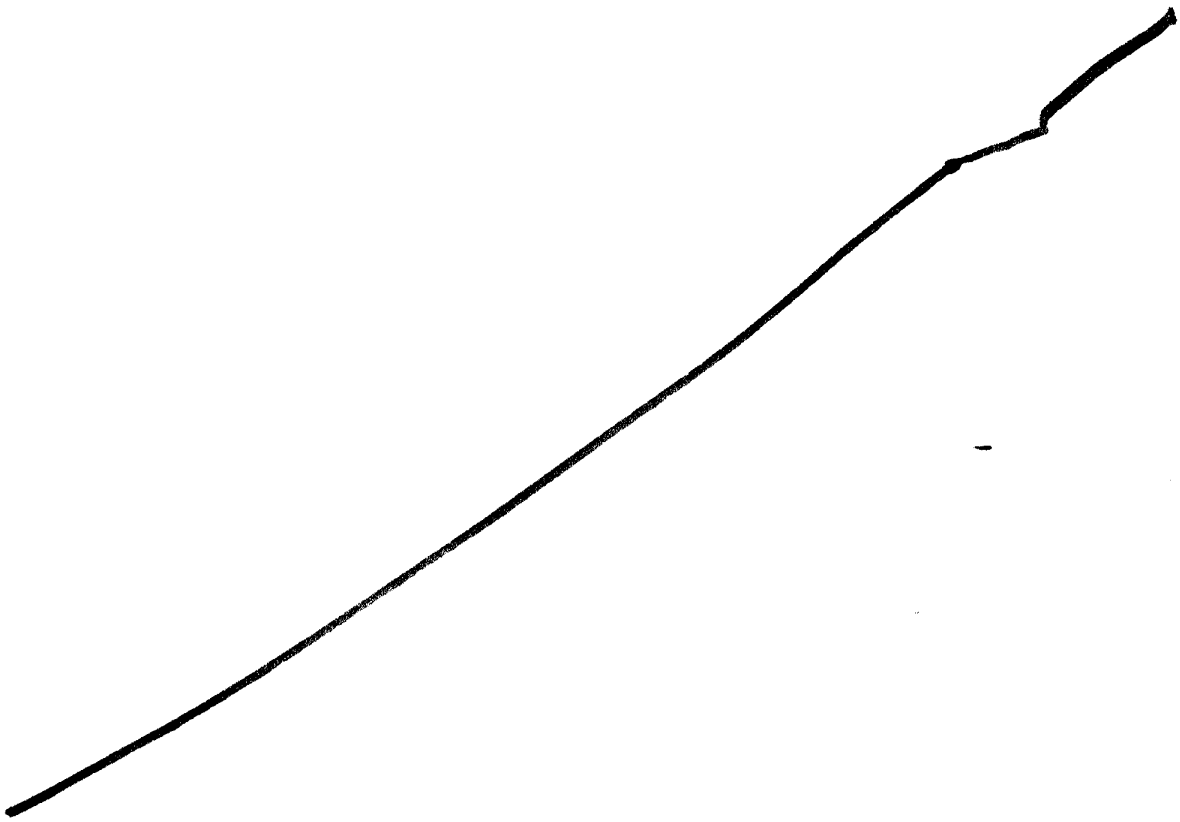




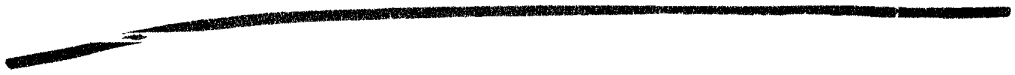
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

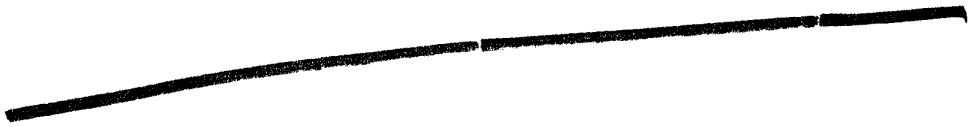




Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

PHARMCHEM
LABORATORIES, INC.
TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 ☐ (817)215-8601 ☐ (800)867-6378 ☐ Fax (817)215-6663
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park, California 94025 ☐ (800)446-6177 ☐ Fax (650)688-1122

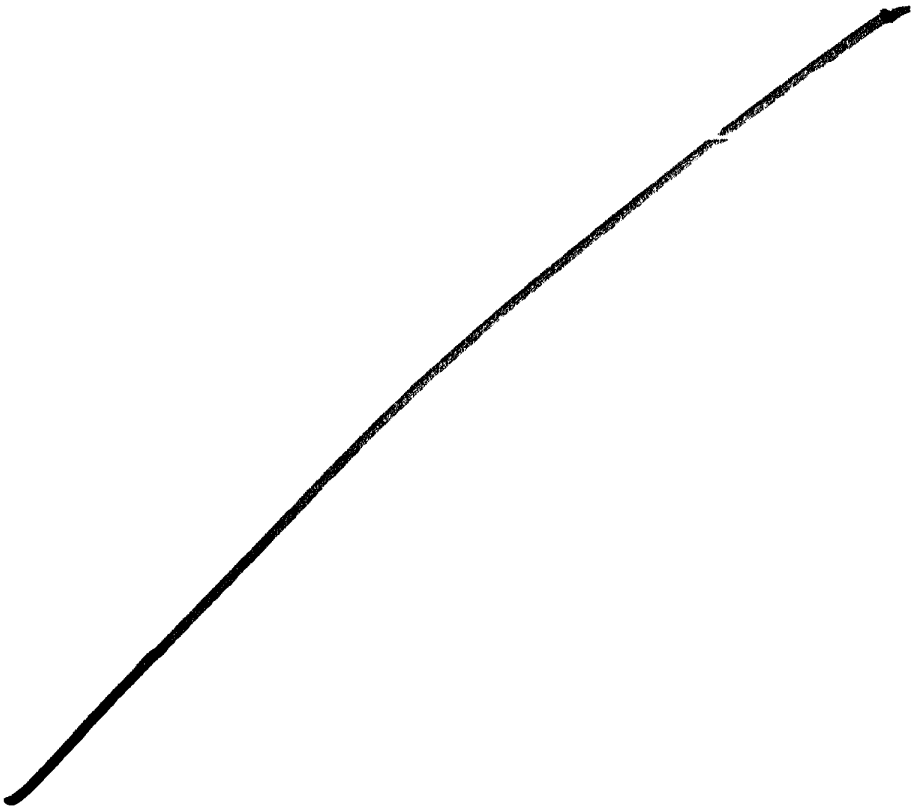
February 4, 2000

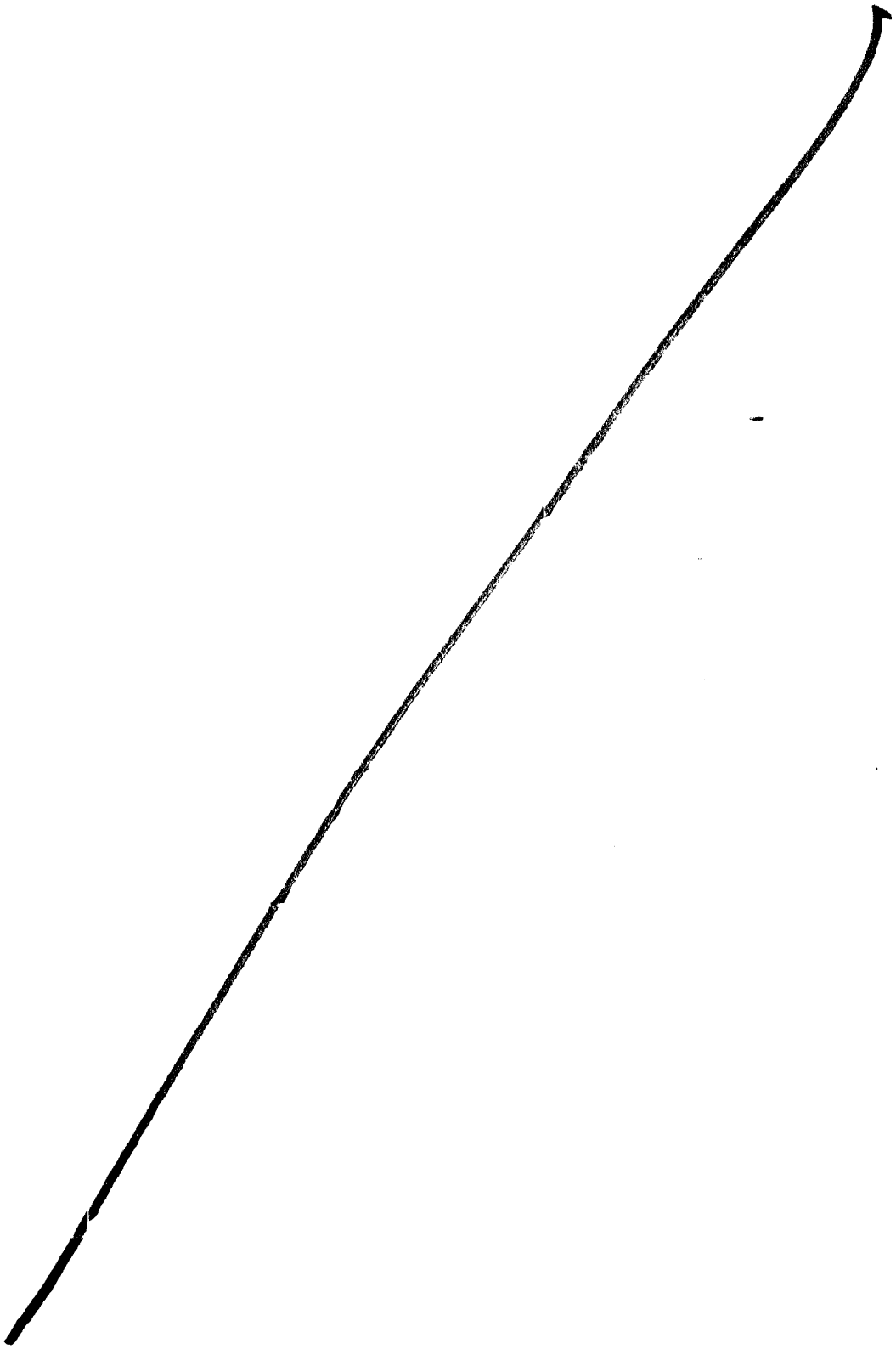
Ms. Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, North Carolina 27709-2194

