

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program



January 21, 1999

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fishinger:

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 acceptable. However, the following issues were raised:

I. The Confirmatory Test section

[Redacted content]

J. The Records Audit section

[Redacted content]



K. The Reporting section

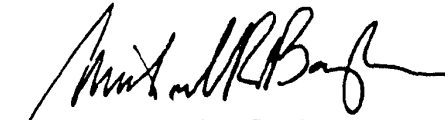
The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of the Program and the issues addressed in this correspondence. 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.

Dr. Fishinger
January 21, 1999
Page 3 of 3

If you have any questions or if we can be of further assistance, please call me at (919) 541-7043 or Deborah J. Denson at (919) 541-7265.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael R. Baylor". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael R. Baylor, Ph.D.
Sr. Forensic Toxicologist

Enclosure

cc: Project Files/M14

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NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UNILAB

Location: Tarzana, CA

Document Reviewed: Application Form
 Inspection Report #M14 Date: 10 December 1998
 Other _____

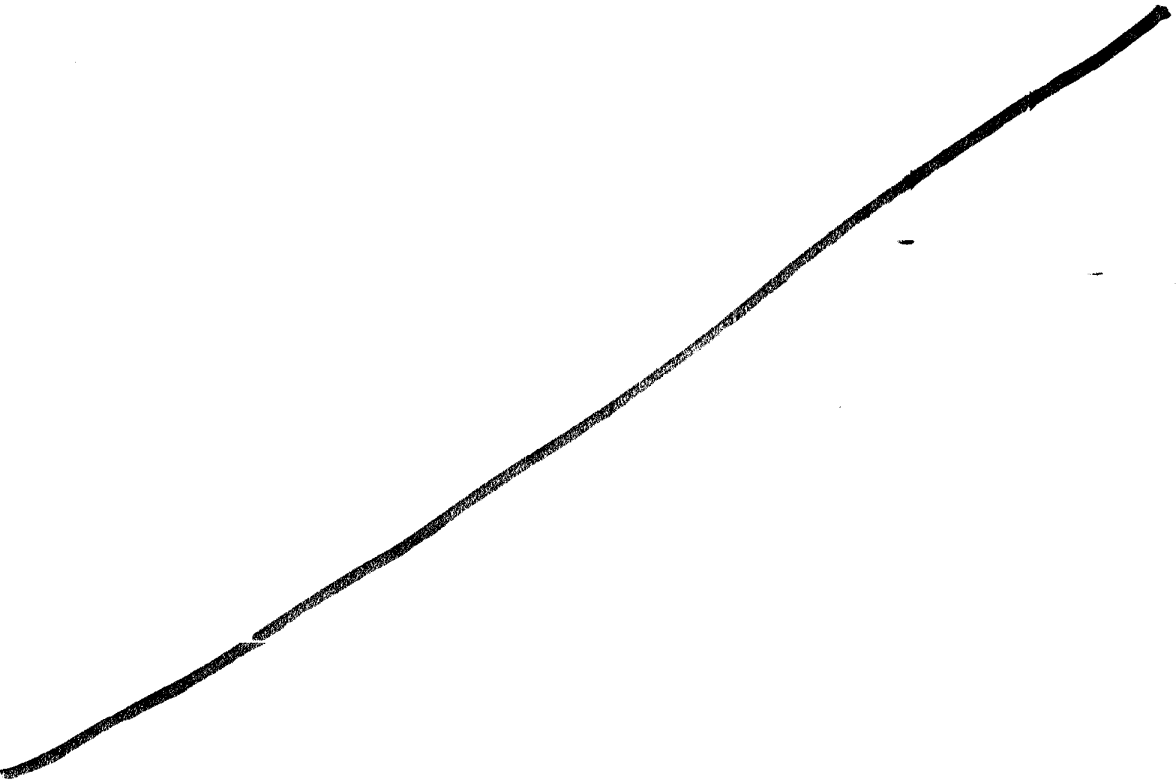
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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:

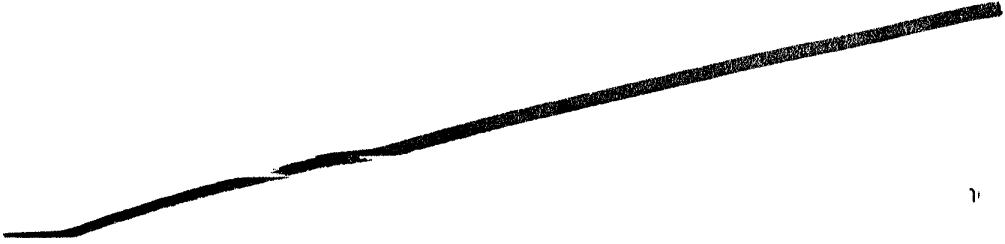
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



[Redacted]

Section H. Initial Tests

[Redacted]

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]

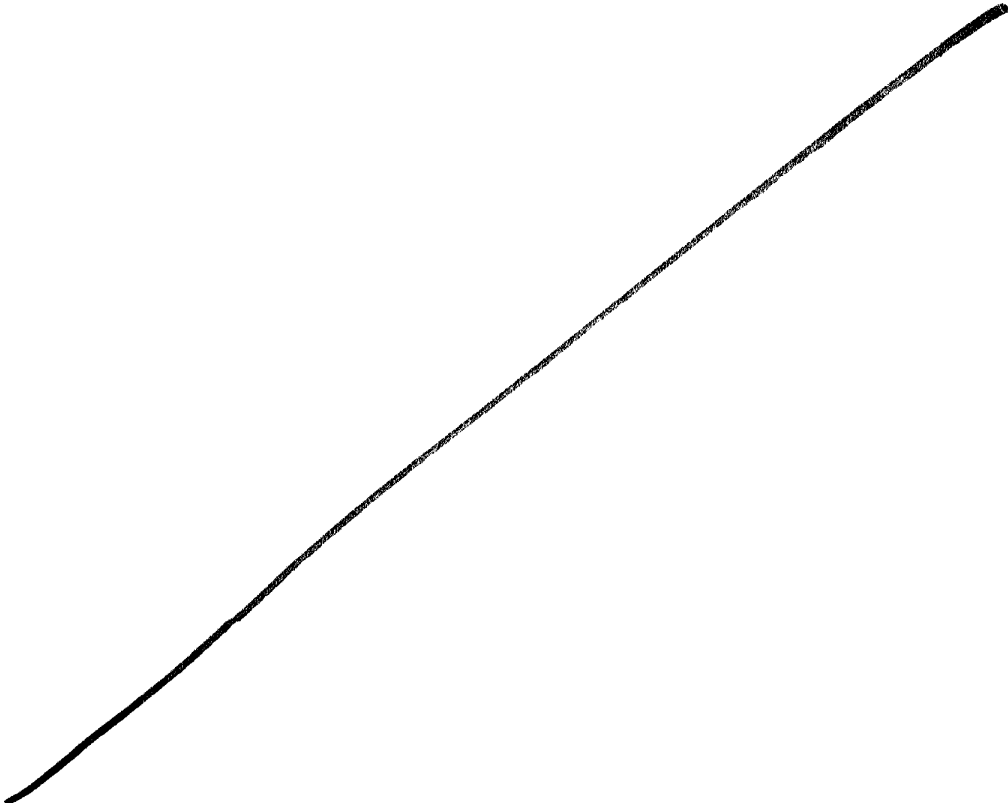


Dr. Michael R. Baylor, Ph.D.
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park
North Carolina 27709-2194 USA

P. 1 of 8

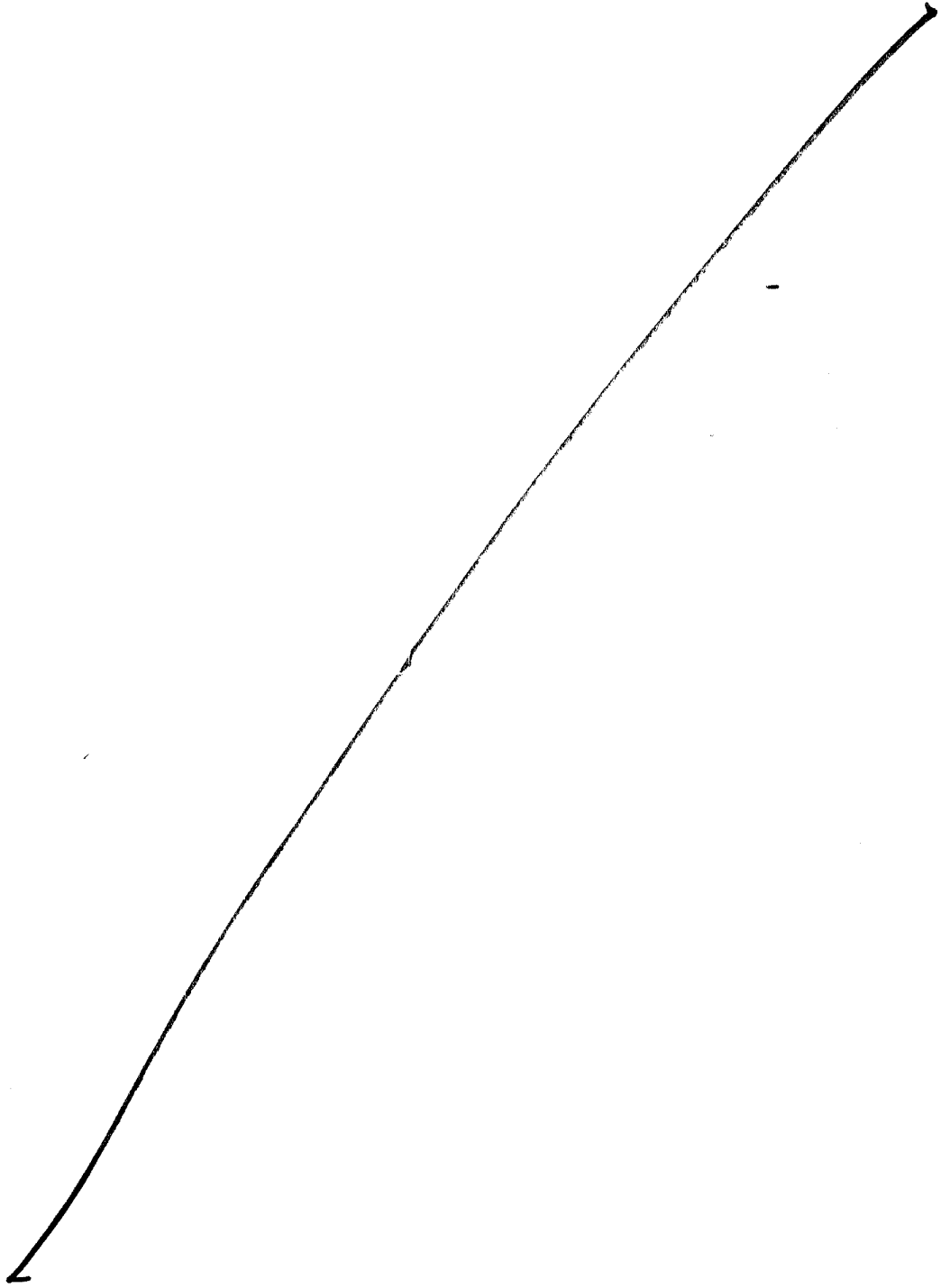
Dear Dr. Baylor,

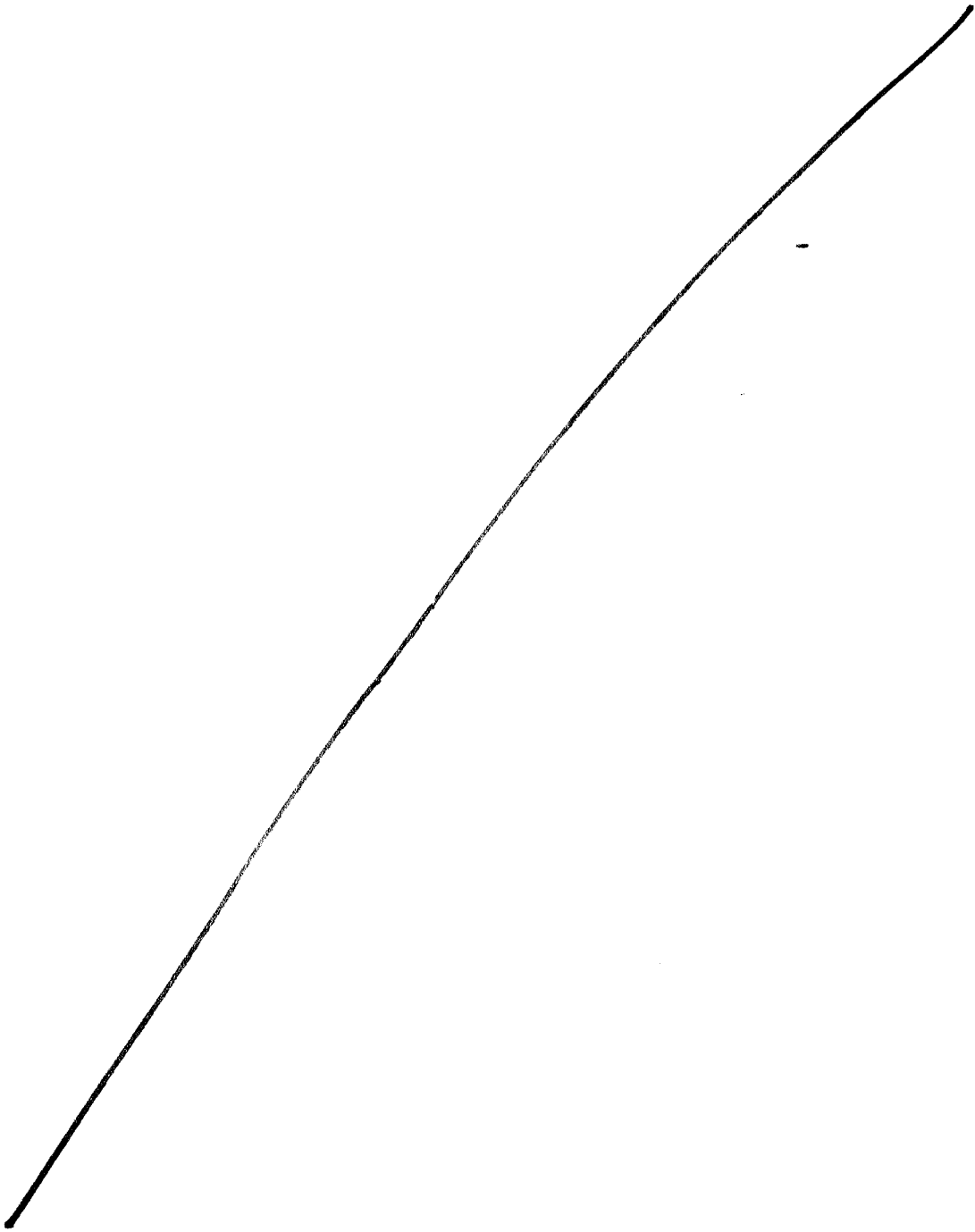
We are responding to the critique from the inspection reports of the inspectors who conducted the fourteenth maintenance inspection of our laboratory # 0135 under the National Laboratory Certification Program (NLCP). Please refer to the following items presented in the same order as in the critique letter dated 1/21/99 with corrective actions and appropriate documentation:

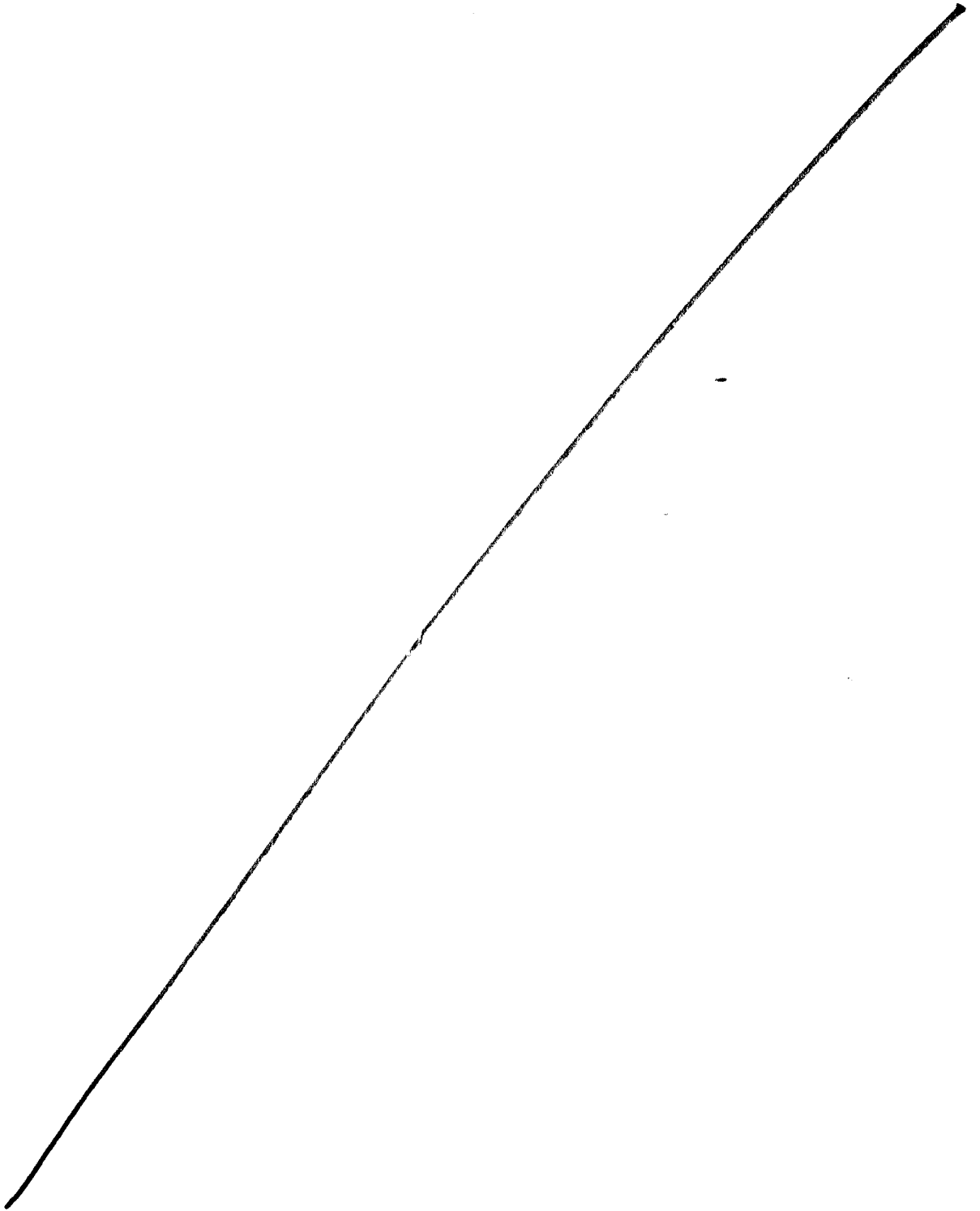


Unilab Corporation

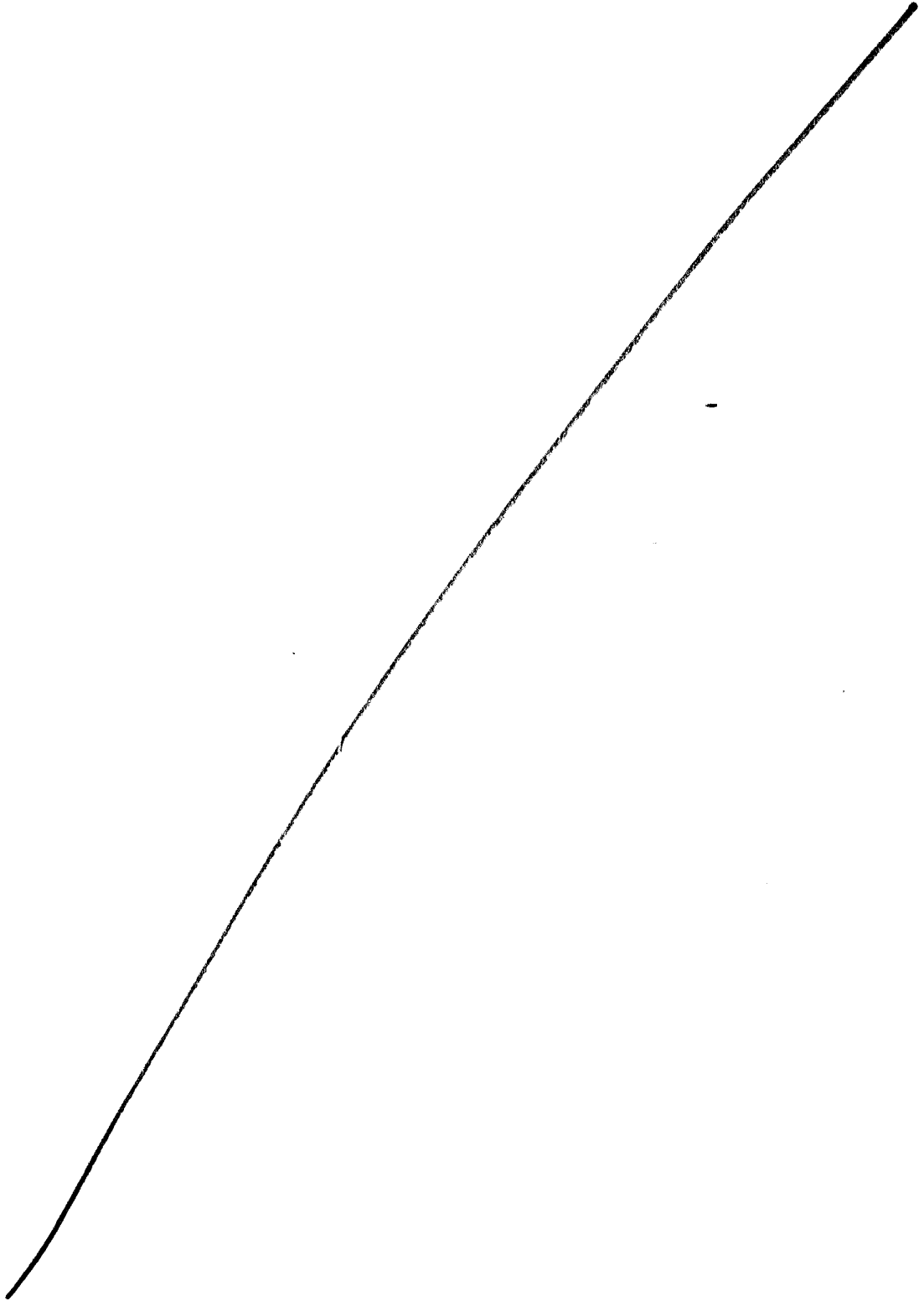
18408 Oxnard Street • Tarzana, California 91356 • 818 996-7300

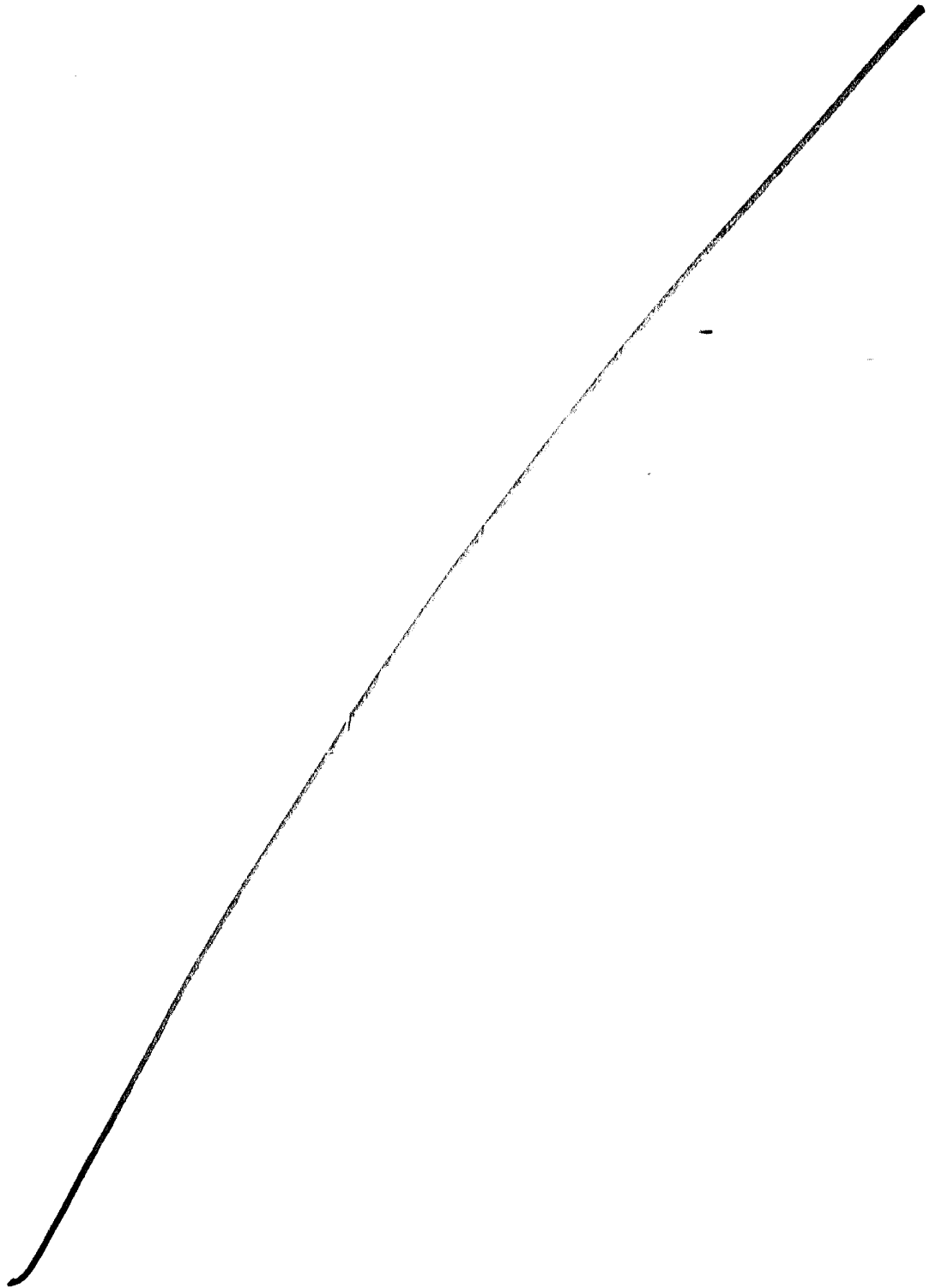


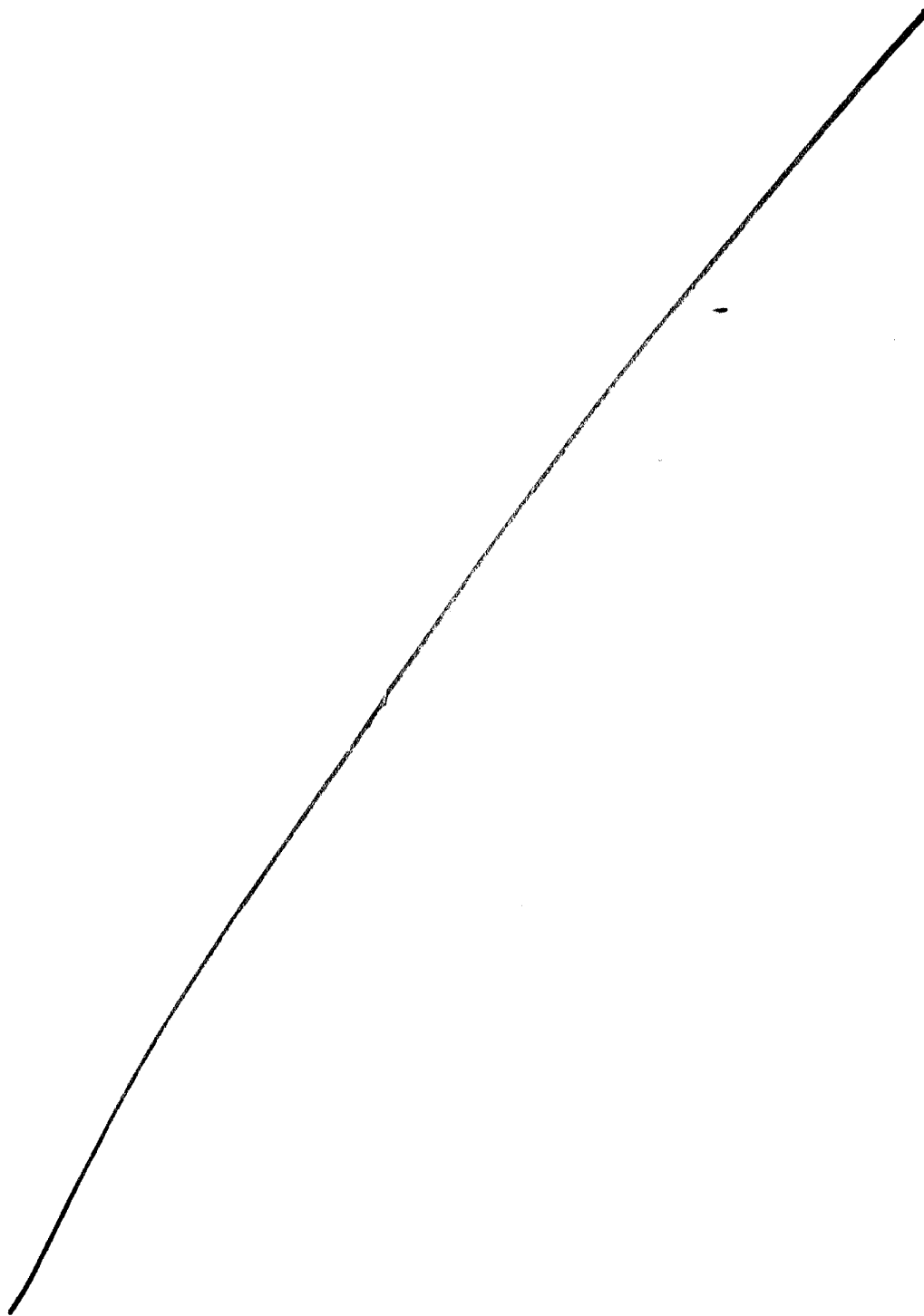


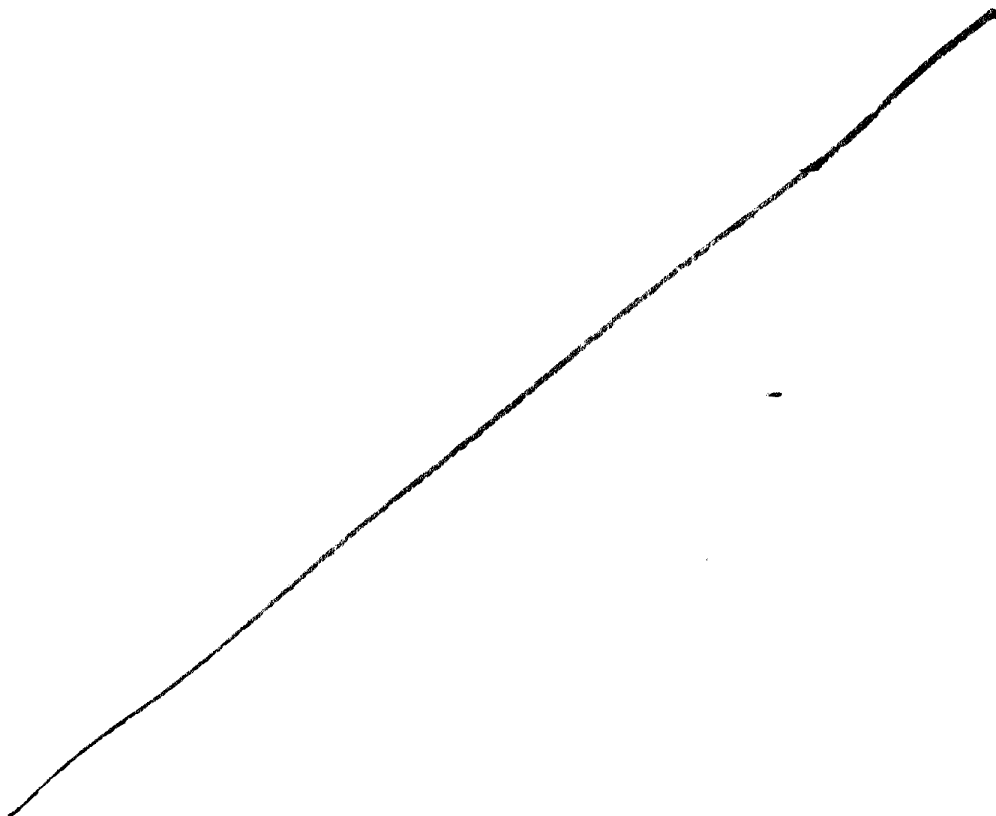


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Thank you for your helpful critique. If there should be anything else required or further clarification, I can be readily reached at 1-800-492-0800 X 4639 or X4669.

Sincerely,

Andrew J. Fischinger Ph.D.