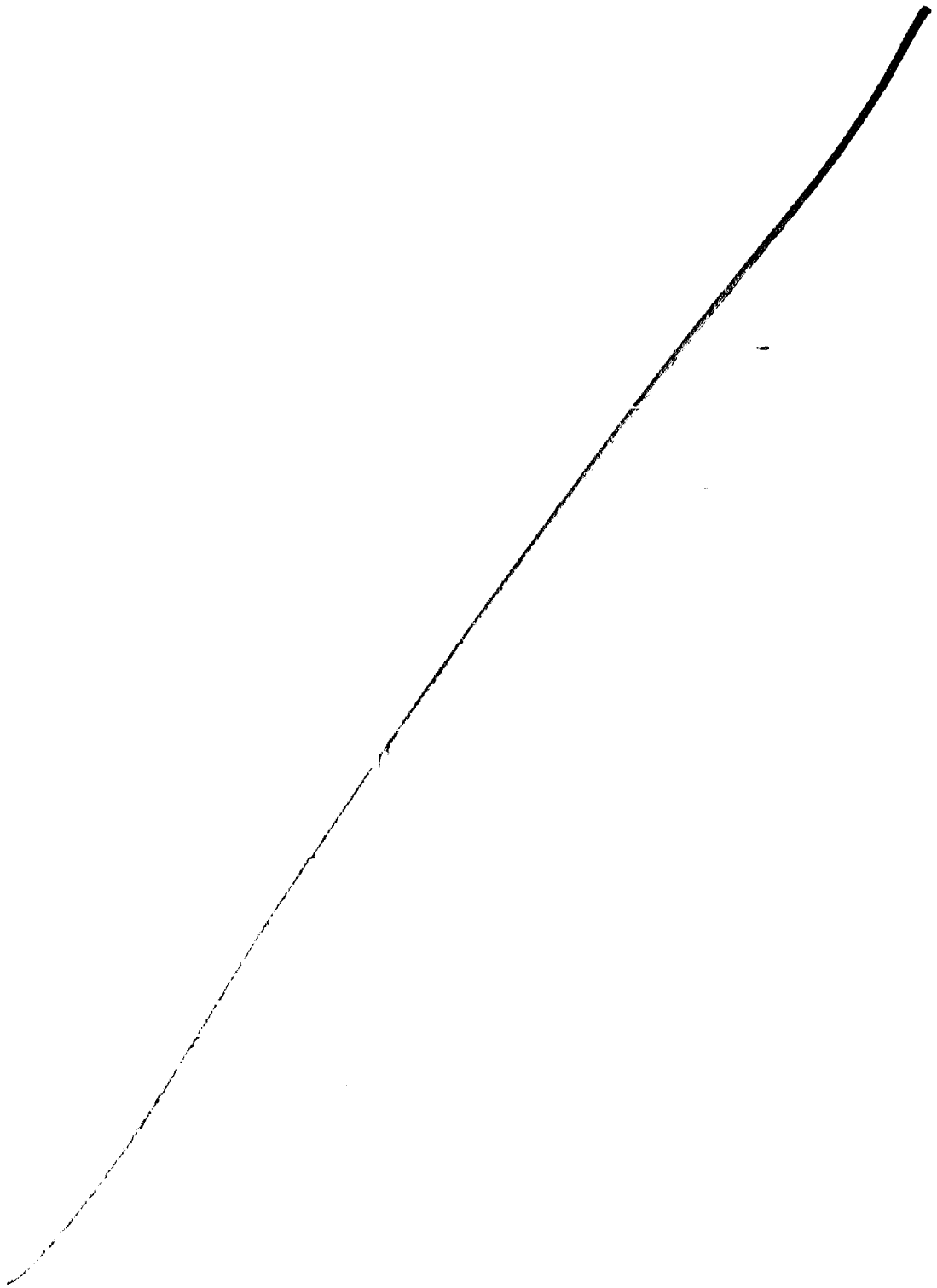
Dear Ms. Denson:

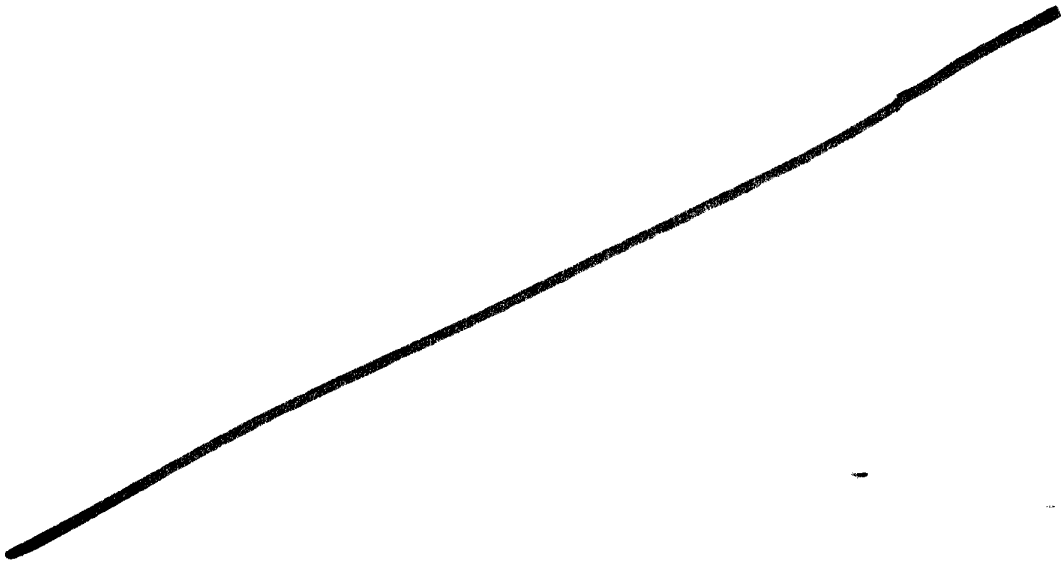
In response to the inspection critique from the seventeenth maintenance inspection of PharmChem Laboratories-Texas Division, the following documentation and corrective actions are submitted. The information submitted is organized and identified according to the sections and item numbers as listed in the inspection critique. In some of the attachments, the portion applicable to the specific critique item has been highlighted.