Andrew J. Fischinger Ph.D.
Responsible Person, Lab # 0135
2-18-99



RESEARCH TRIANGLE INSTITUTE

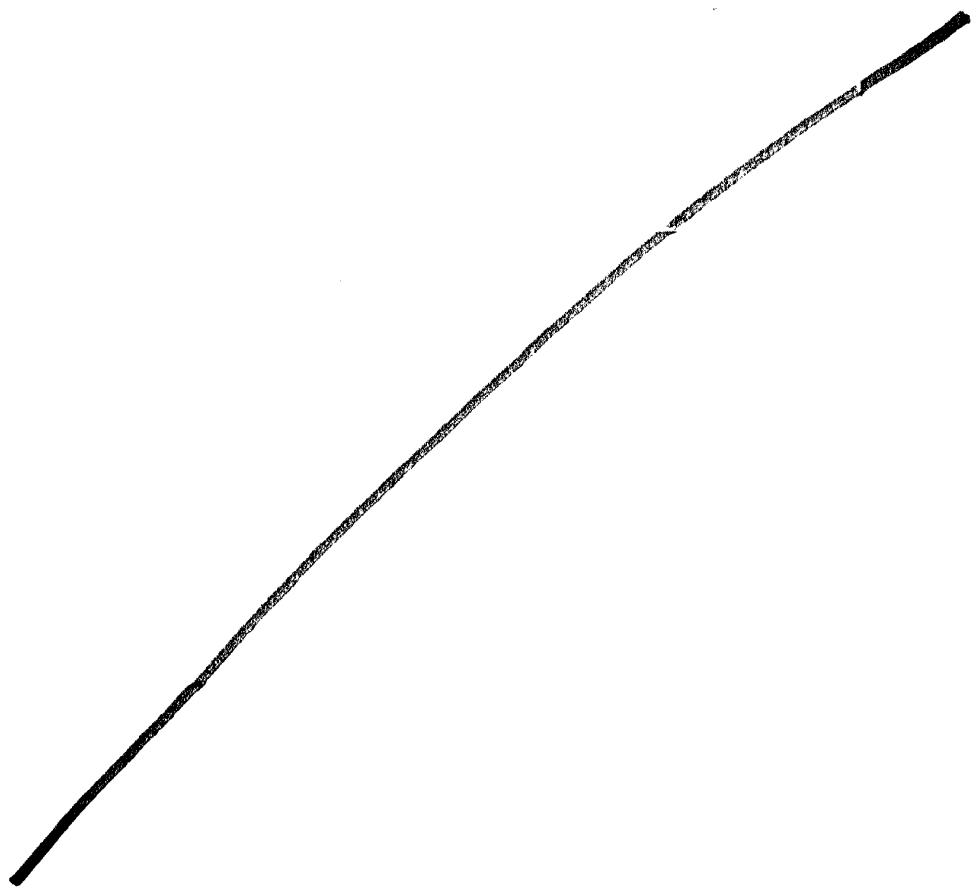
National Laboratory Certification Program

March 4, 1999

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Déar Dr. Fishinger:

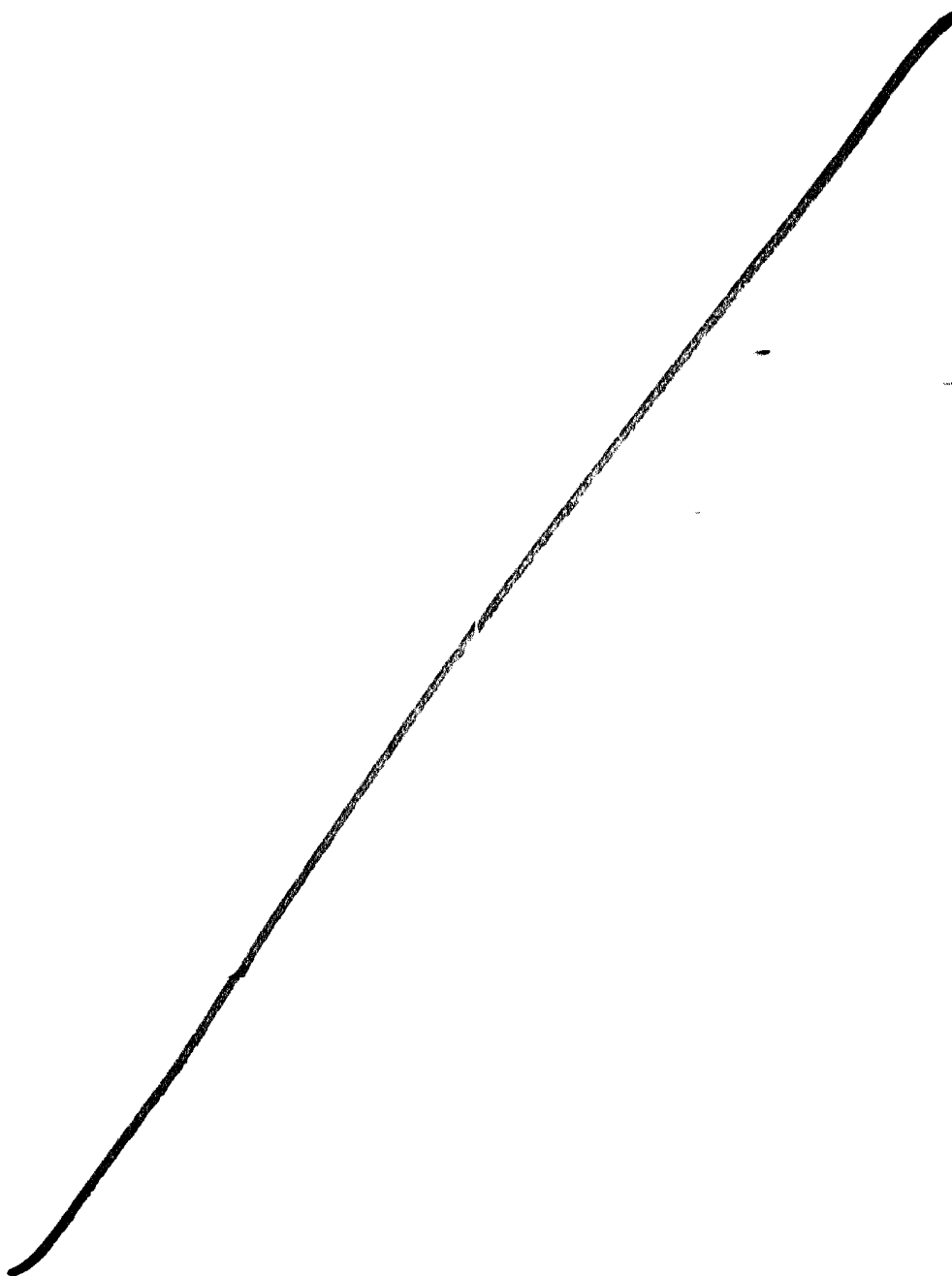
We have reviewed the material provided in your correspondence of February 18, 1999, submitted in response to issues raised during the fourteenth inspection of your laboratory as outlined in our correspondence of January 21, 1999. The information submitted by the laboratory appears to demonstrate that 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
Telephone 919 541-6709 • Fax 919 541-7042



Dr. Fishinger
March 4, 1999
Page 2 of 3

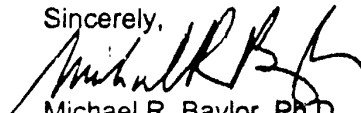


Dr. Fishinger
March 4, 1999
Page 3 of 3

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) 541-7043 or Deborah J. Denson at (919) 541-7265.

Sincerely,



Michael R. Baylor, Ph.D
Sr. Forensic Toxicologist

cc: Project Files/M14

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:

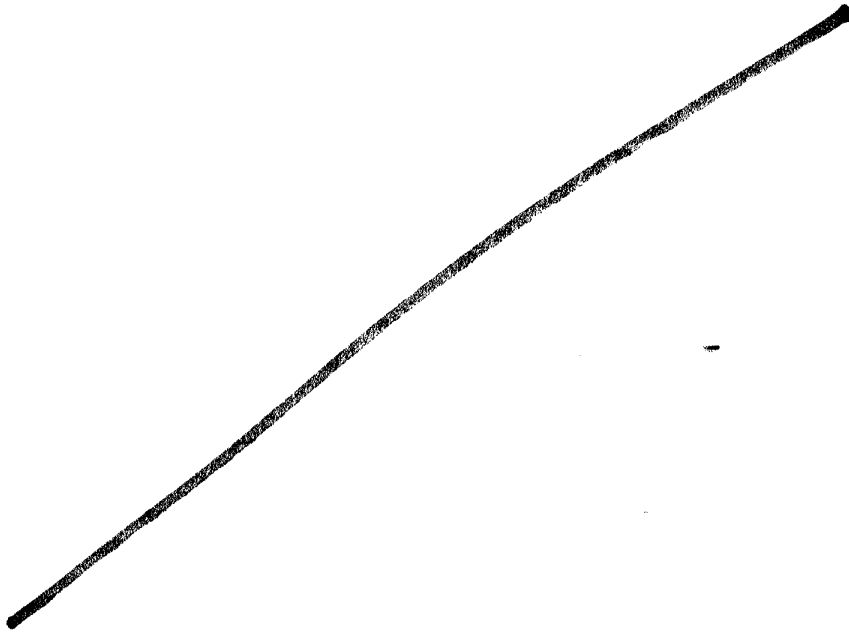
The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory has failed this inspection. The laboratory must complete the following remedial actions:

E. The Standard Operating Procedures (SOP) section



G. The Quality Control section





H. The Initial Tests section

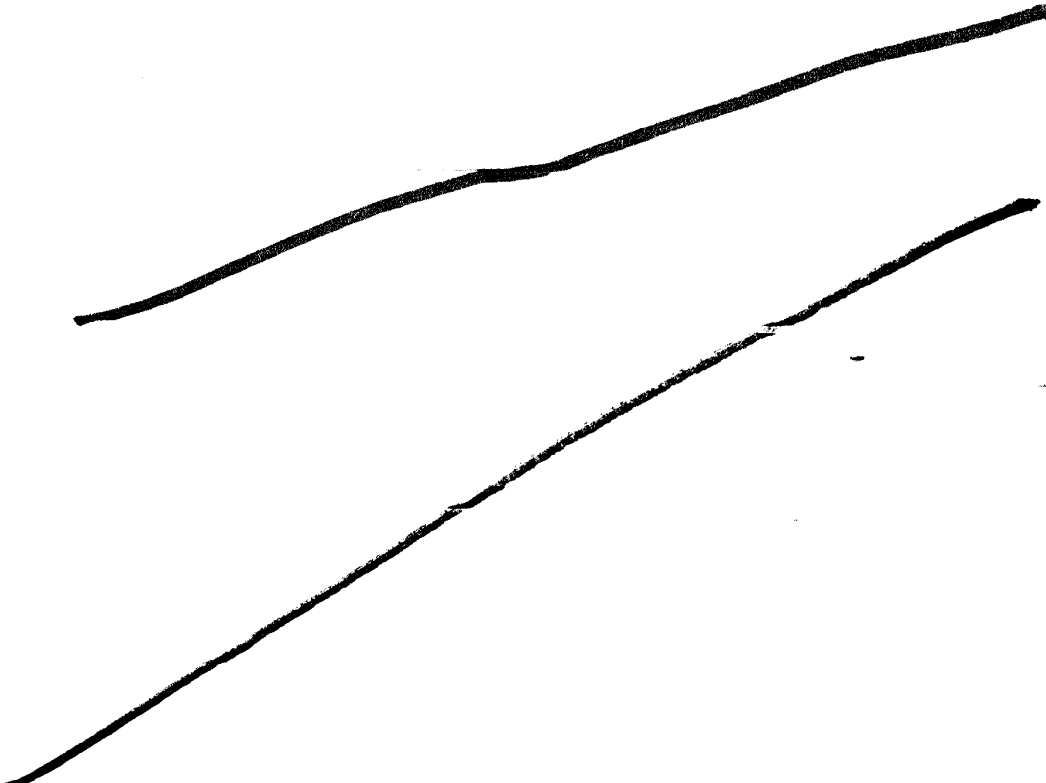


J. The Records Audit section



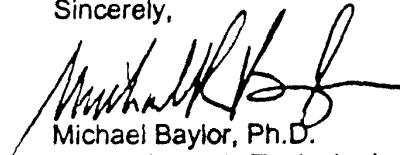


Dr. Fischinger
Page 3 of 3
07/28/99



If you have any questions or if we can be of further assistance, please call me at (919) 541-7043 or Mr. Kenneth Davis at (919) 541-6709.

Sincerely,



Michael Baylor, Ph.D.
Senior Forensic Toxicologist

Enclosure

cc: Dr. Donna Bush/SAMHSA



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UNILAB

Location: Tarzana, CA

Document Reviewed: Application Form
 Inspection Report #M15 Date: 17 June 1999
 Other _____

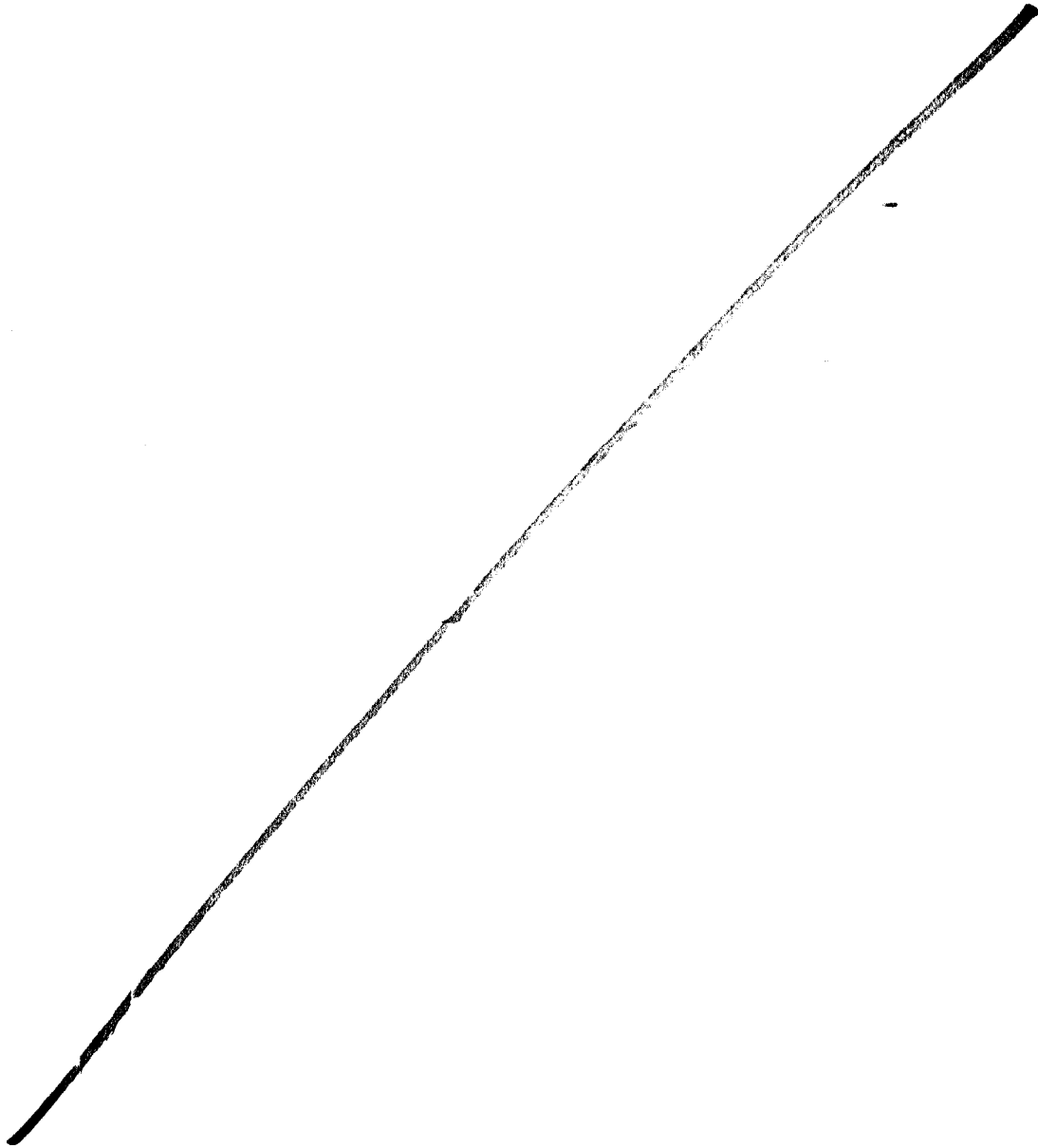
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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 failed 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:

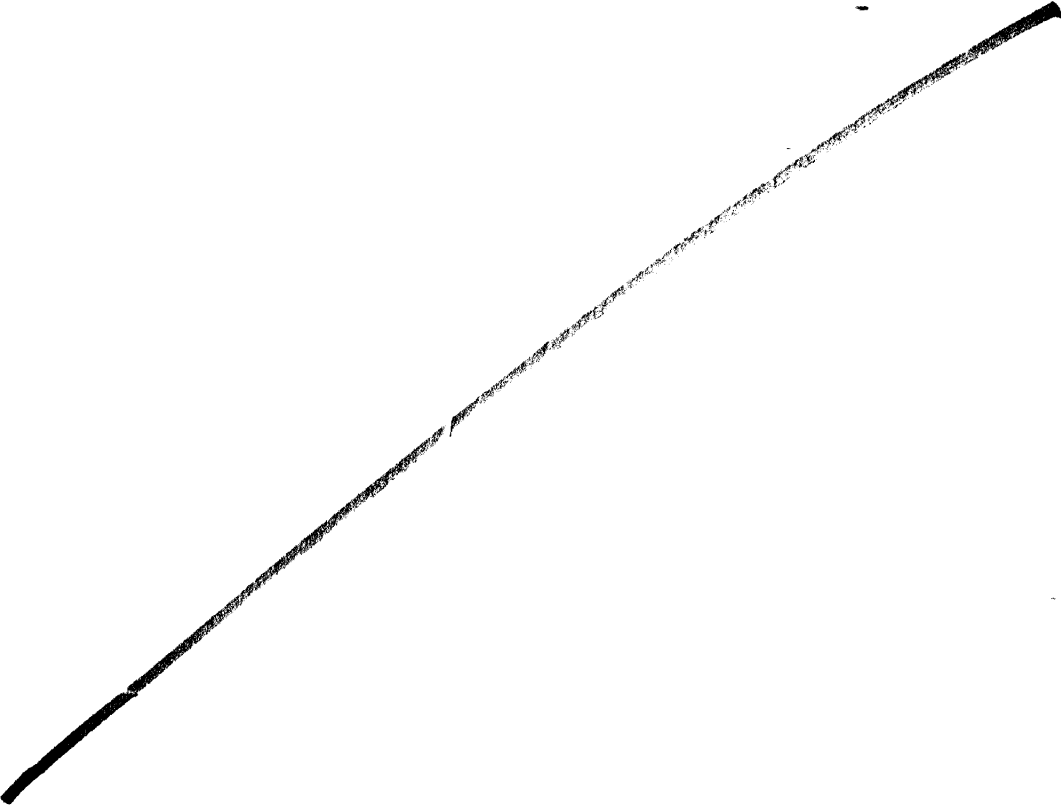
Section E. Standard Operating Procedures - Procedures Manual