Section E. Standard Operating Procedures – Procedures Manual

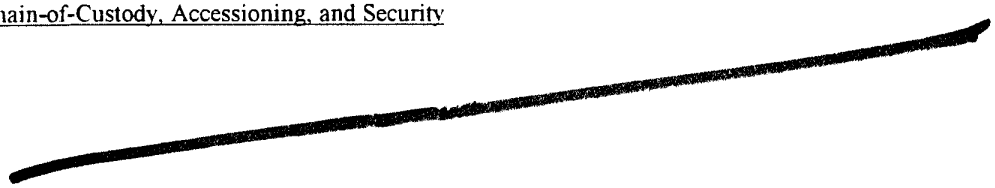




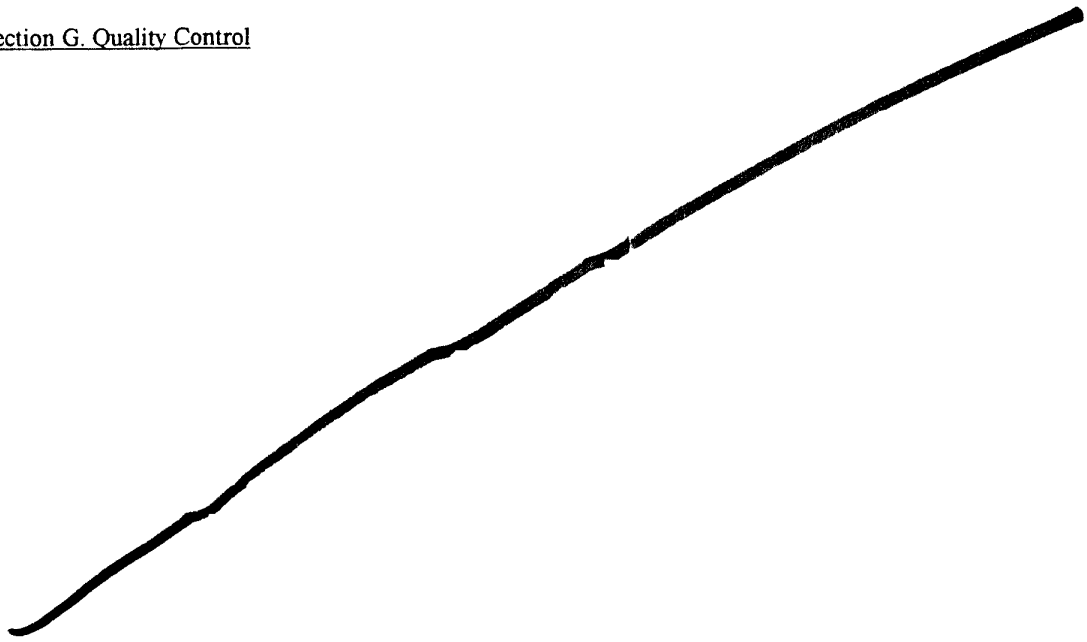


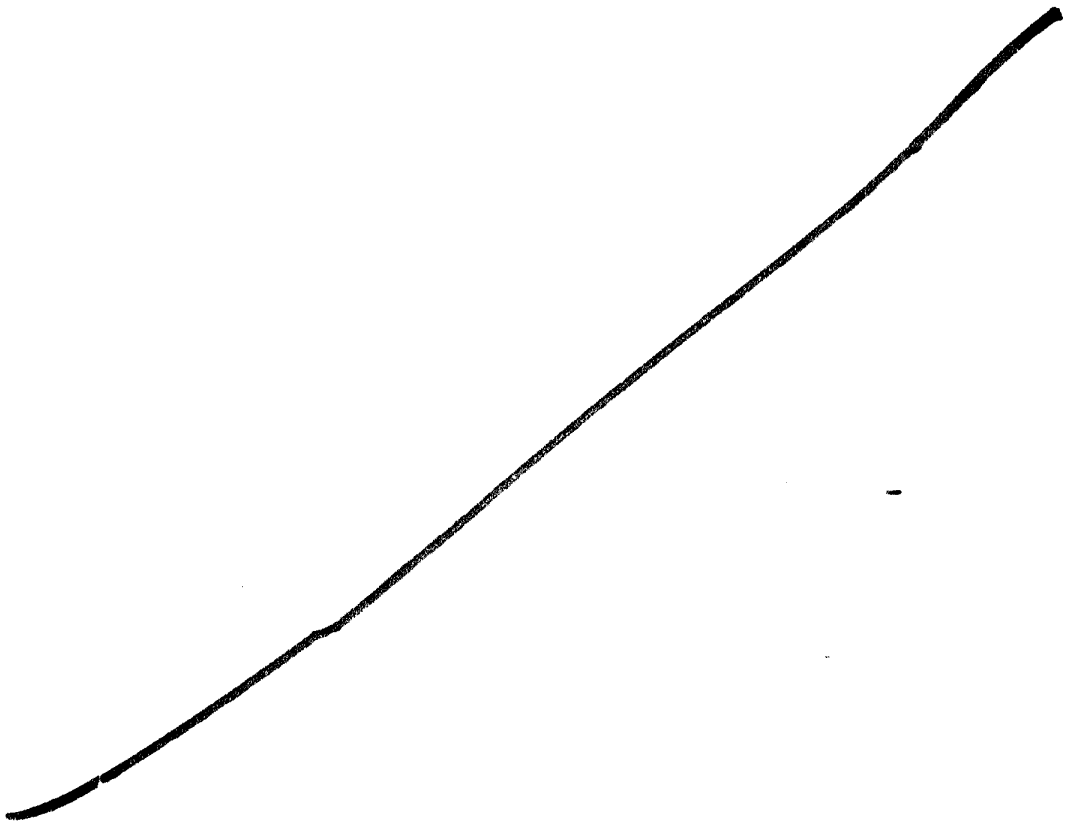


Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control

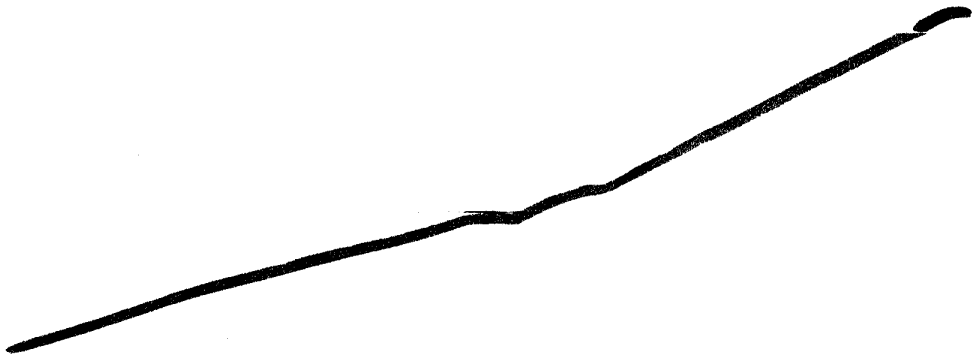




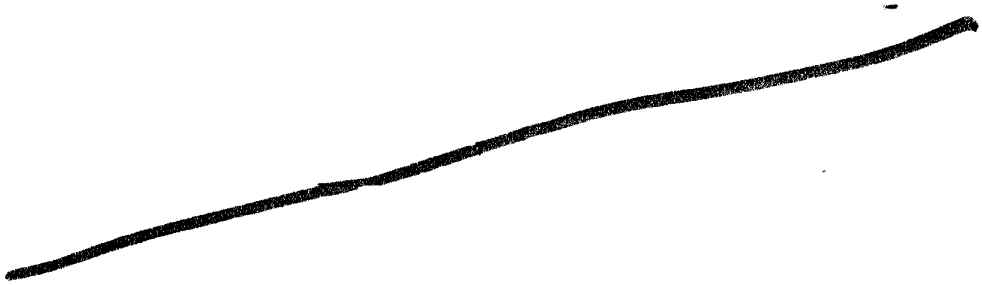
Section H. Initial Tests

Section I. Confirmatory Tests

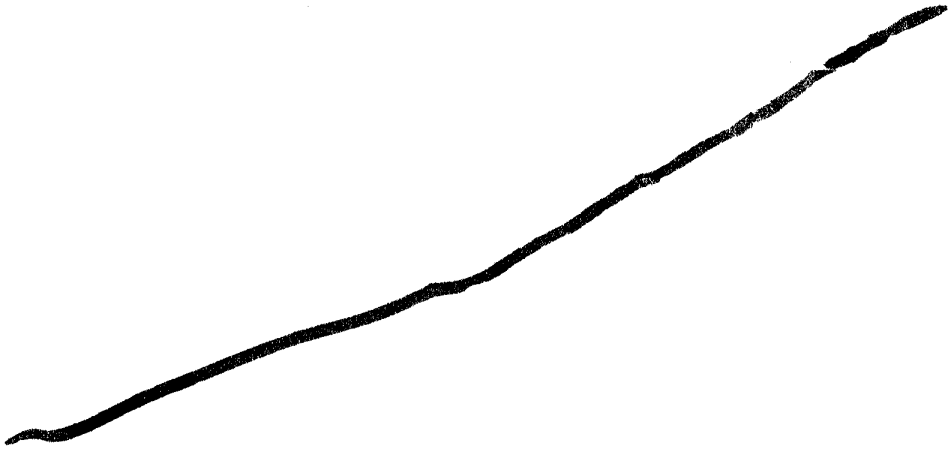
Section J. Records Audit



Section K. Reporting



Section M. Equipment and Maintenance



Section N, Personnel

If we can provide any additional information or clarification, please contact us.

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

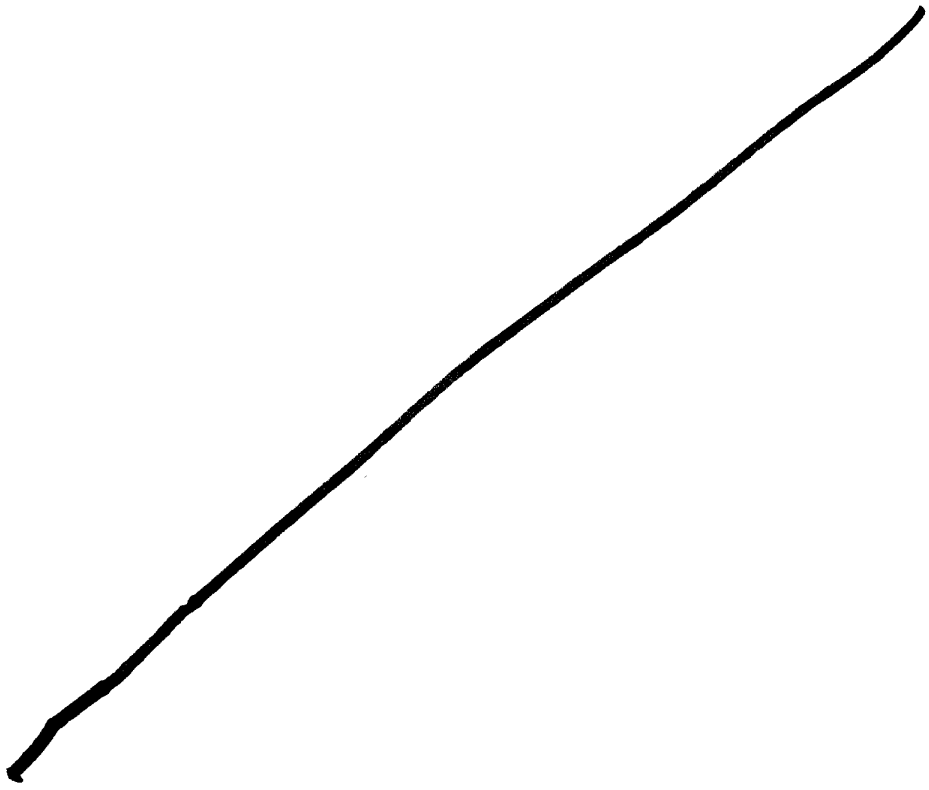
National Laboratory Certification Program

February 22, 2000

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of February 04, 2000, submitted in response to issues raised during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of January 12, 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:



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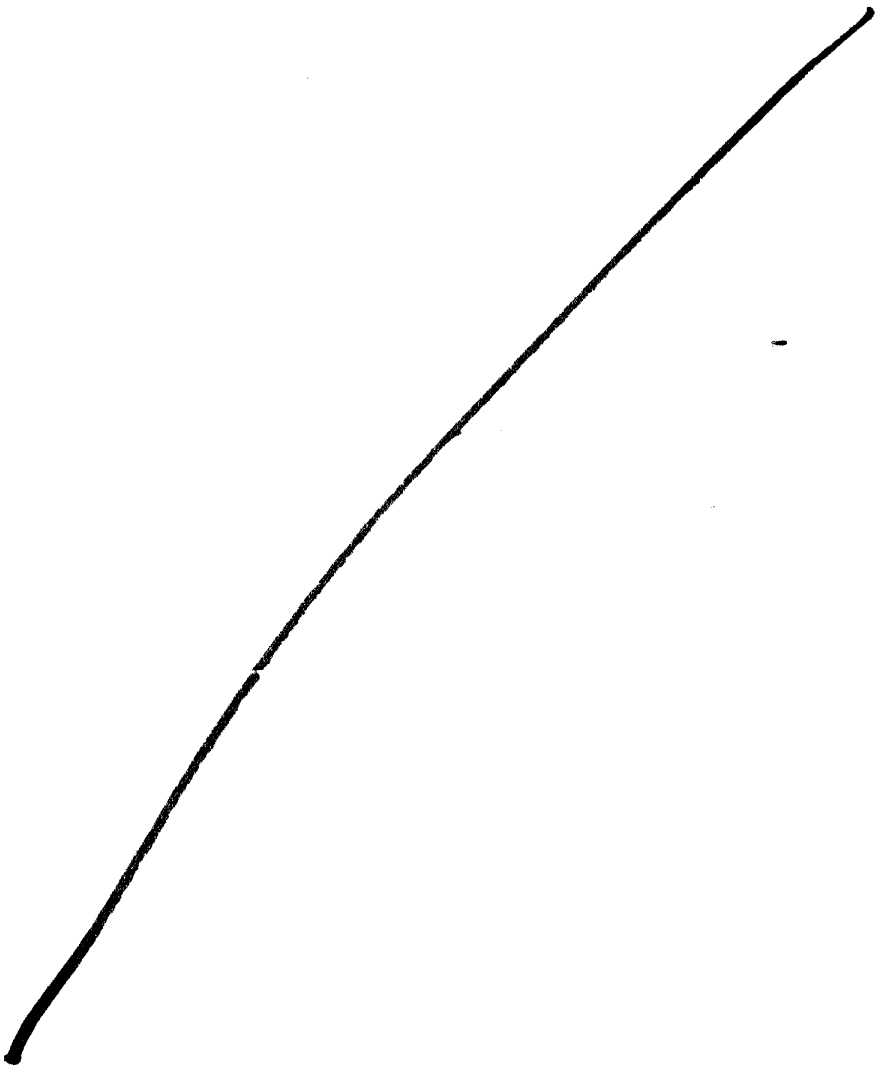
Telephone 919 541-6709 • Fax 919 541-7042



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.