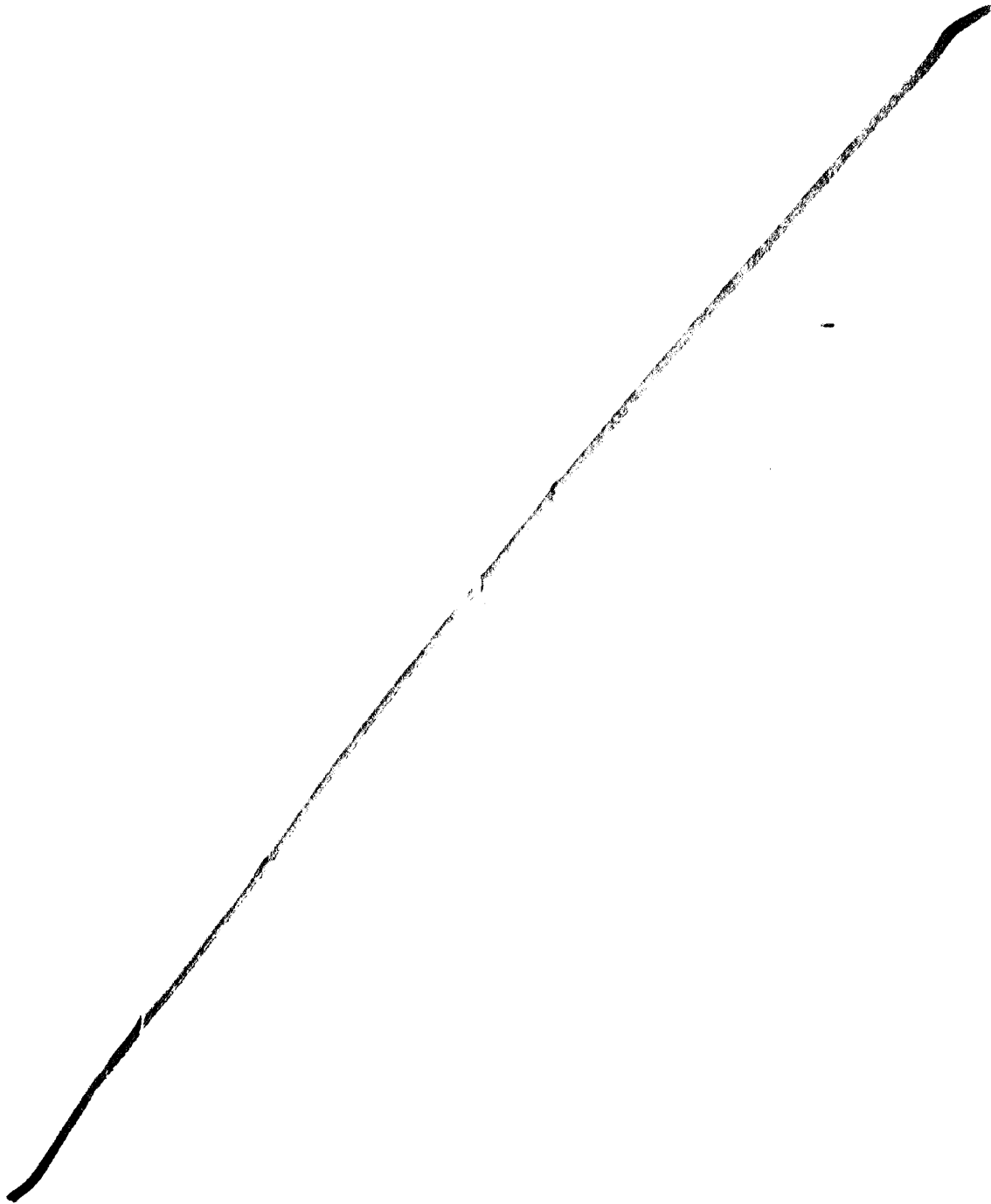


Section F. Chain-of-Custody, Accessioning, and Security



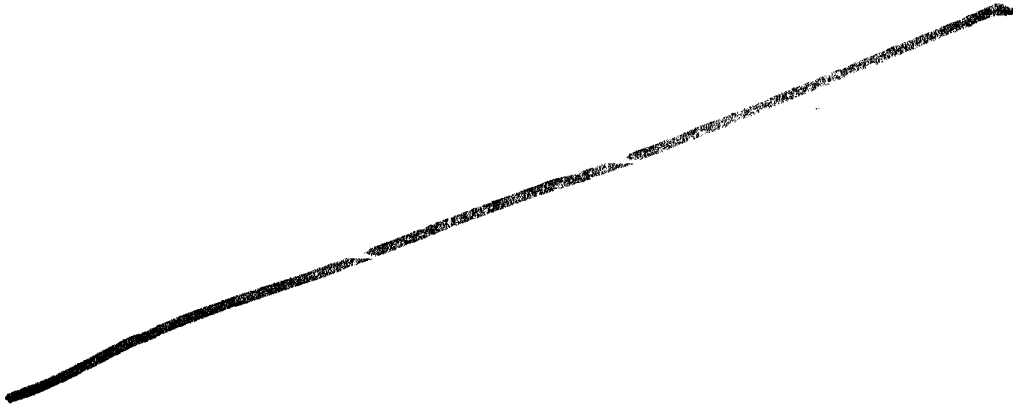
Section G. Quality Control







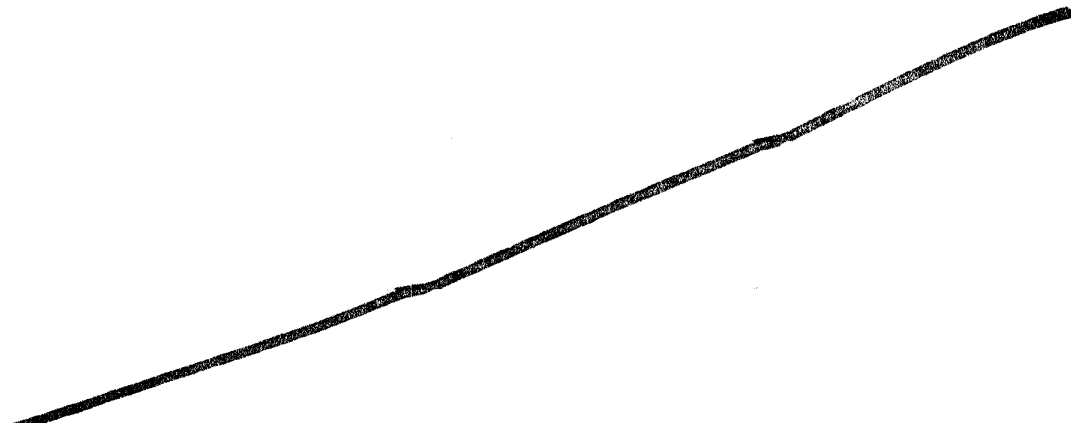
Section H. Initial Tests



Section I. Confirmatory Tests



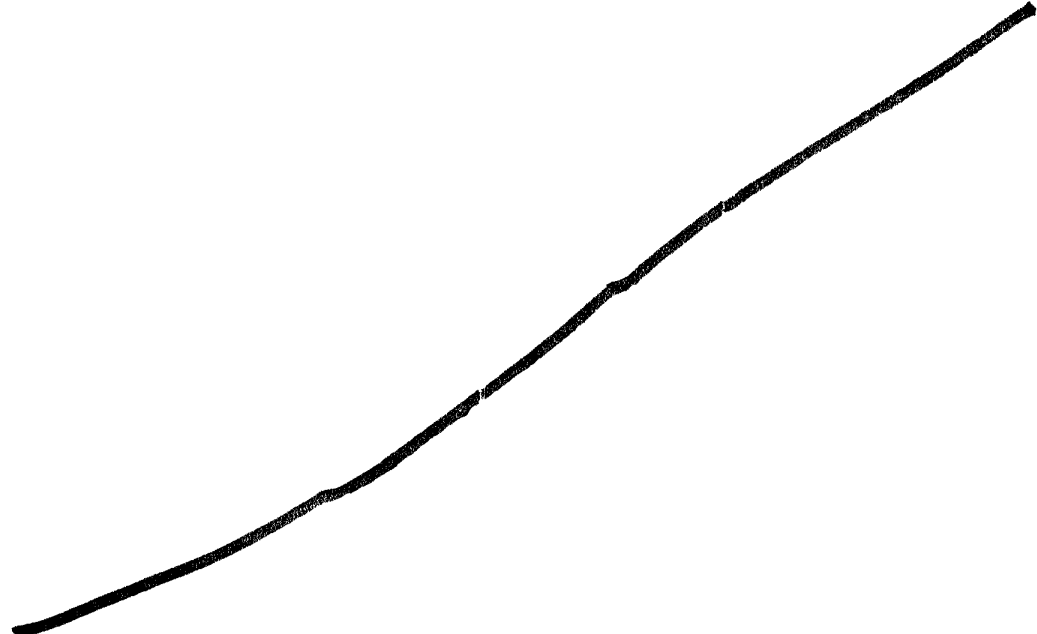
Section J. Records Audit



Section K. Reporting



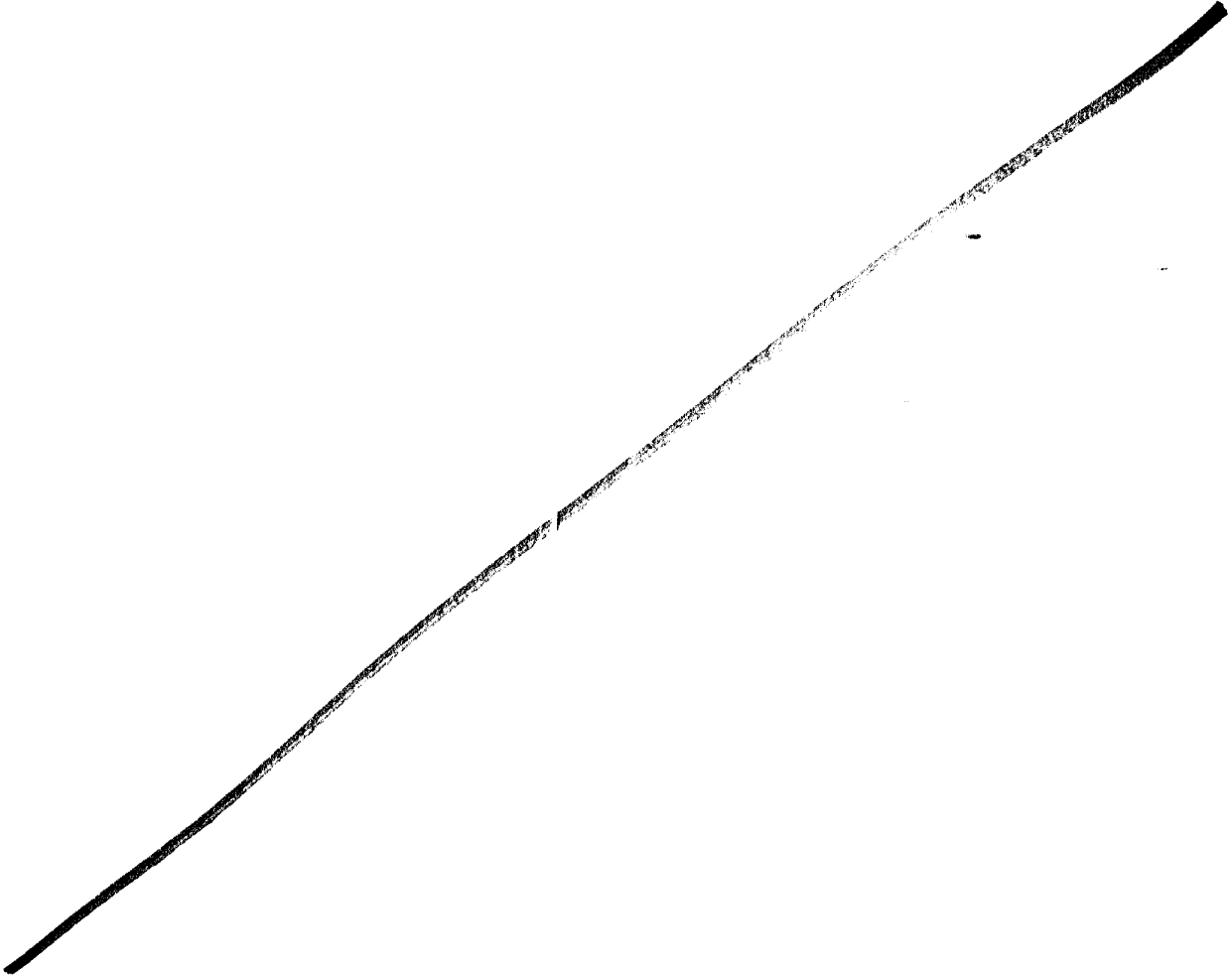
Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel





received
8/5/99 SOC

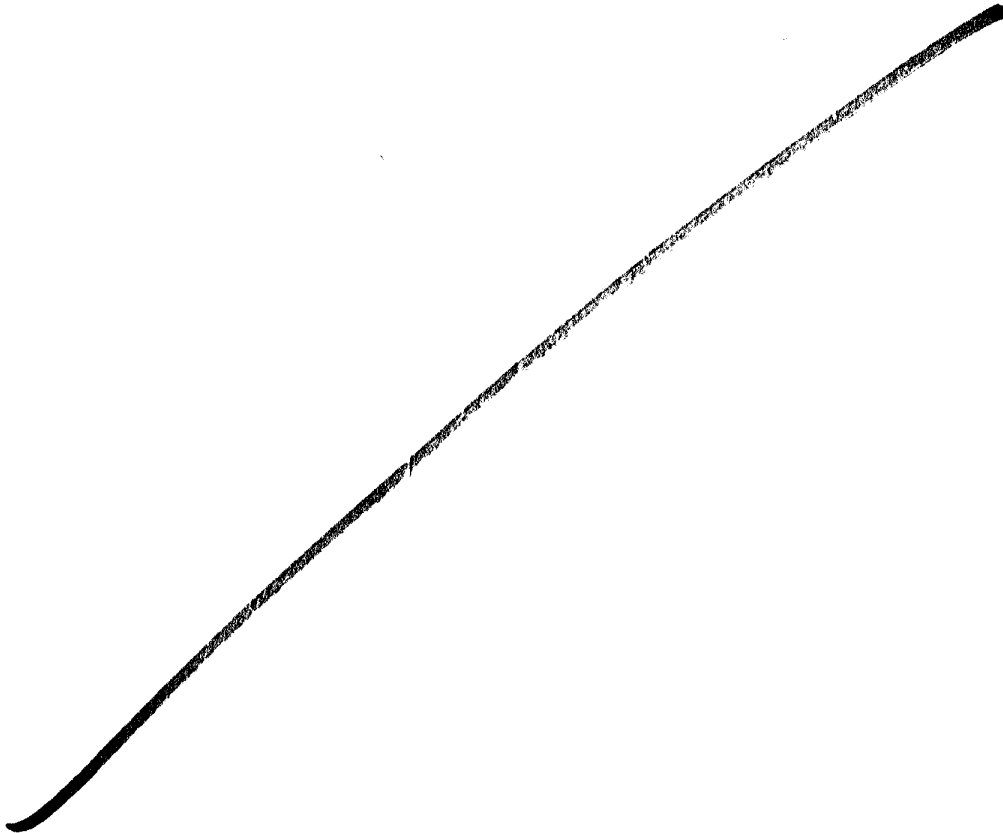
Dr. Michael Baylor, Ph.D.
Senior Forensic Toxicologist
Research Triangle Institute
3040 Cornwallis Road, P.O. BOX 12194
Research Triangle Park, NC 27709-2194

August 3, 1999

PI.

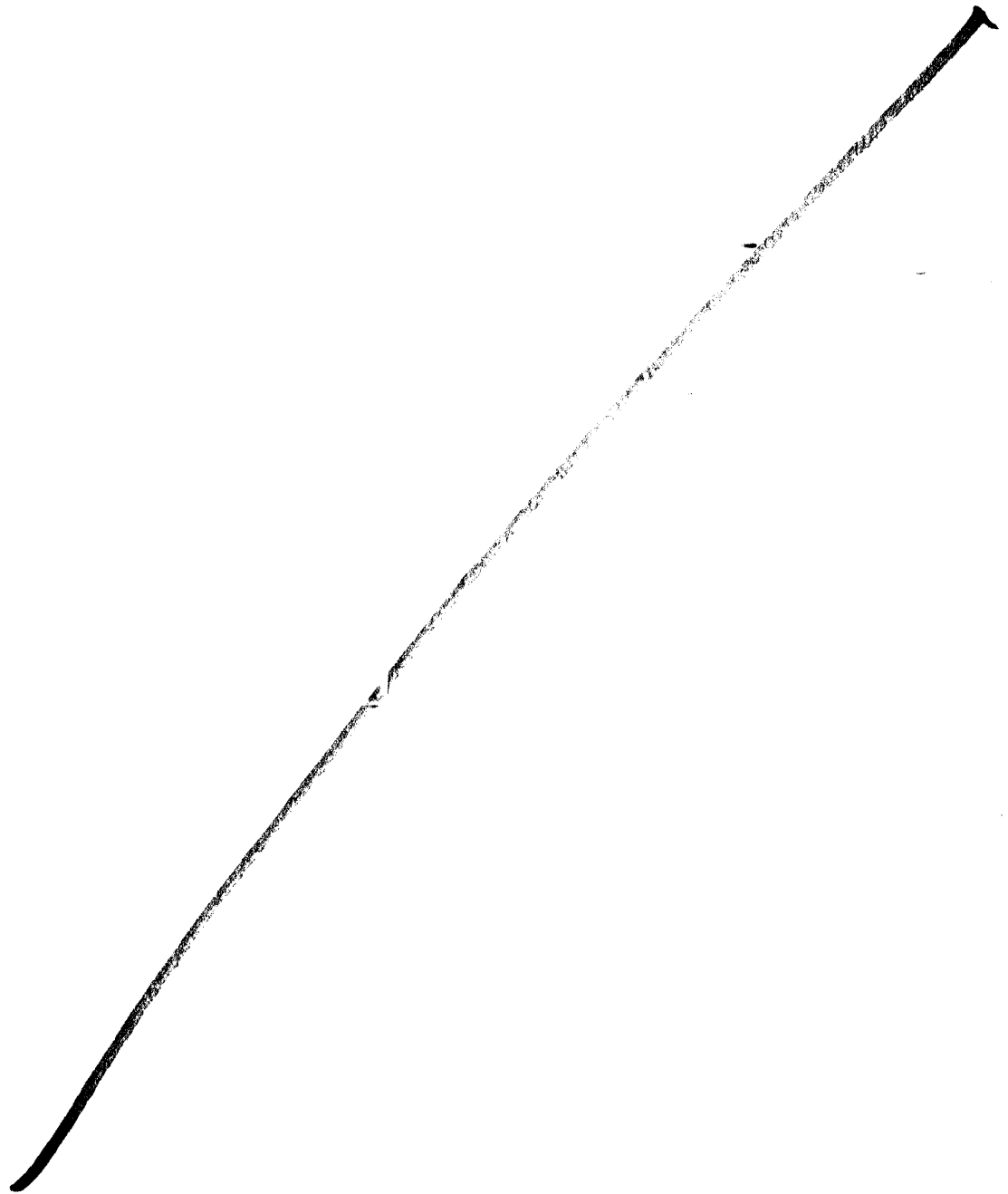
Dear Dr. Baylor:

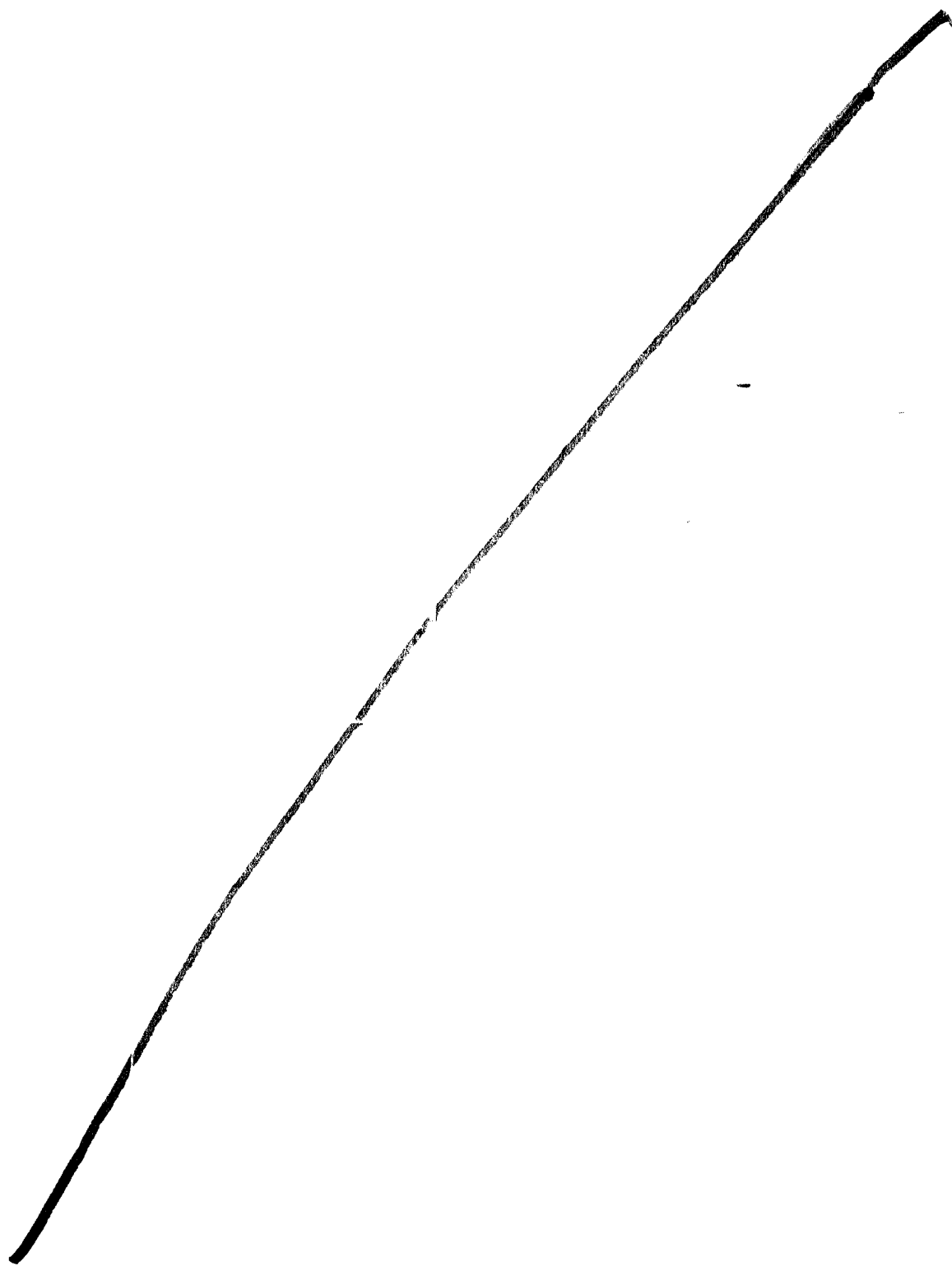
Regarding Unilab's (ID #0135) inspection of June 17-18, 1999, by the two inspectors of the National Laboratory Certification Program (NLCP), we are responding with a plan to complete and implement all remedial actions listed in your critique letter of July 28, 1999.

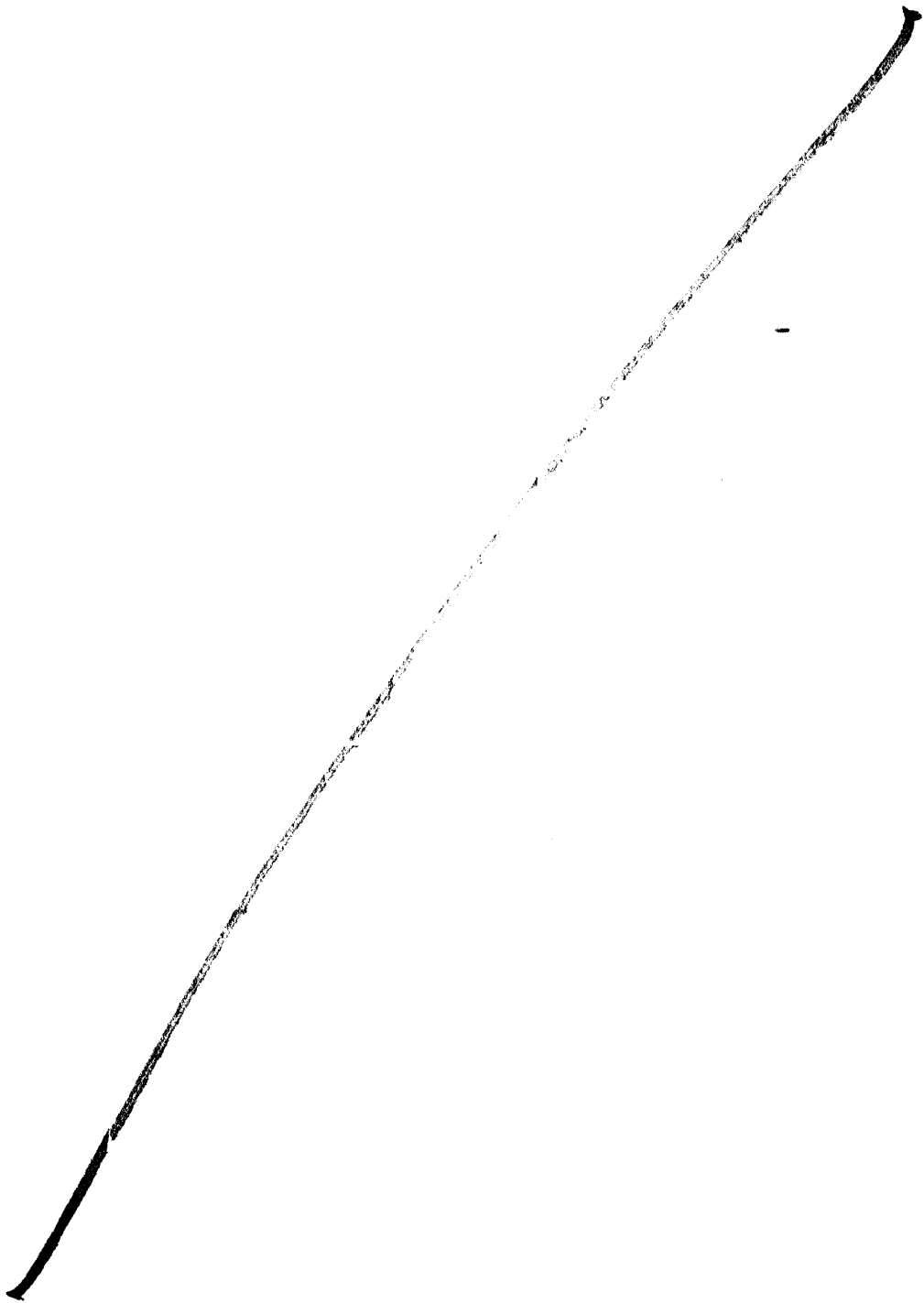


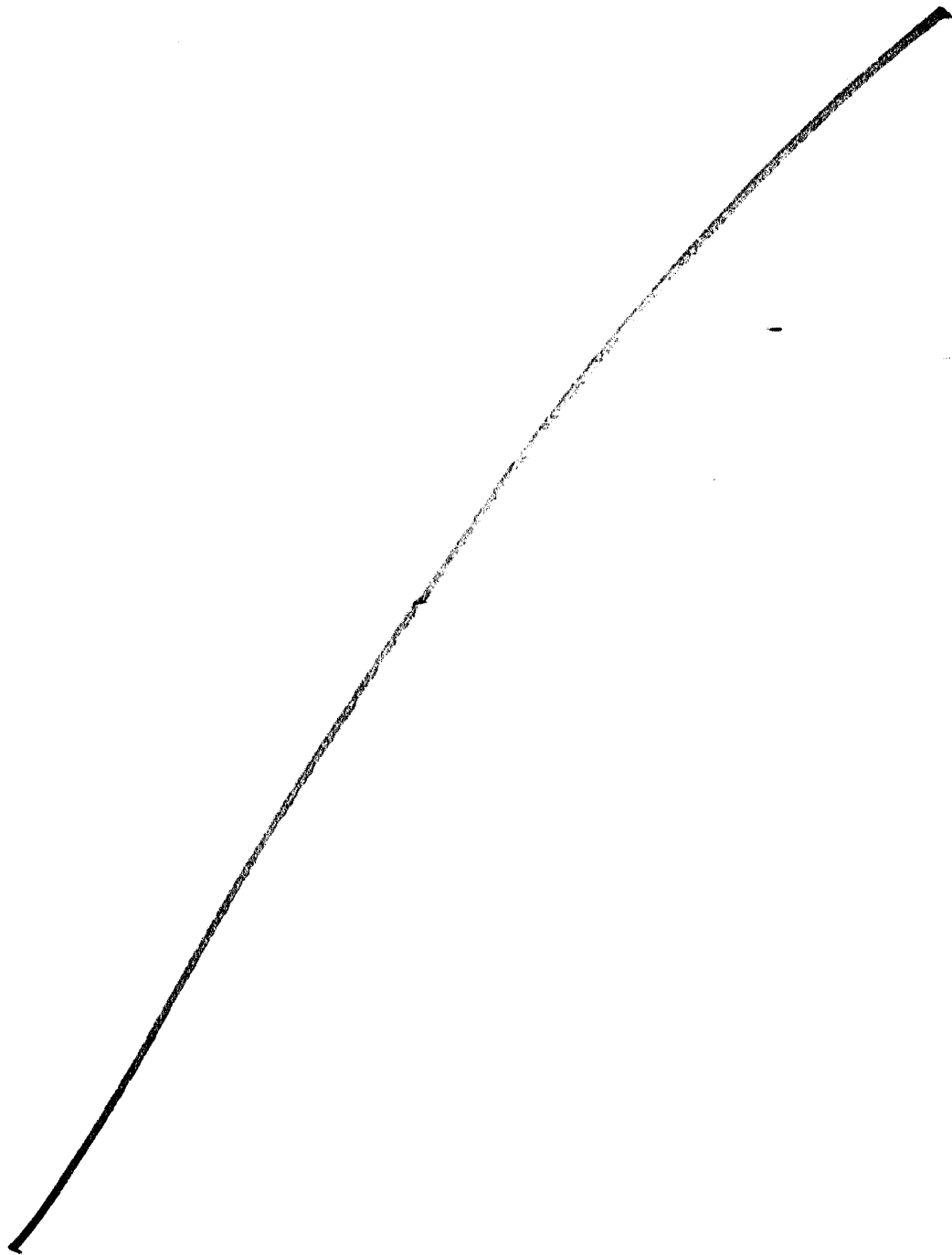
Unilab Corporation

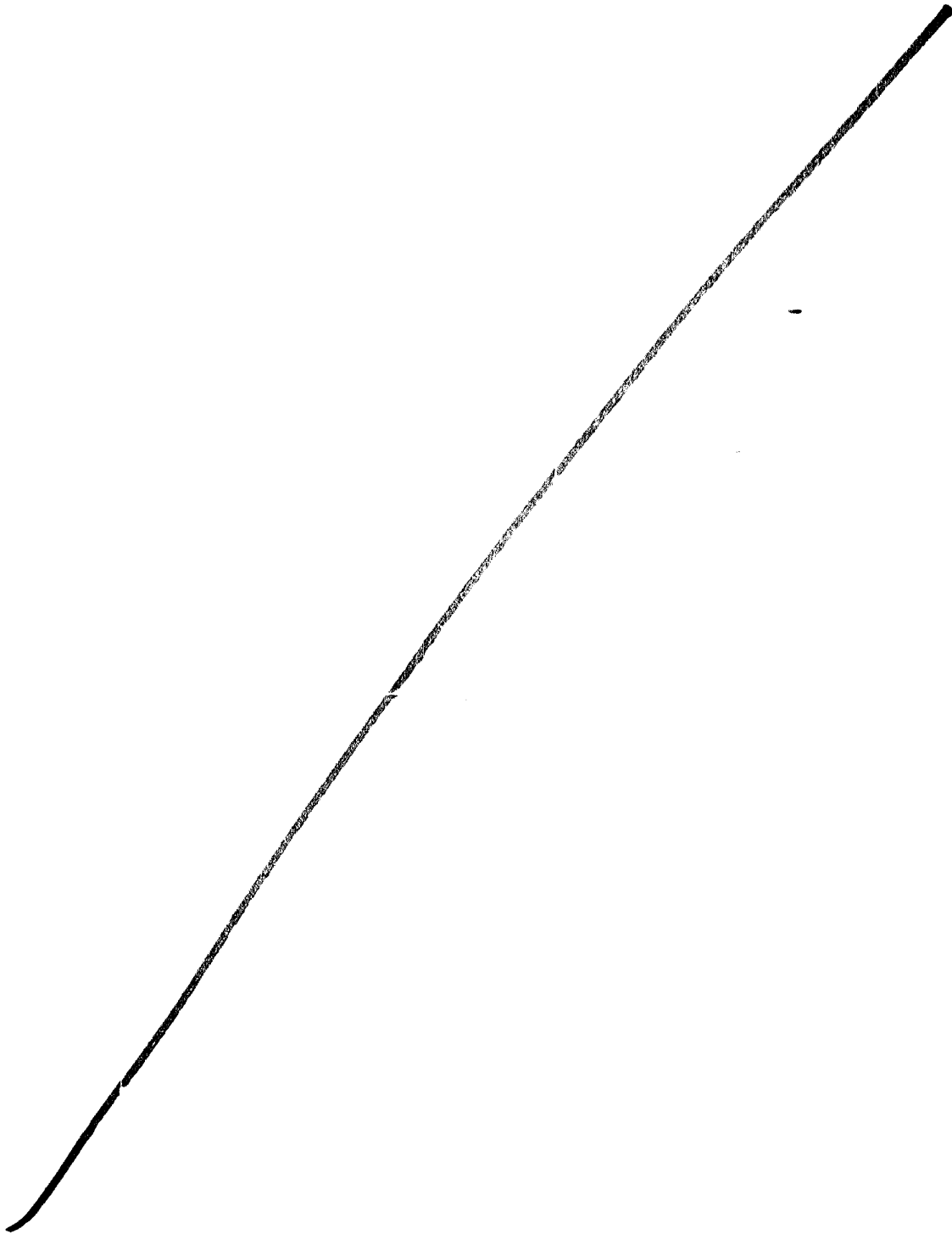
18408 Oxnard Street • Tarzana, California 91356 • 818 996-7300







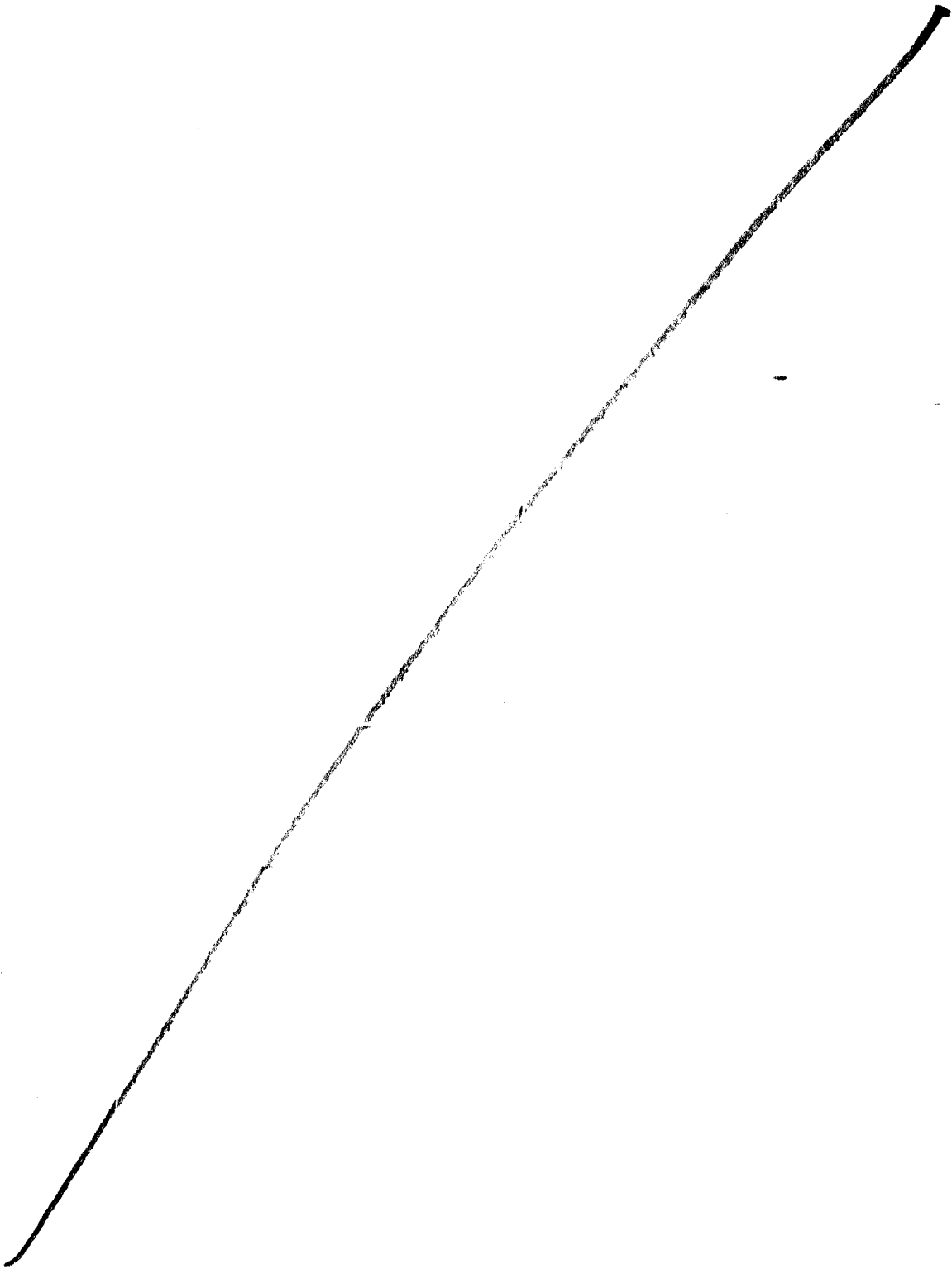


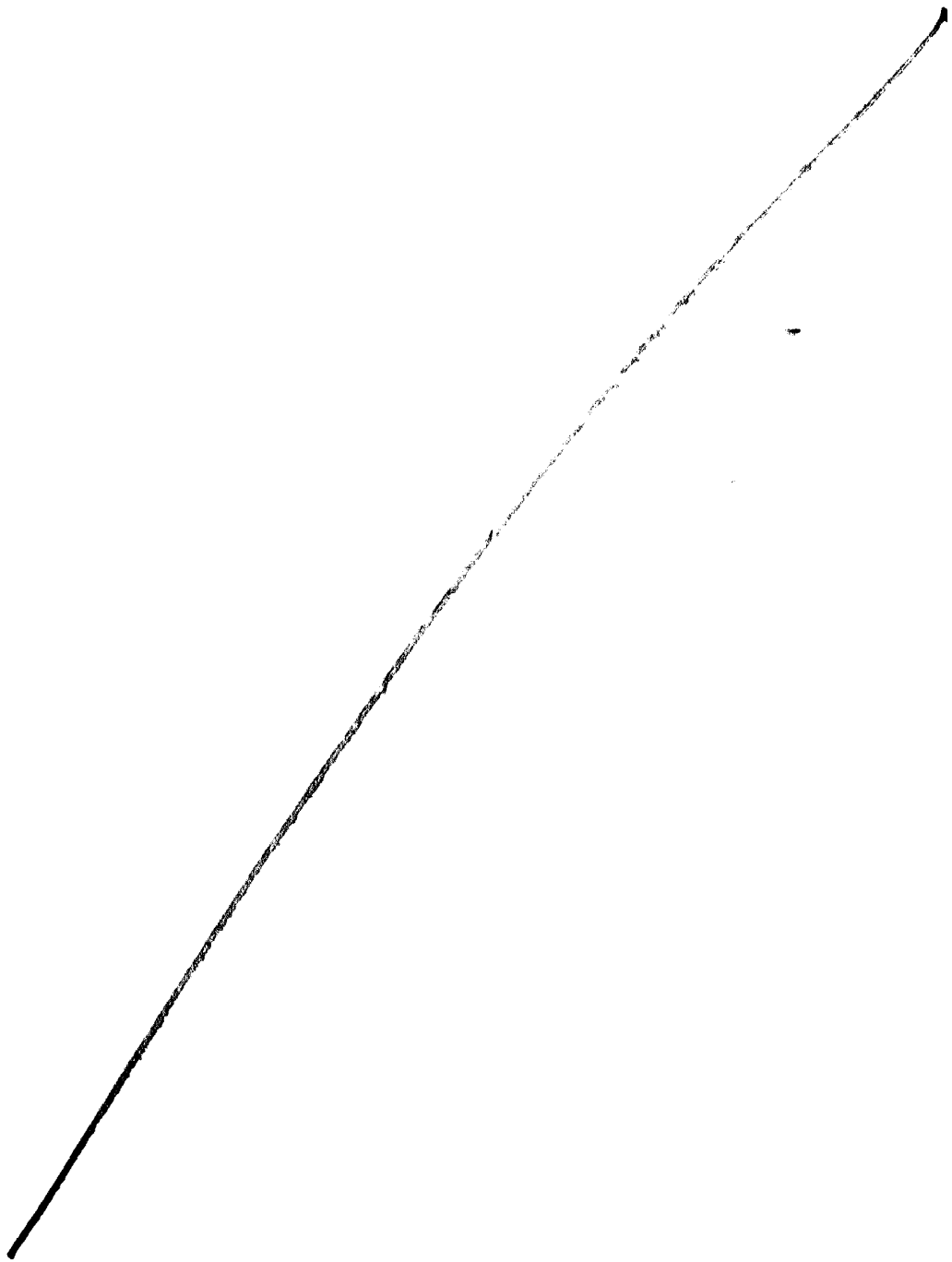


P7

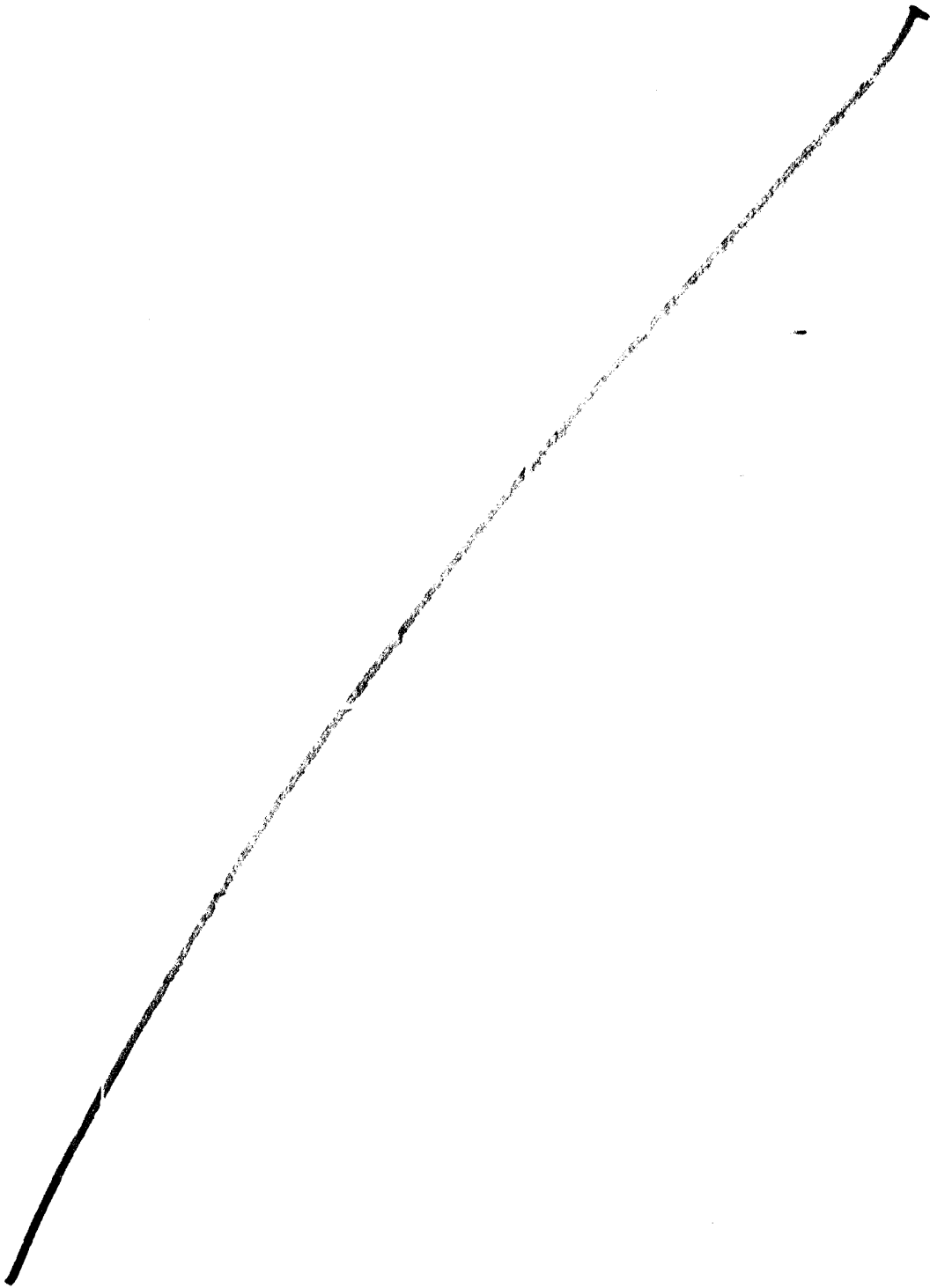


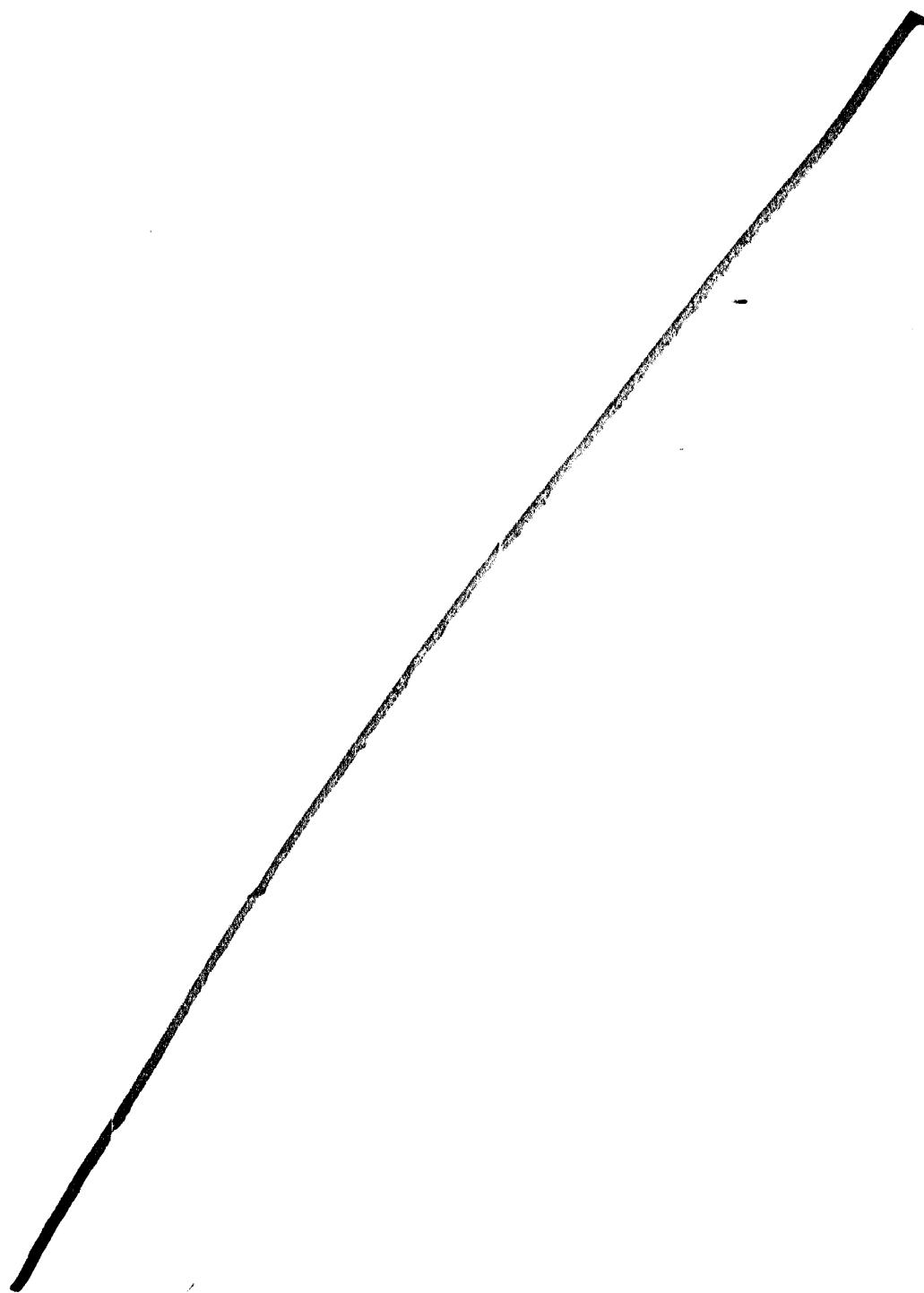
P8



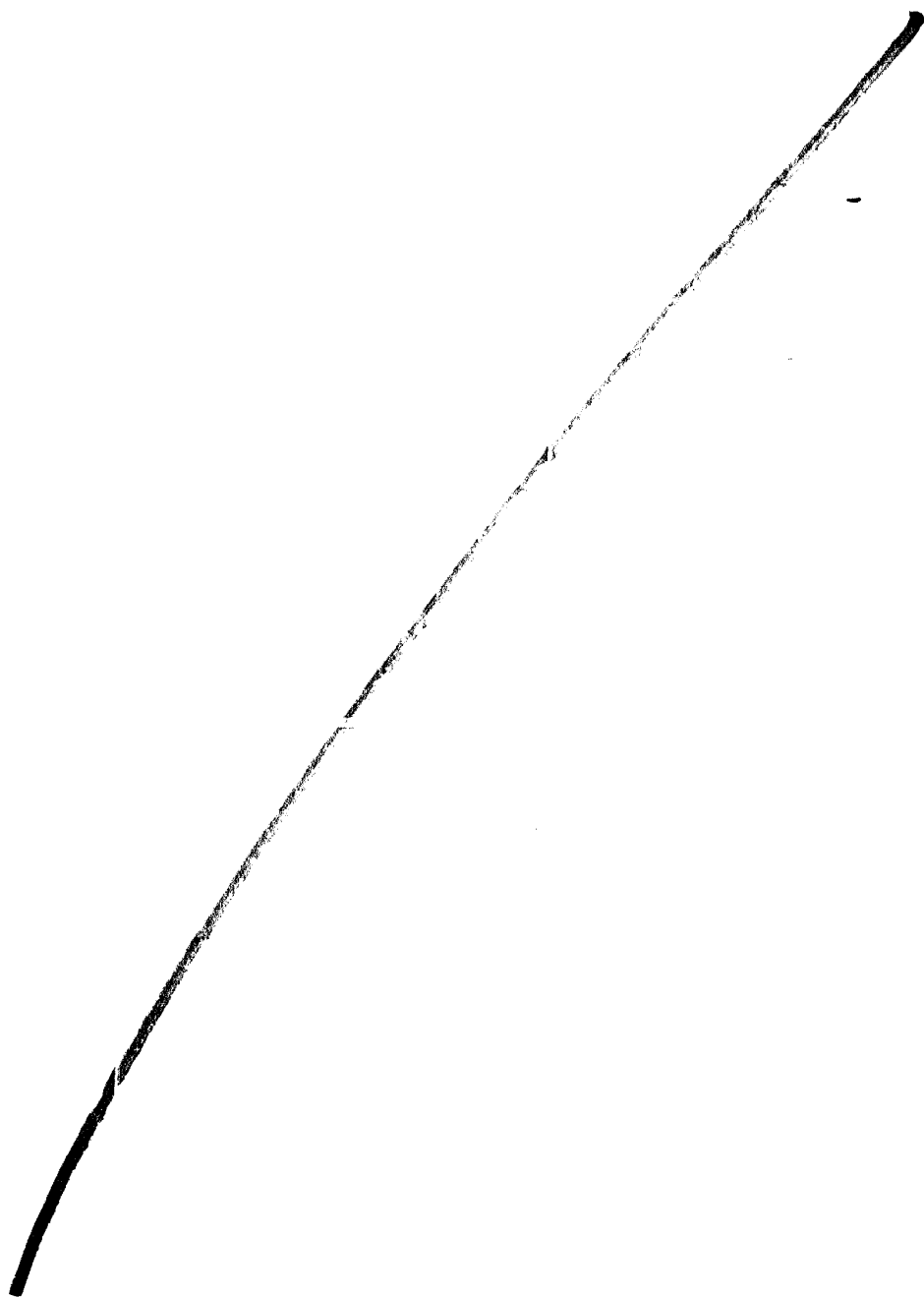


P10





P12



P13

Sincerely,

Andrew J. Fischinger Ph.D. 8-4-99

Andrew J. Fischinger Ph.D. R.P. (#0135)