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 Inspection Analyst

cc: Project Files/M17

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

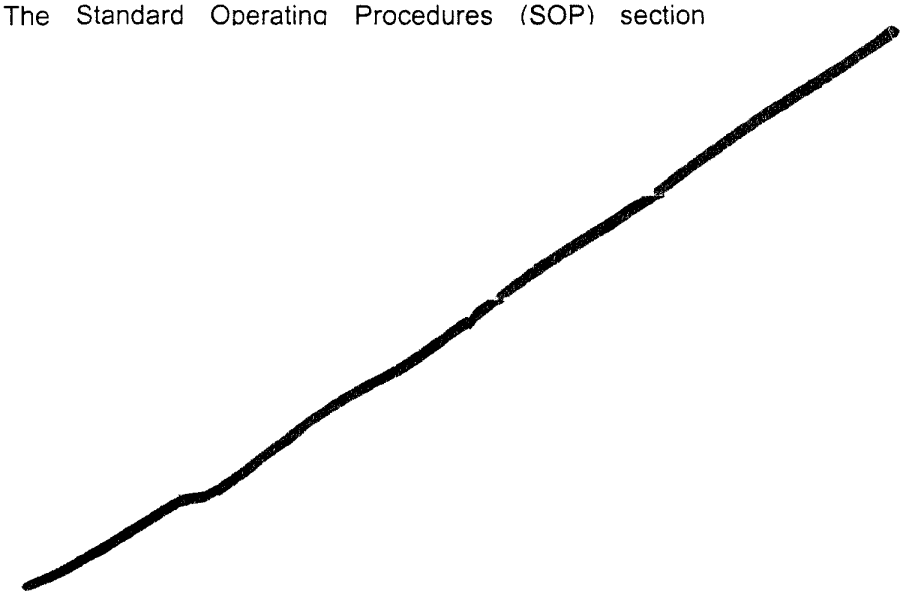
June 22, 2000

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

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. 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



H. The Initial Tests section

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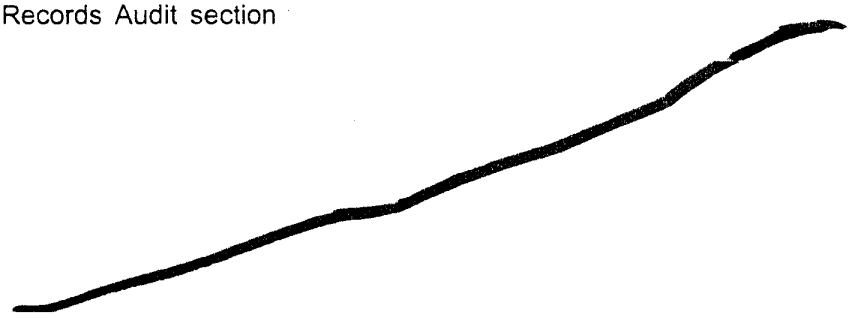
Telephone 919 541-6709 • Fax 919 541-7042

I. The Confirmatory Tests section

J. The Records Audit 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 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

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M18

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Texas Division

Location: Fort Worth, TX

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M18 Date: 4 May 2000
[ ] Other _____

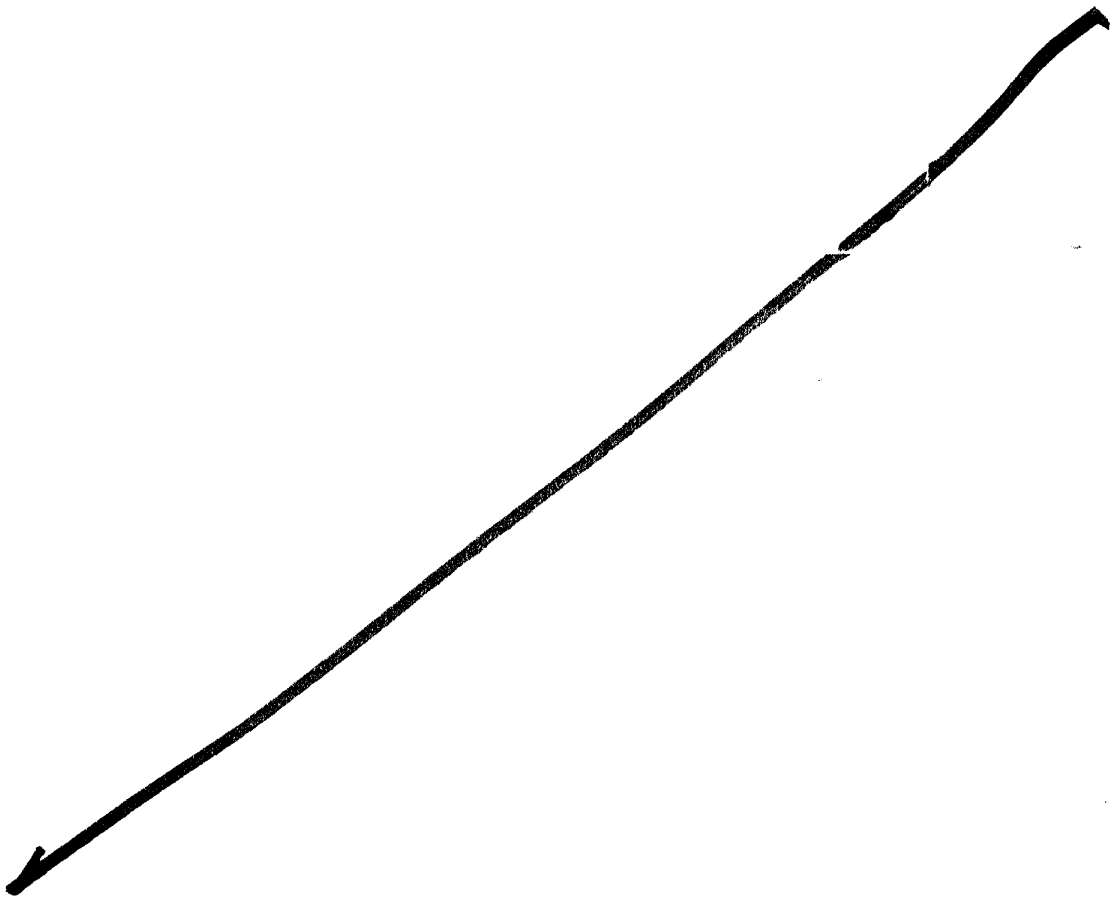
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

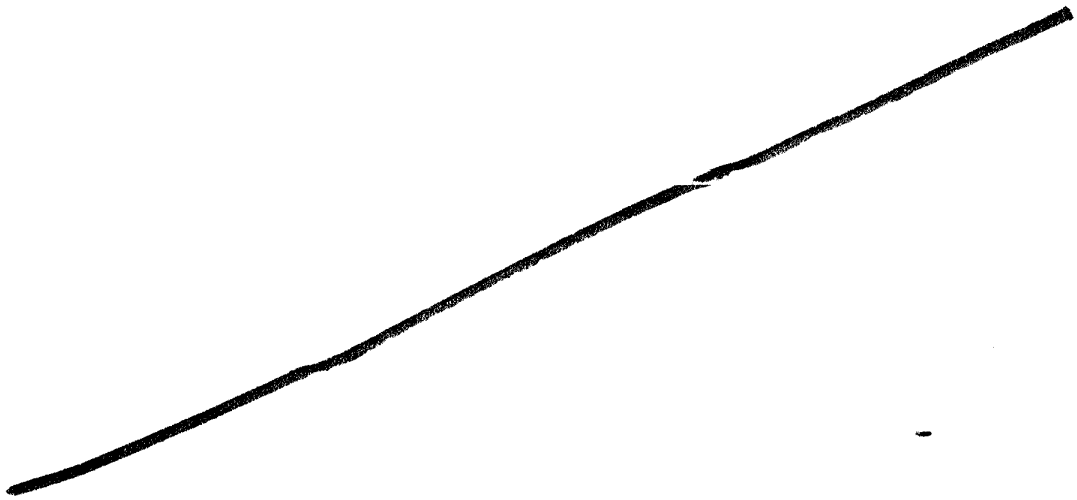


Section F. Chain-of-Custody, Accessioning, and Security

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

January 11, 2001

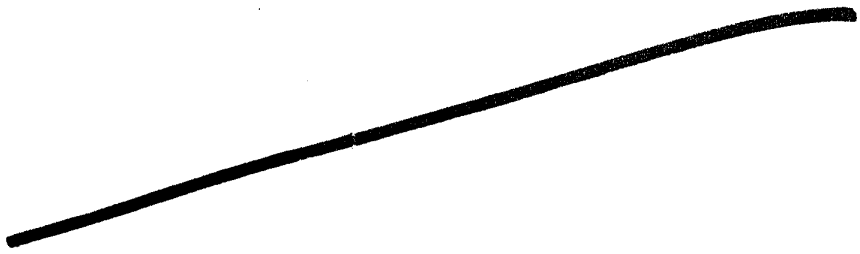
0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the outcome of the laboratory's performance in this inspection is unacceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following remedial actions:

E. The Standard Operating Procedures (SOP) section

G. The Quality Control and Quality Assurance section



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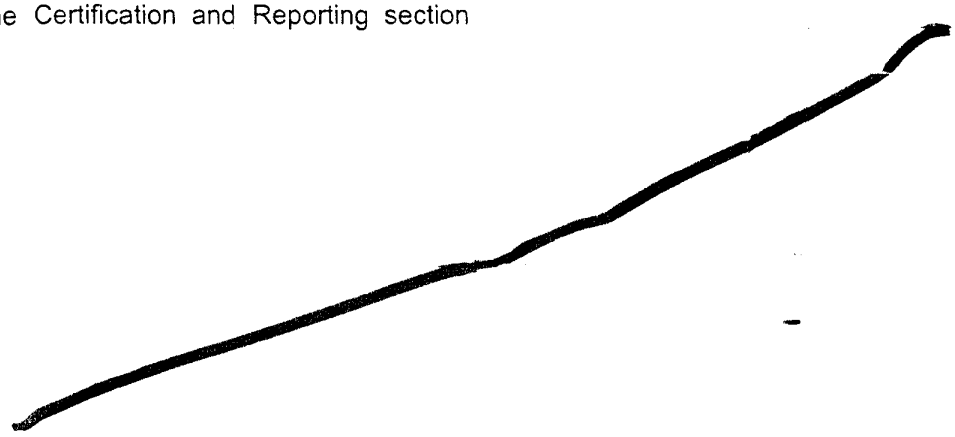
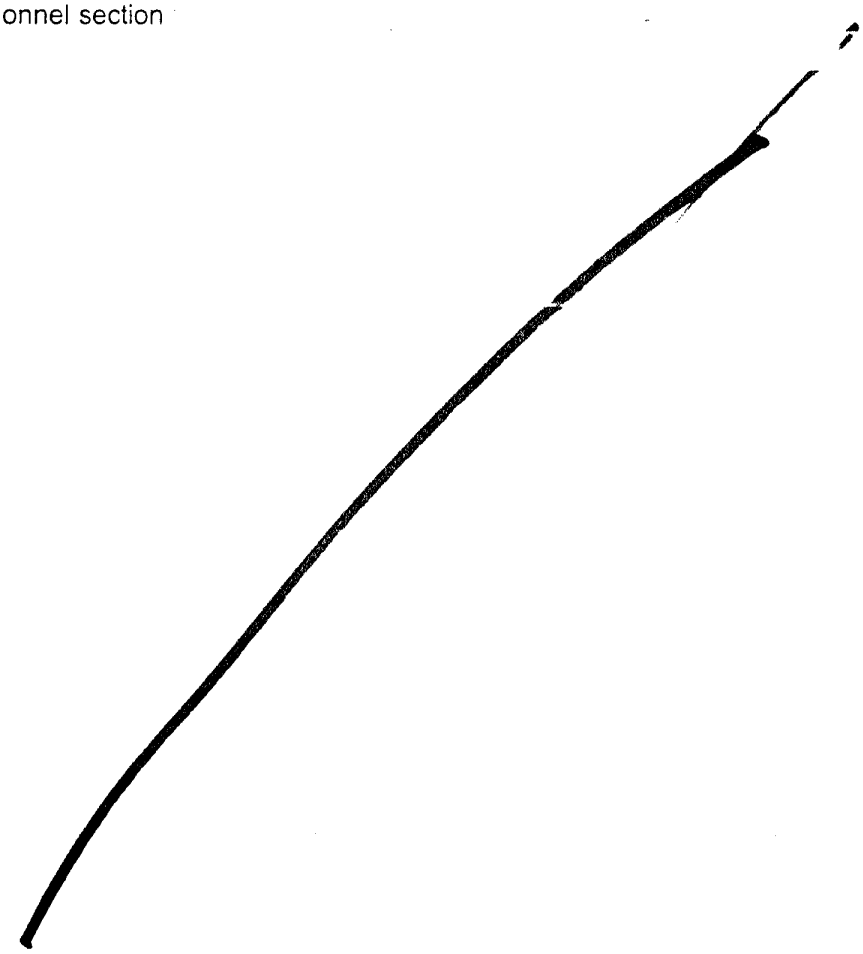
Telephone 919 541-6709 • Fax 919 541-7042

J. The Confirmatory Tests section

L. The Certification and Reporting section



N. The Personnel section



The laboratory must submit, within 5 calendar days of receipt of this letter, a plan to complete all remedial actions. Once this plan is approved, the laboratory will have a maximum of 30 calendar days to implement the plan and to complete all necessary remedial actions. If the laboratory fails to provide and execute an approved plan, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be suspended and/or revoked. The laboratory should also review the enclosed critique and take all necessary corrective actions.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to sustain acceptable performance in the inspection phase of this program may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the Mandatory Guidelines.

In responding to the issues raised, please organize the material in accordance with the item numbers listed in the text of this letter. If we can be of assistance or answer any questions, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Fort Worth, TX

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M19 Date: 2 November 2000
[ ] Other _____

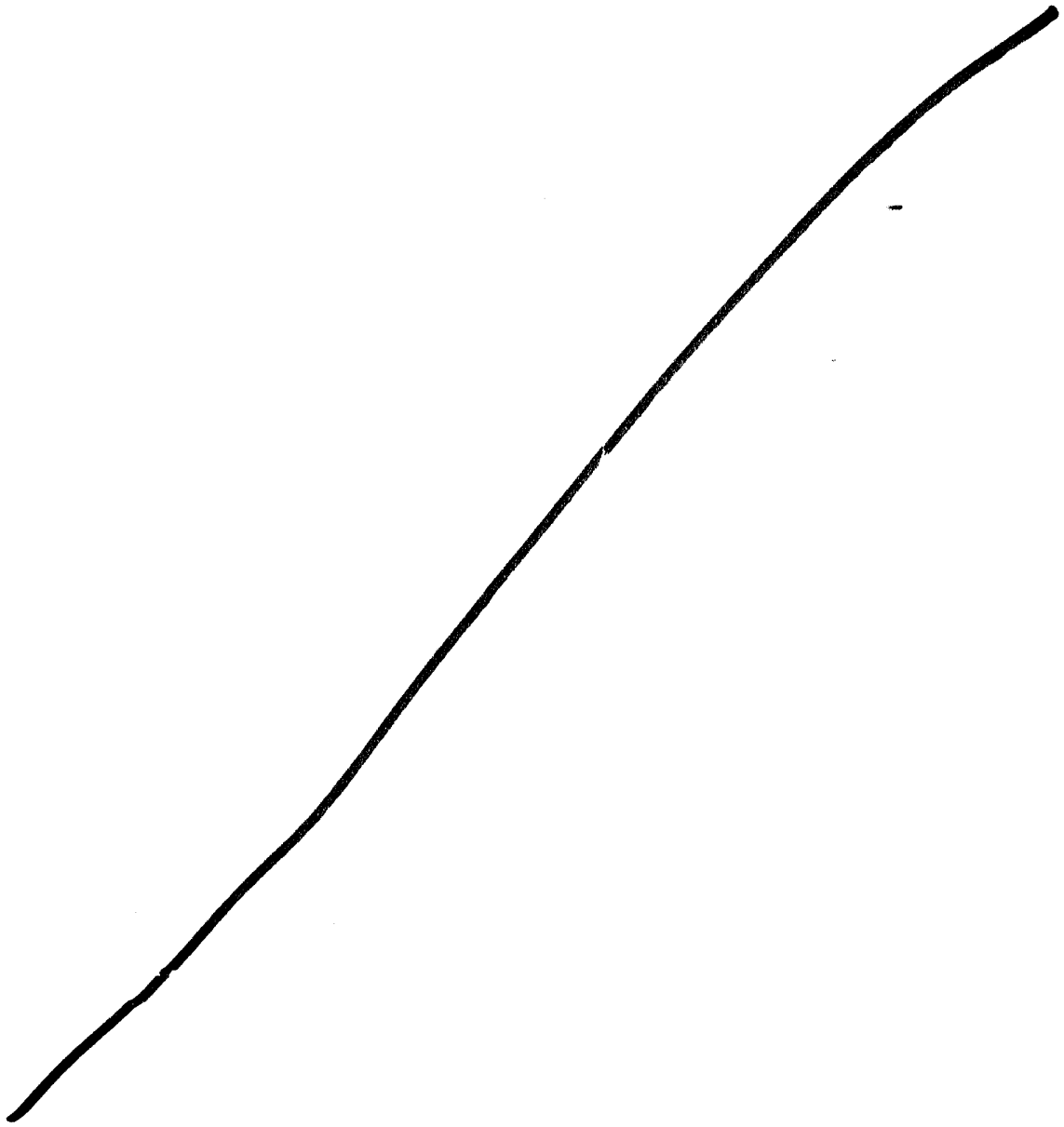
Status: [ ] Highly Acceptable [ ] Acceptable
[XX] Unacceptable [ ] Failure

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 not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required for continued certification.

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.