RESEARCH TRIANGLE INSTITUTE

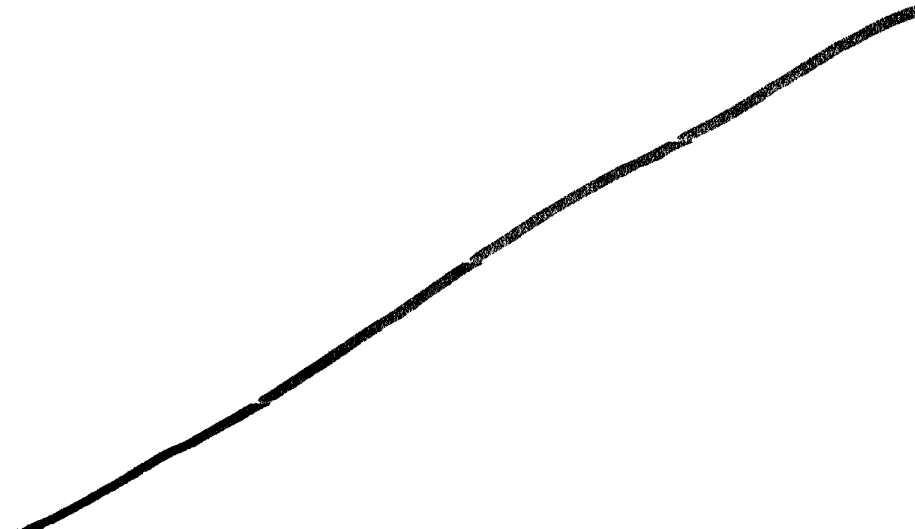
National Laboratory Certification Program

August 25, 1999

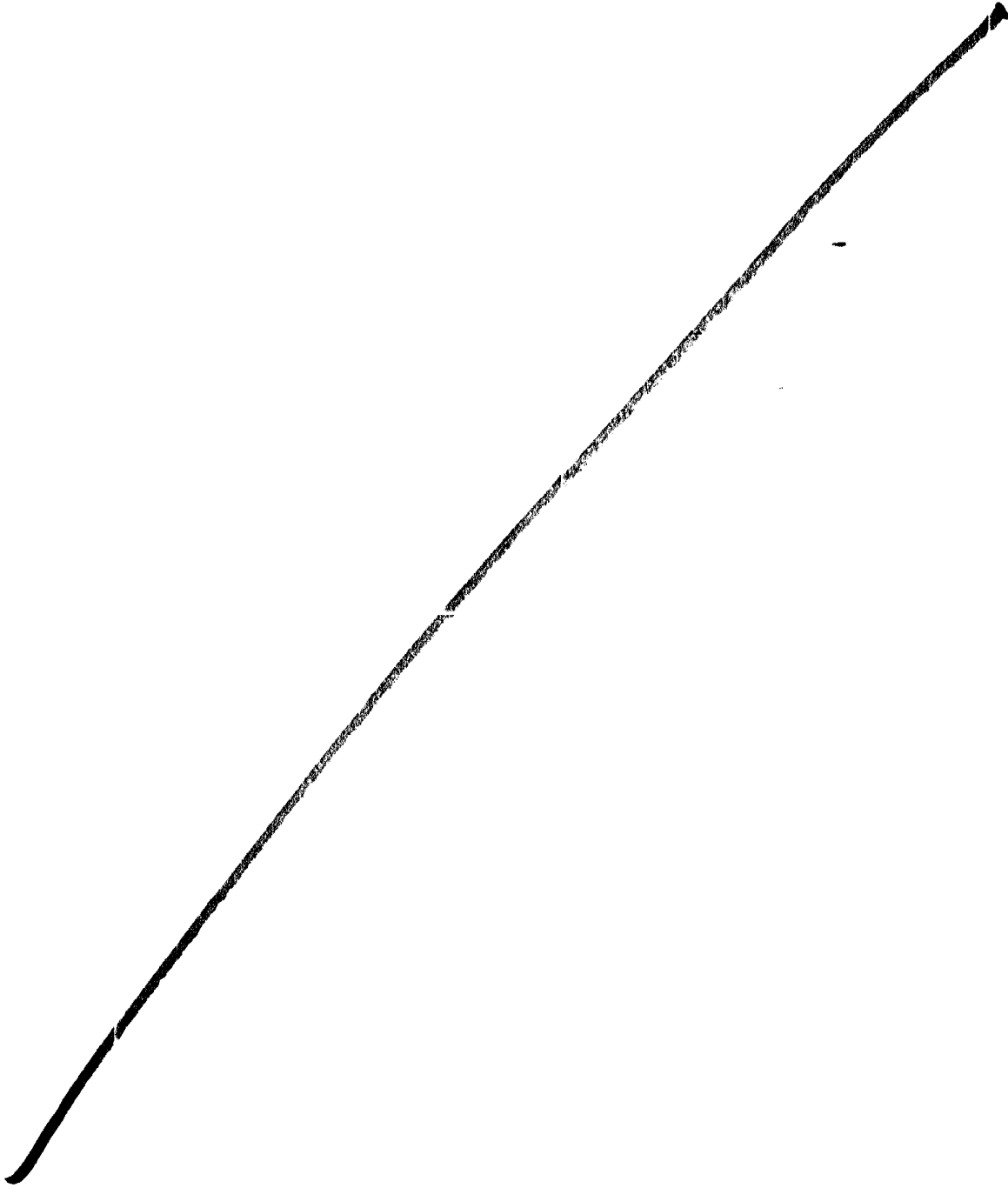
0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

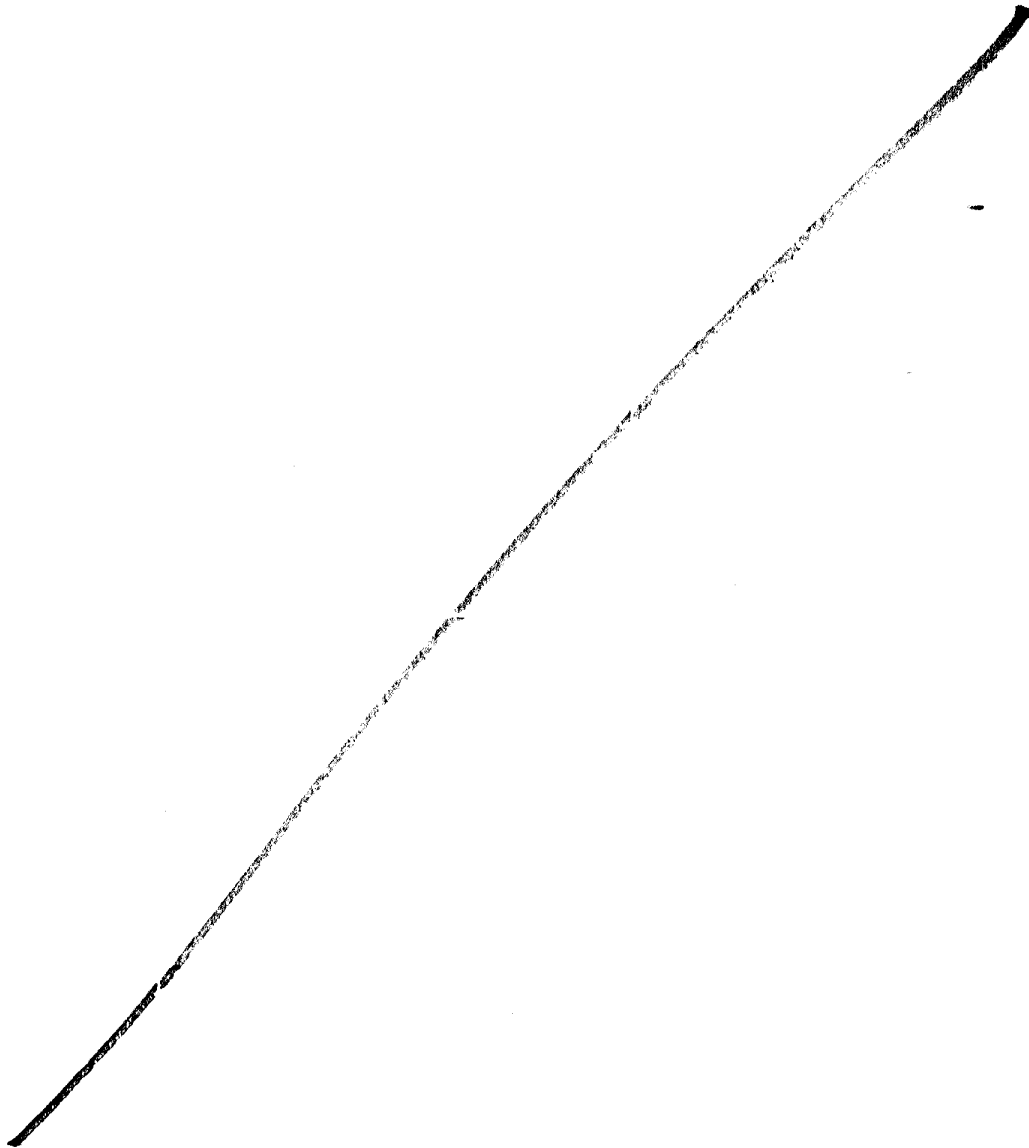
Dear Dr. Fischinger:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of August 3, 1999, provided in response to the deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of July 28, 1999. The plan to clarify and/or correct the deficiencies noted was found overall acceptable. However, the following issues were raised during our review of the laboratory's submission:

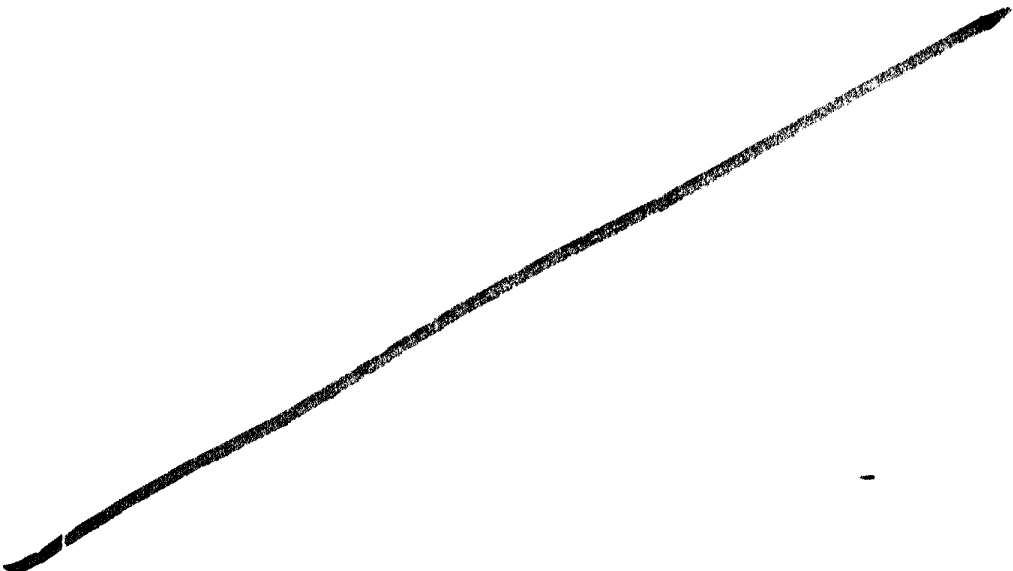


Dr. Fischinger
Page 2 of 4
08/25/99





Dr. Fischinger
Page 4 of 4
08/25/99



The laboratory must document completion of the remedial actions outlined in its August 3, 1999, correspondence and to address issues cited above. It is *not* necessary to submit a written response to RTI. **All documentation of remedial actions and implementation of revised procedures will be reviewed at the special inspection.**

If you have any questions or want to further clarify any of these issues, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/135



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 29, 1999

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:

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

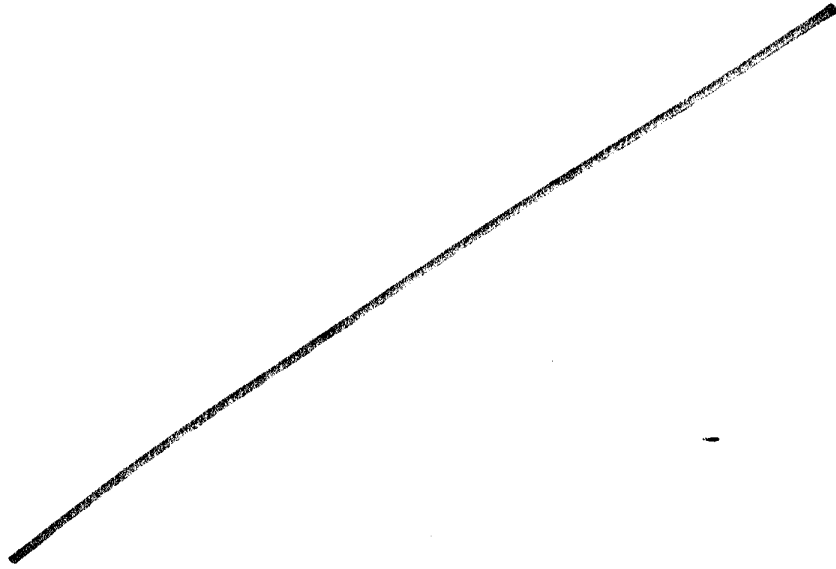
E. Standard Operating Procedures section

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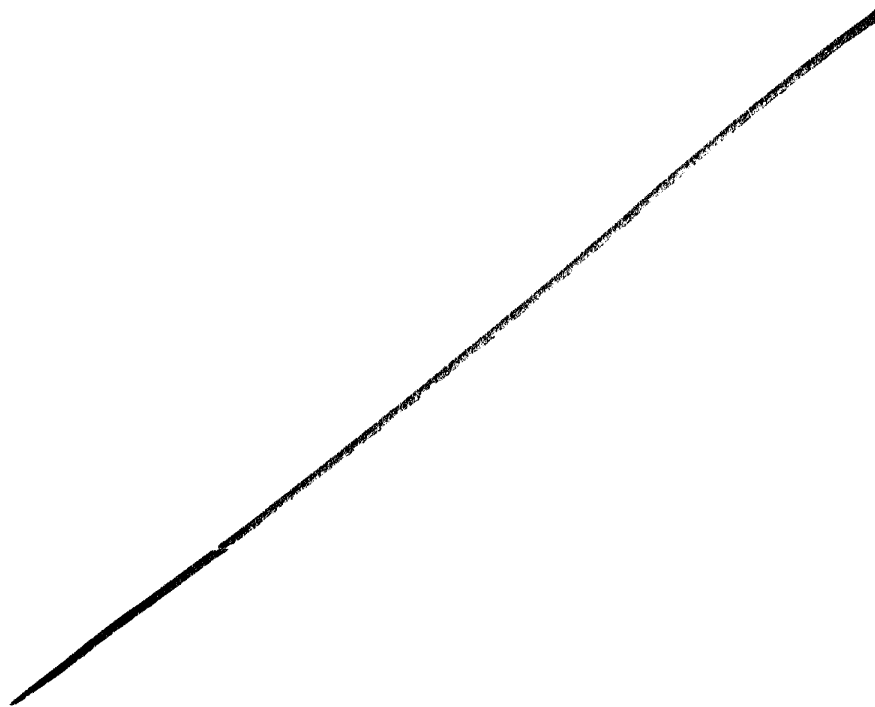
F. The Chain of Custody, Accessioning, and Security section

A large, thick black diagonal line redacts the text below item F.

Dr. Fishinger
October 29, 1999
Page 2 of 5



G. The Quality Control section



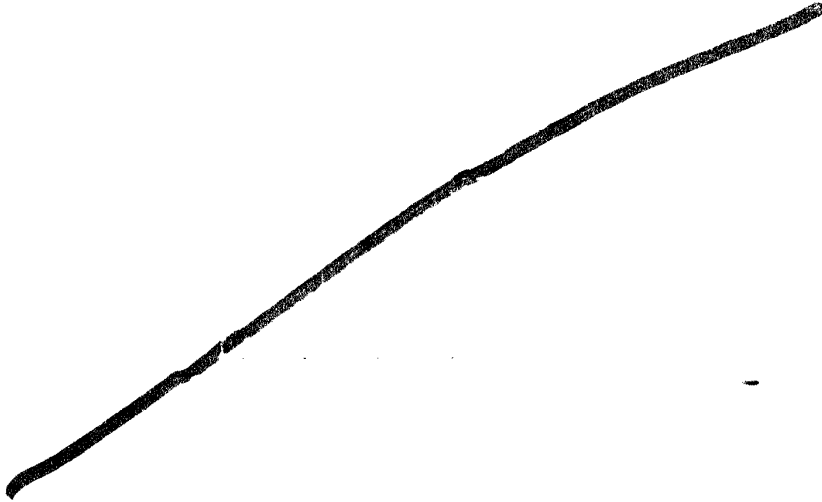
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H. The Initial Tests section

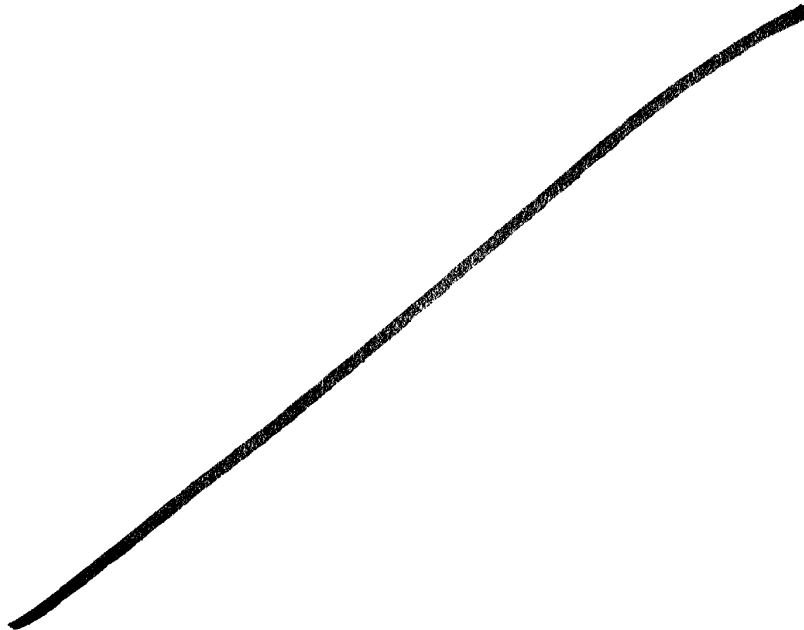
[Redacted line]

I. The Confirmatory Tests section

[Redacted line]



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


Dr. Fishinger
October 29, 1999
Page 5 of 5

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) 541-7043, Mr. Kenneth Davis, Jr. at (919) 541-6709, or Deborah Denson at (919) 541-7265.