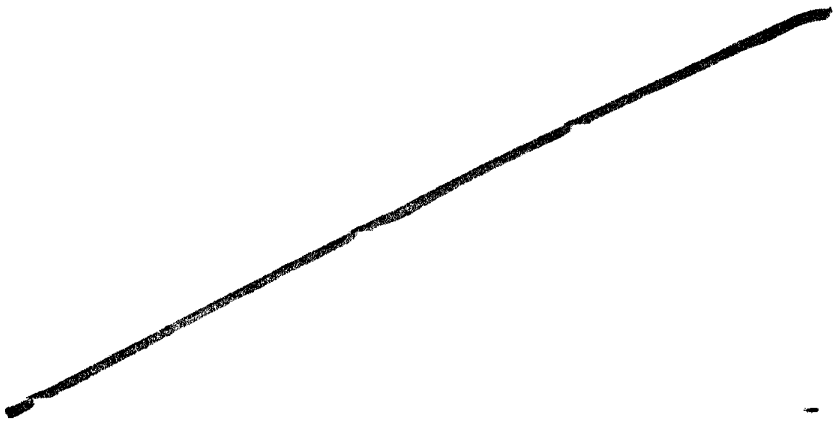
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



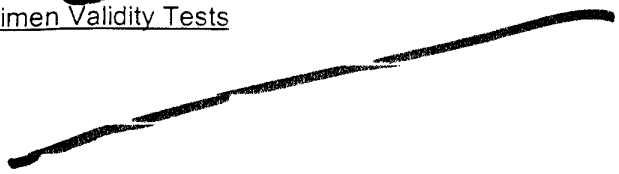
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

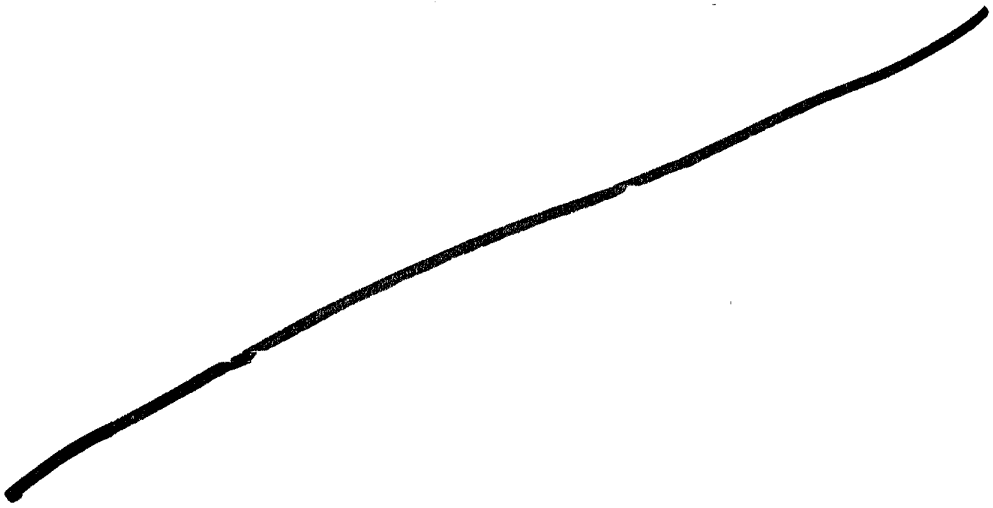


Section H. Initial Tests

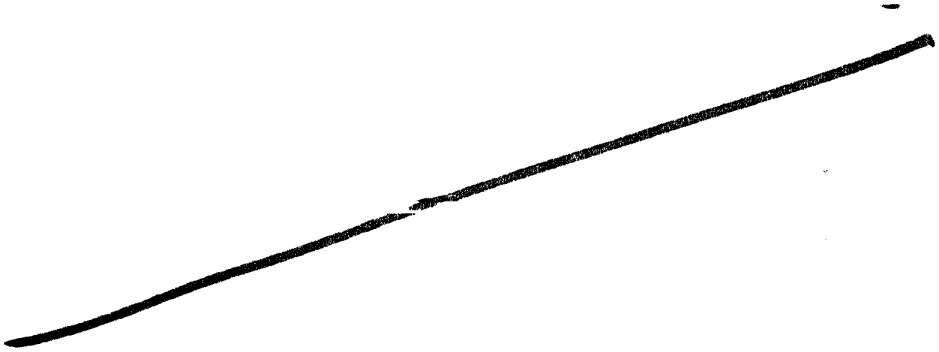
Section I. Specimen Validity Tests



Section J. Confirmatory Tests



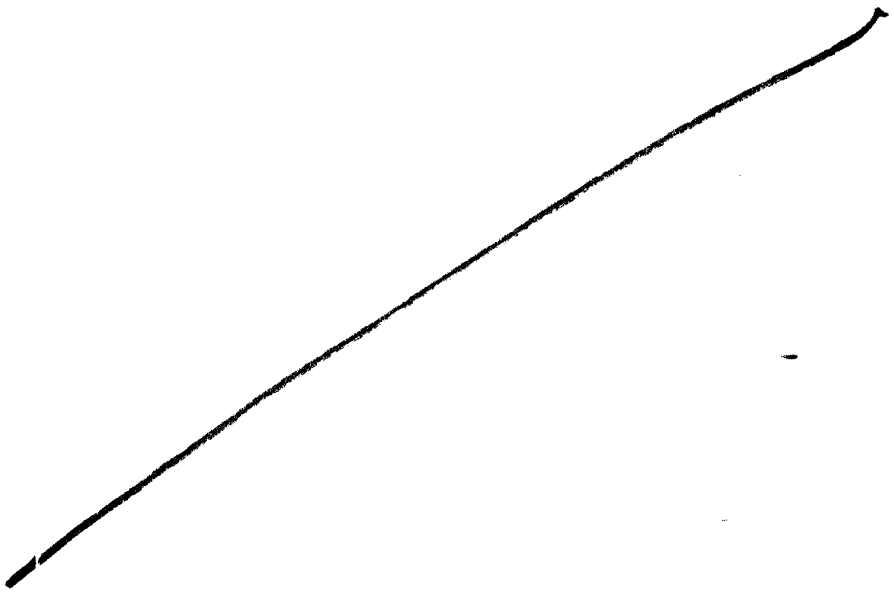
Section K. Records Audit



Section L. Certification and Reporting

Section M. Laboratory Information Management System

Section N. Personnel



PHARMCHEM
LABORATORIES, INC.

TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 ☐ (817)215-8800 ☐ 1(800)687-6378 ☐ Fax (817)215-8869
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park, California 94025 ☐ (800)446-5177 ☐ Fax (650)688-1122

January 18, 2001

Ms. Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road,
PO Box 12194,
Research Triangle Park NC 27709-2194

Dear Ms. Denson,

In response to your letter dated January 11, 2000, PharmChem Texas Division is responding to the issues raised in the inspection report for the 19th NLCP inspection carried out on November 2nd–3rd, 2000.

Please do not hesitate to contact me at (800) 446 5177 ext 809 if you have any questions about the information provided.

Sincerely,

Robert O. Bost, PhD.

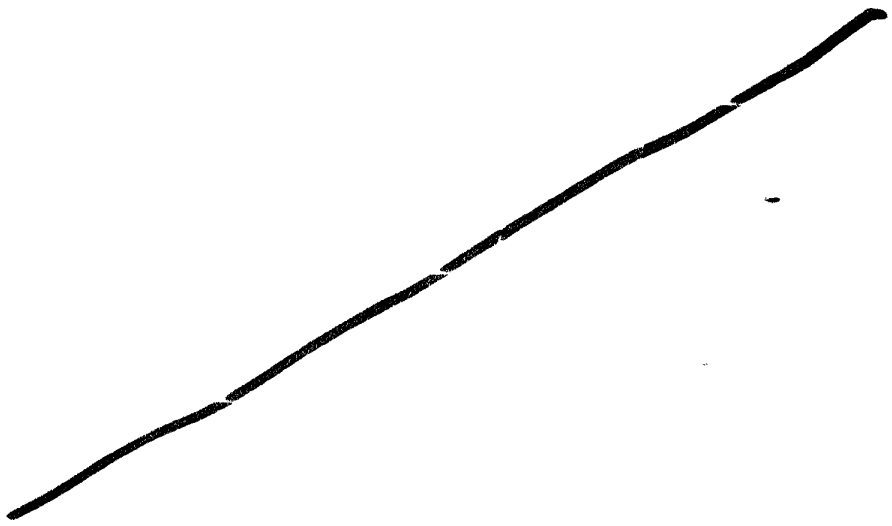
Robert O. Bost, Ph.D.
Laboratory Director

Cc Joseph W. Halligan, President and CEO, PharmChem Inc.
Neil Fortner, Vice-President, Laboratory Operations.
Compliance

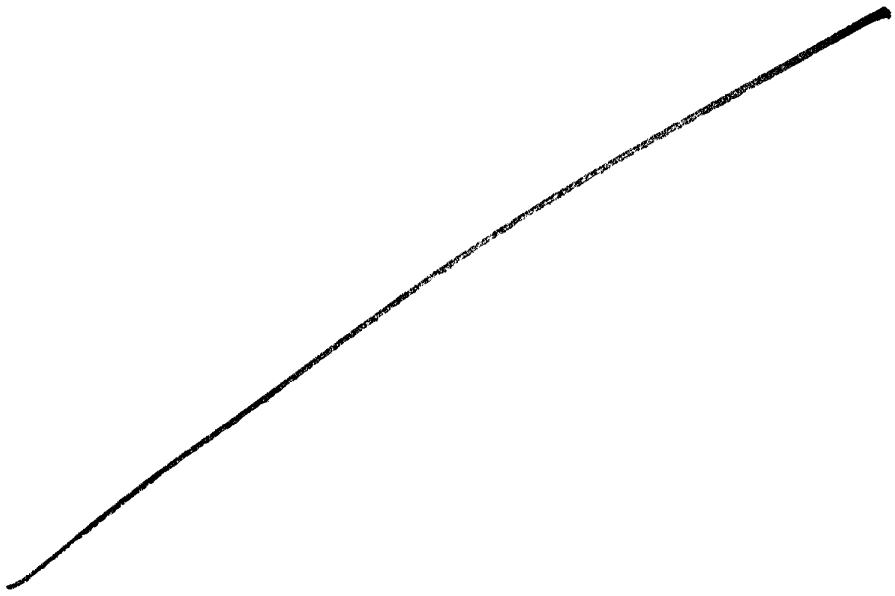
PHARMCHEM TEXAS DIVISION (Lab 108)

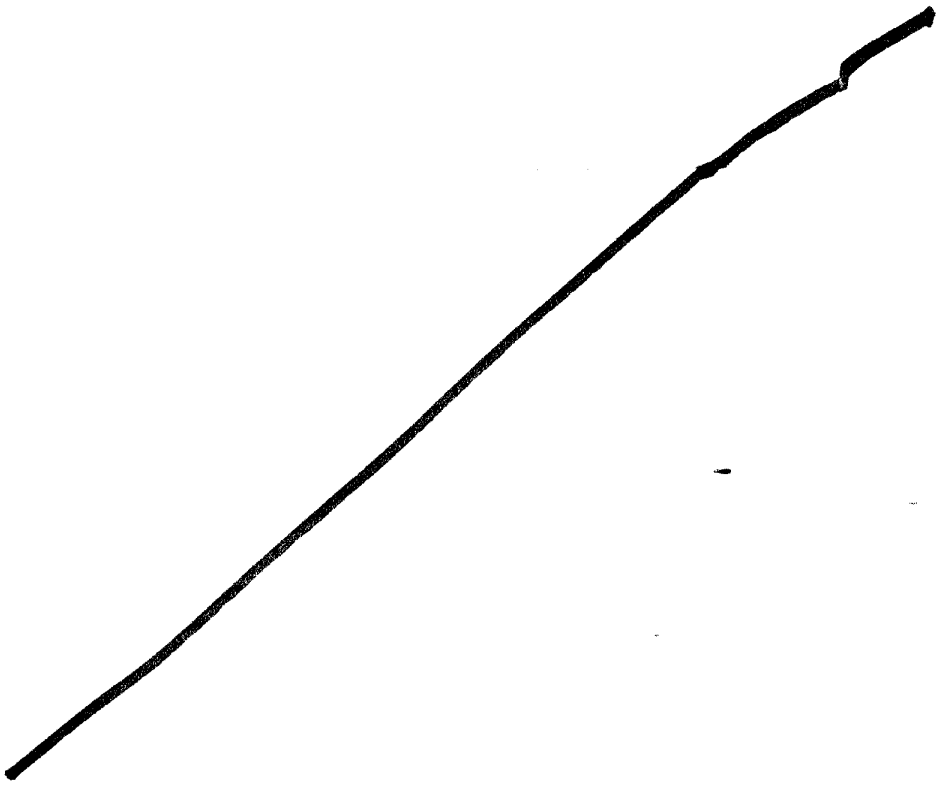
CORRECTIVE ACTION PLAN IN RESPONSE TO THE 19TH NLCP INSPECTION

E The Standard Operating Procedures (SOP) section was not found fully acceptable

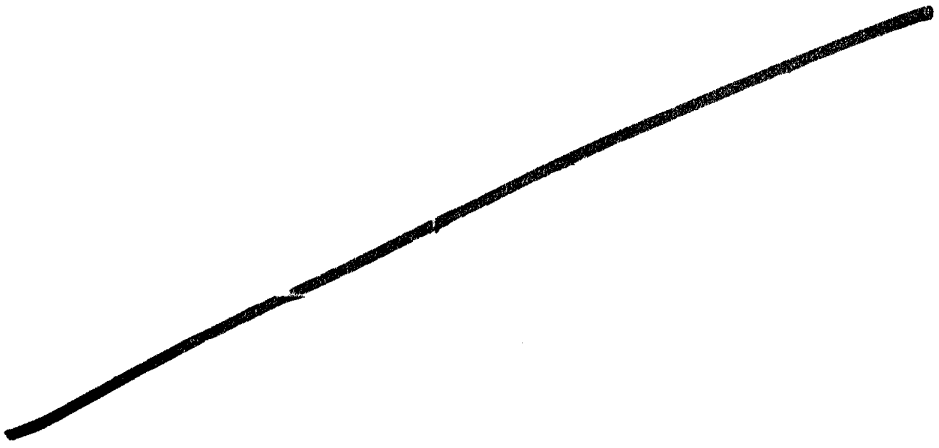


G The Quality Control and Quality Assurance section was not found fully acceptable

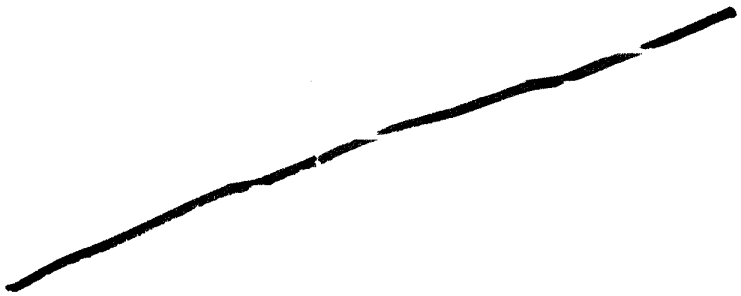




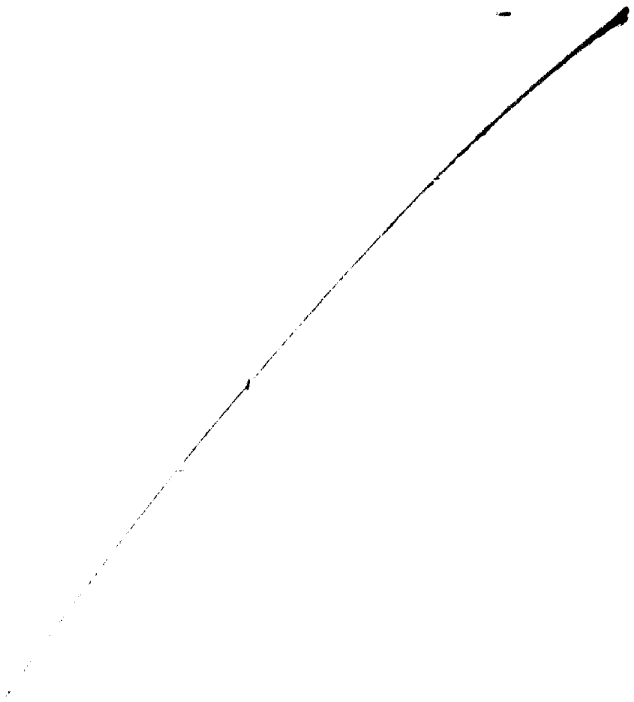
J The Confirmatory Test Section was found to be unacceptable



L The Certification and Reporting section was not found fully acceptable



N **The Personnel section was not found fully acceptable**



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 23, 2001

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of January 18, 2001, provided in response to the deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of January 11, 2001. The plan to clarify and/or correct the deficiencies noted was found acceptable.

The laboratory must submit the final report within 30 calendar days of receipt of this letter. This report must include documentation to demonstrate completion of remedial actions outlined in your correspondence. If you have any questions or want to further clarify any of these issues, please call me at (919) 541-7043 or Ms. Deborah Denson at (919) 541-7265.

Sincerely,

Michael R. Baylor, Ph.D.

cc: Ms. Deborah Denson
Project Files/M19

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

PHOENIX CHEMICAL LABORATORIES, INC.

TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 ☐ (817)215-8800 ☐ (800)967-8378 ☐ Fax (817)215-8863
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park,California 94025 ☐ (800)446-5177 ☐ Fax (650)688-1122

February 21, 2001

Ms. Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Denson:

As directed in your letter of January 11, 2001, we prepared and submitted a plan of action to respond to the issues raised following our M19 National Laboratory Certification Program Maintenance Inspection, conducted November 2-3, 2000.

If you have questions or if we can provide additional information, please contact us (817-215-8826).

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director / Responsible Person

RESEARCH TRIANGLE INSTITUTE

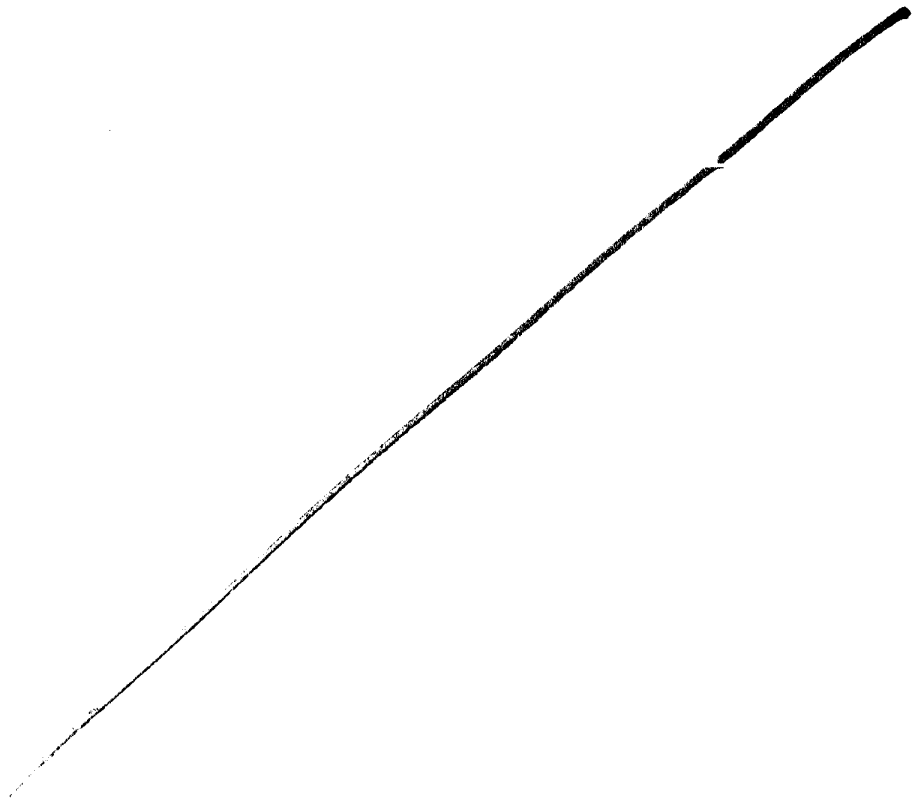
National Laboratory Certification Program

March 08, 2001

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of February 21, 2001, submitted in response to deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of January 11, 2001. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the deficiencies raised. The following is a review of the material submitted:



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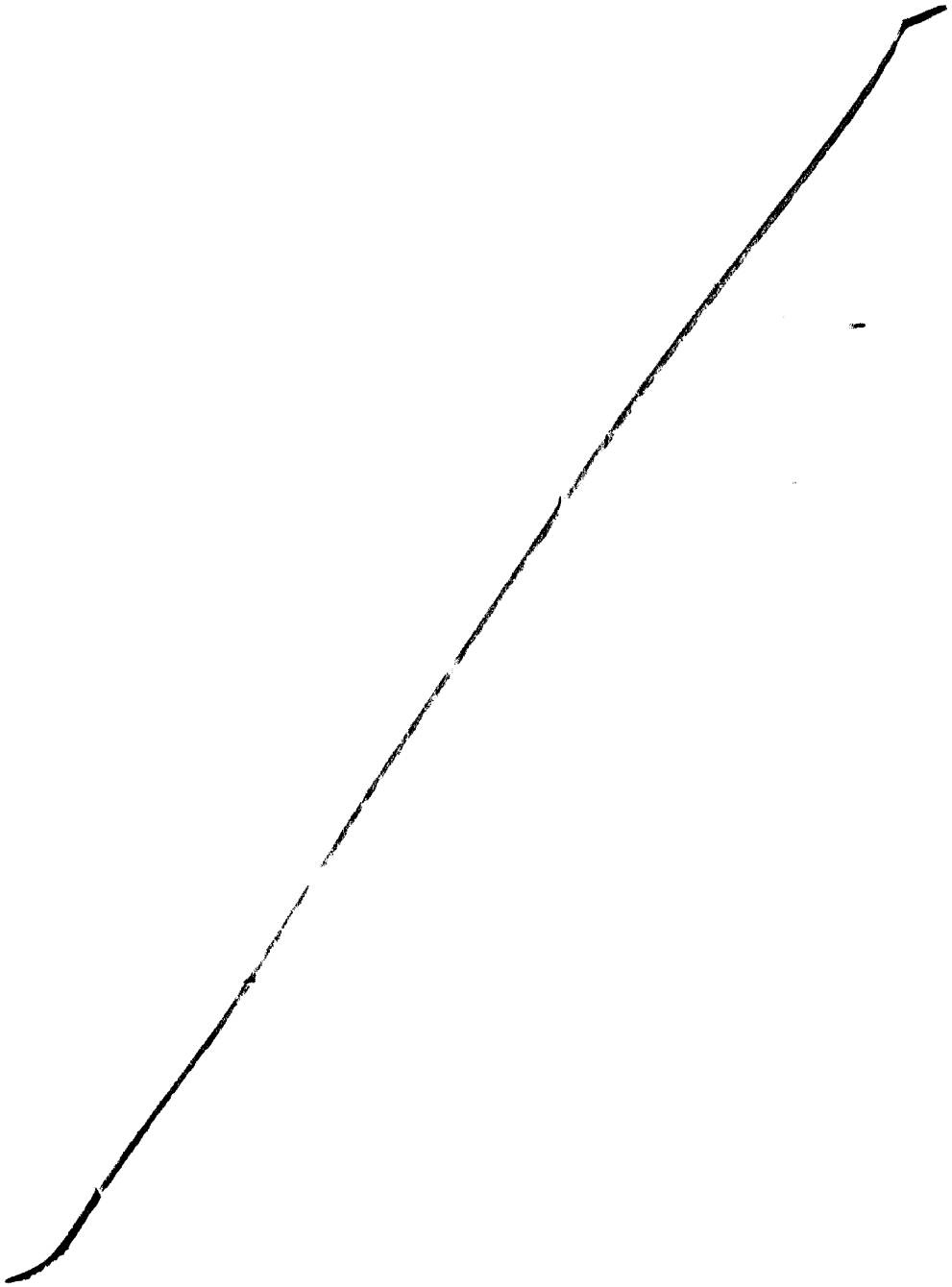
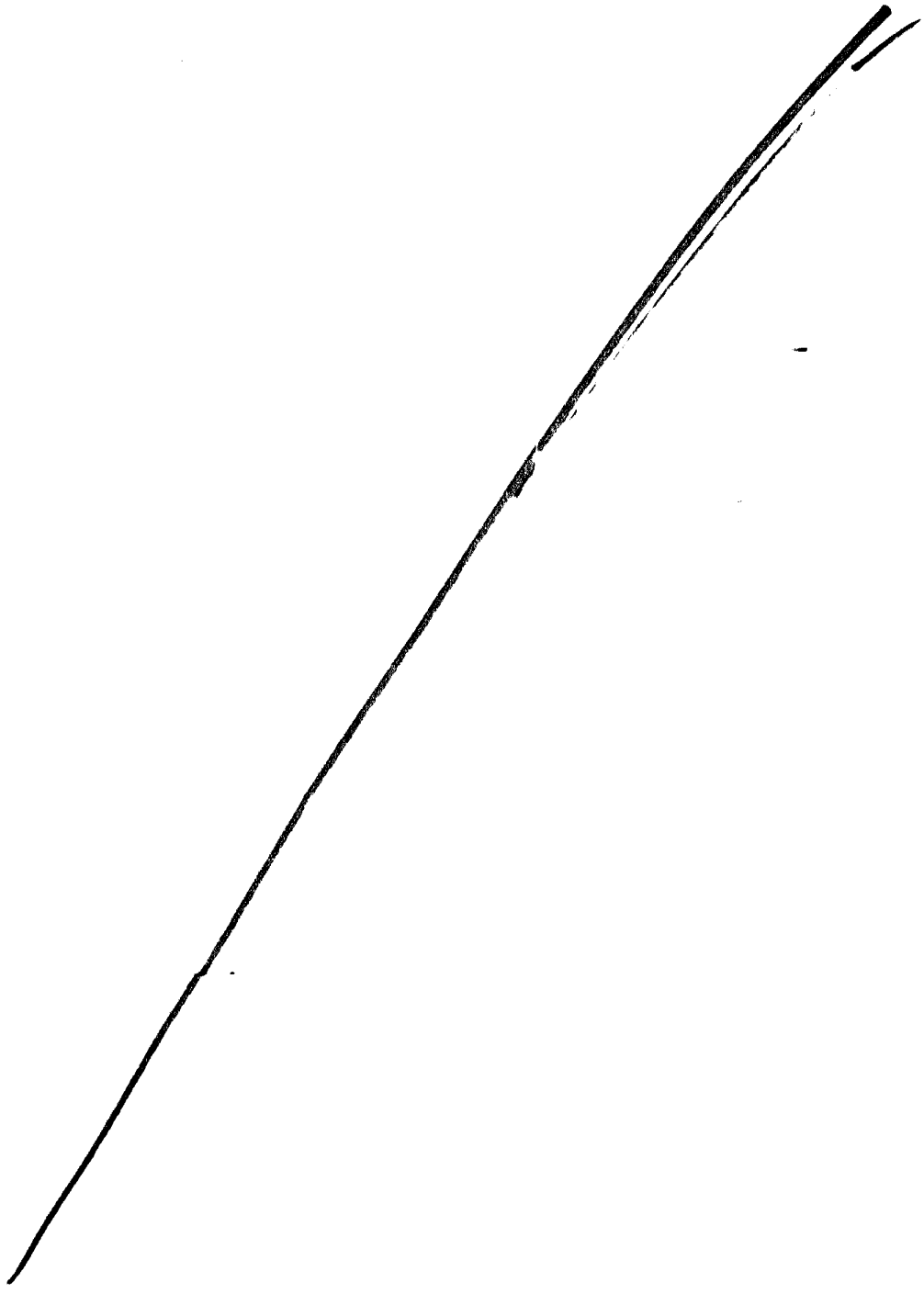
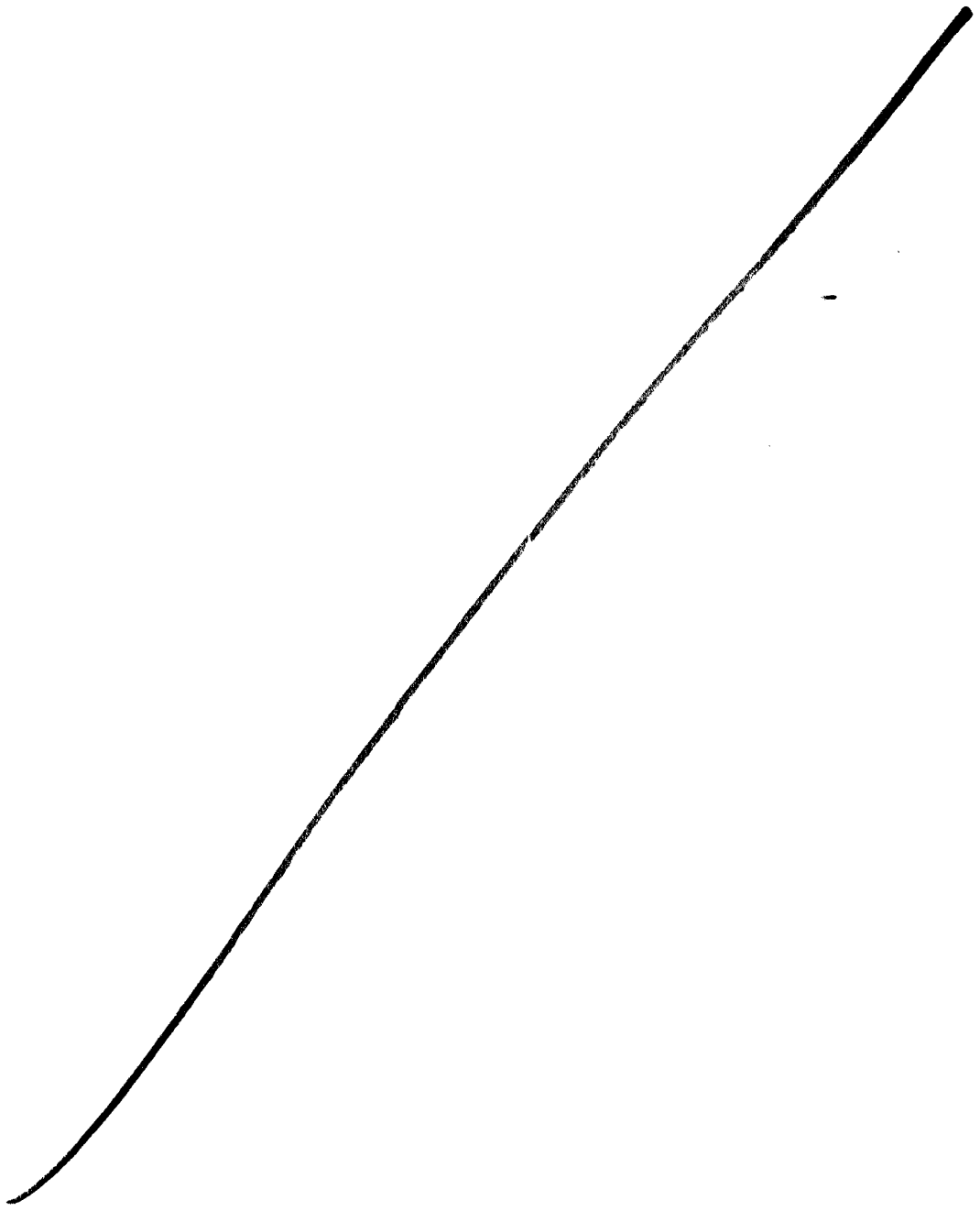
Telephone 919 541-6709 • Fax 919 541-7042







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.

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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M19