Sincerely,



Michael R. Baylor, Ph.D.
Sr. Forensic Toxicologist

Enclosure

cc: Project Files/Special



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UniLab Toxicology

Location: Tarzana, CA

Document Reviewed: Application Form
 Inspection Report: Special
 Other _____

Date: 16 September 1999

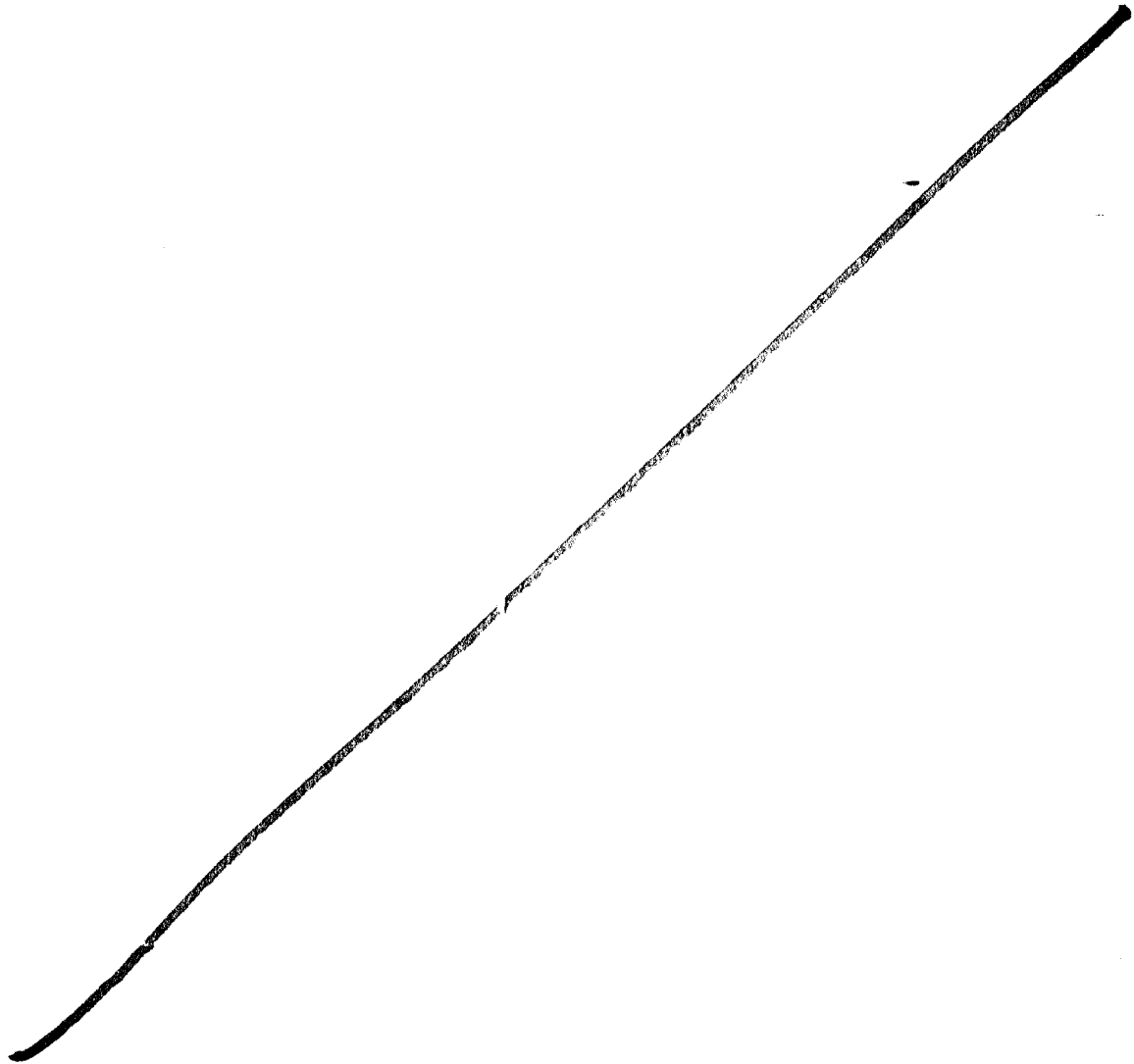
Status: Highly Acceptable Acceptable
 Unacceptable Failure

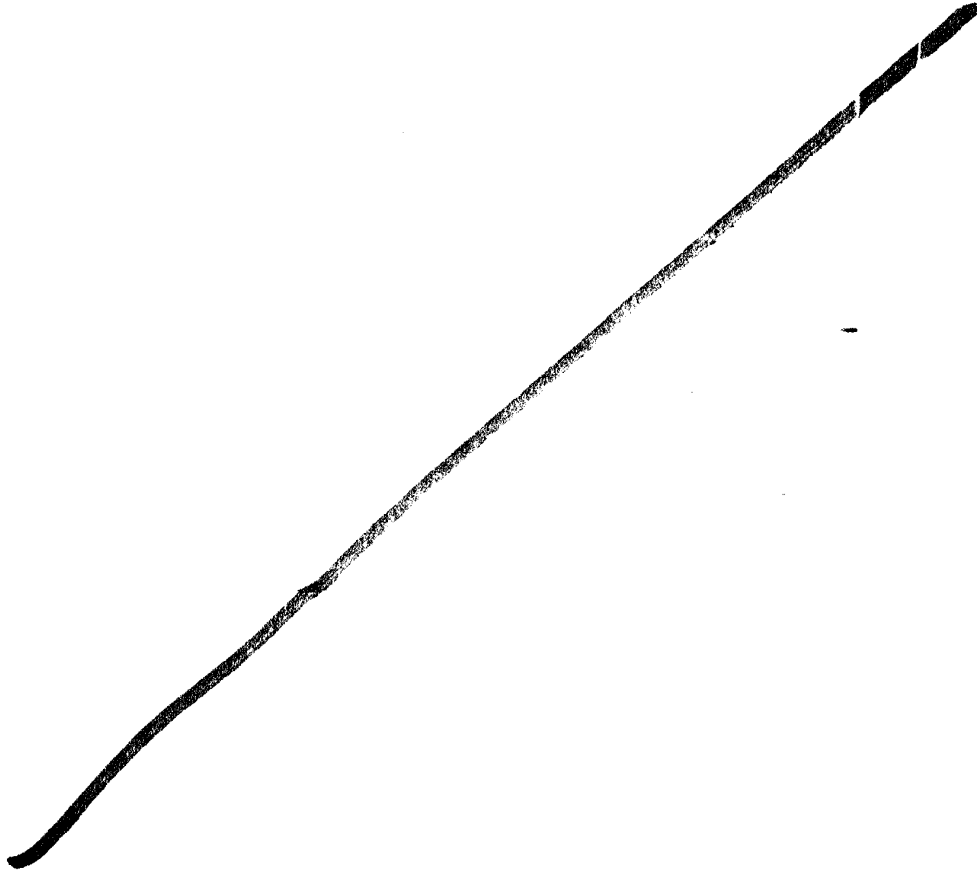
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required 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:

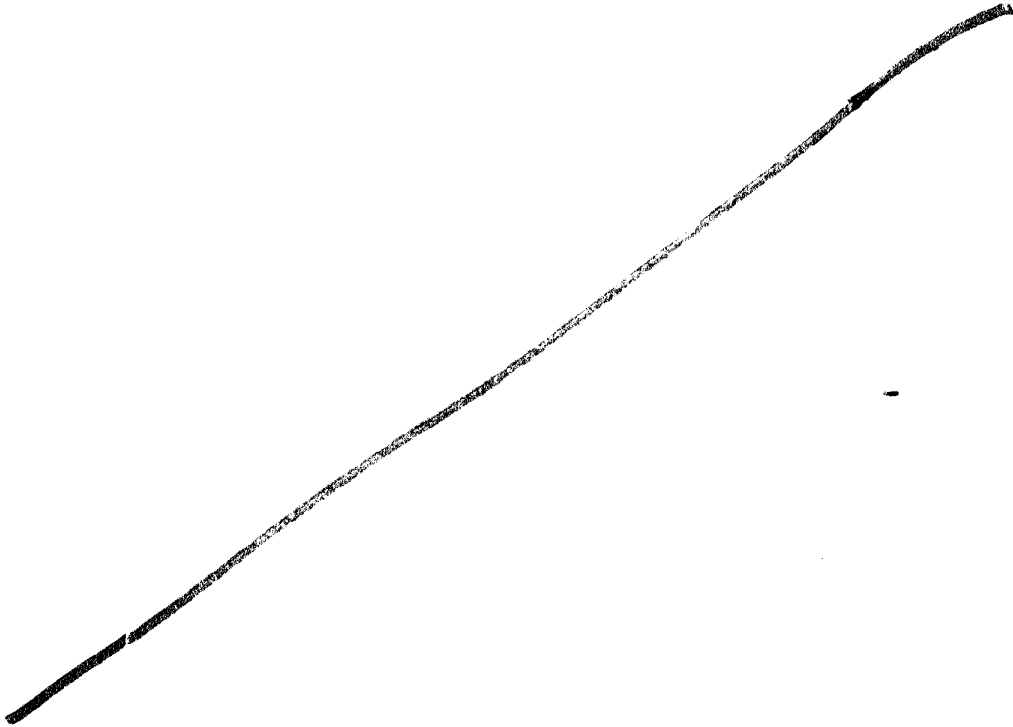
Section E. Standard Operating Procedures - Procedures Manual



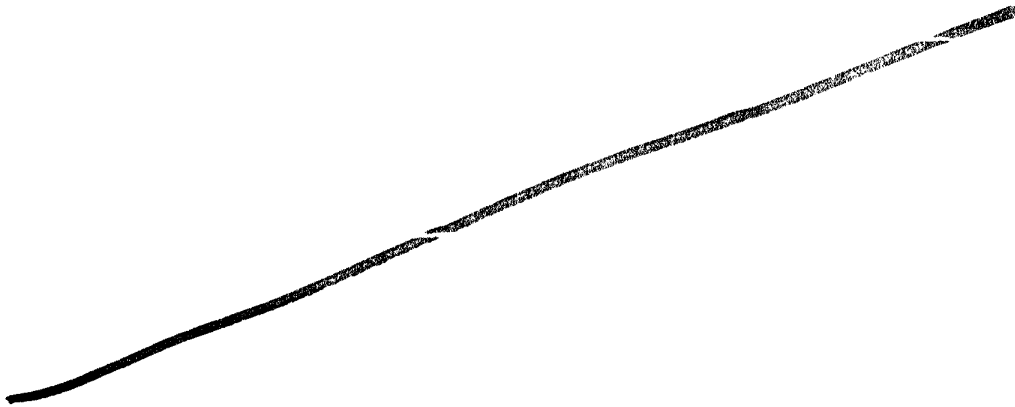


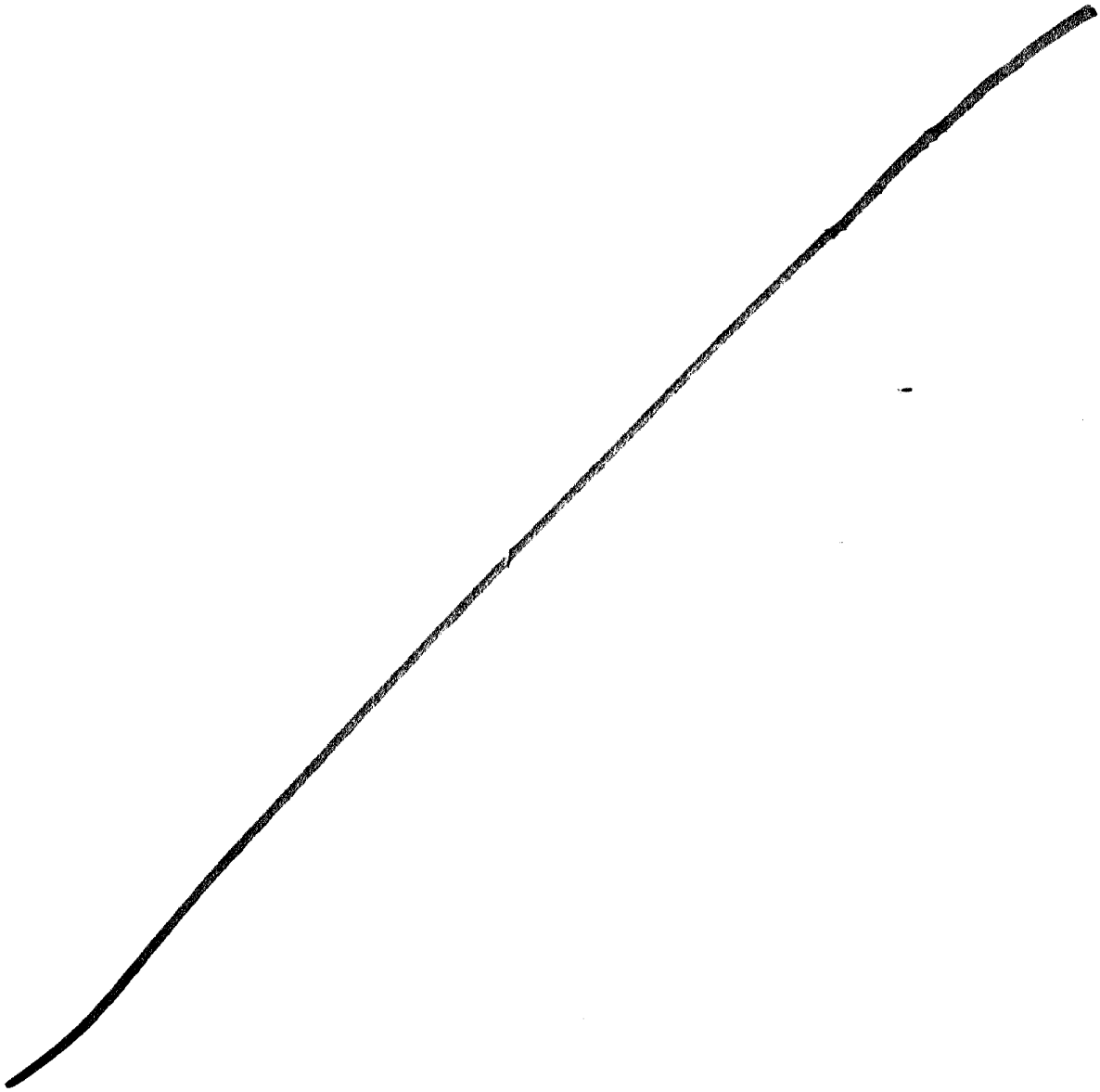
Section F. Chain-of-Custody, Accessioning, and Security





Section G. Quality Control

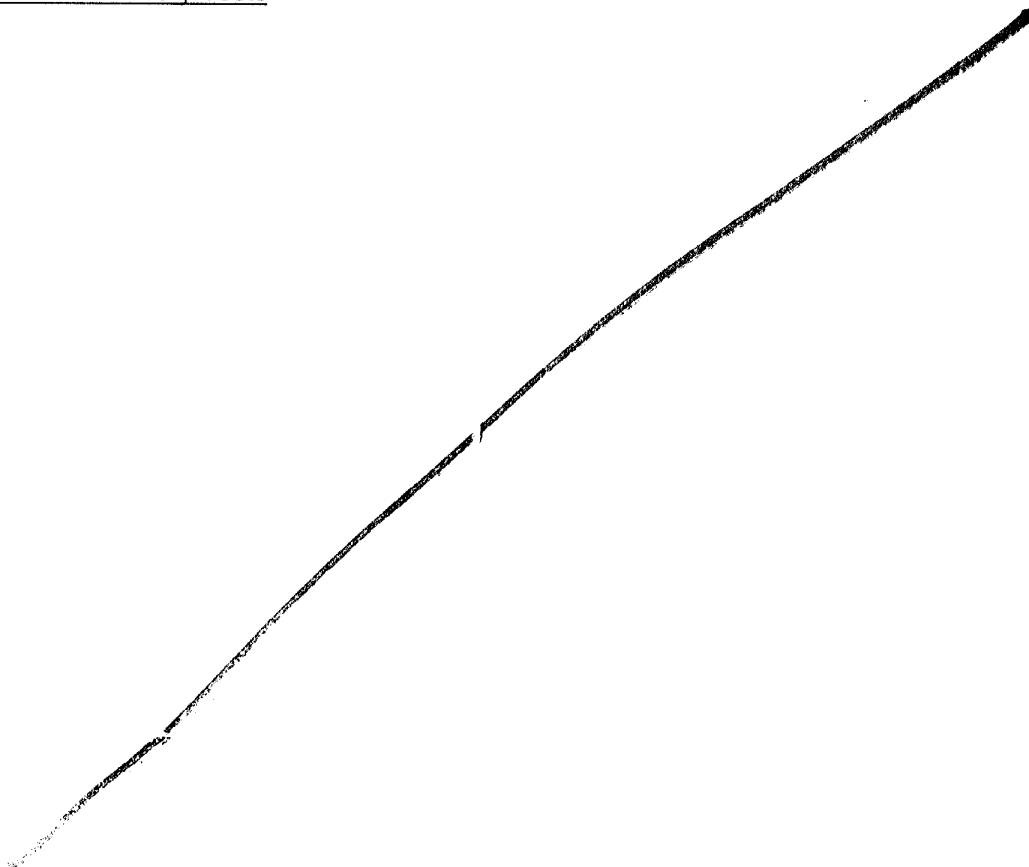





Section H. Initial Tests




Section I. Confirmatory Tests



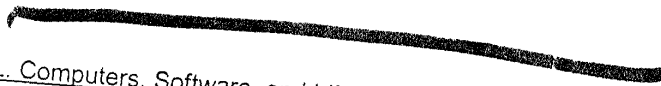
Section J. Records Audit




Section K. Reporting



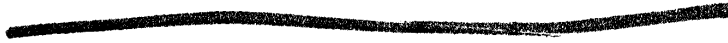

Section L. Computers, Software, and LIMS

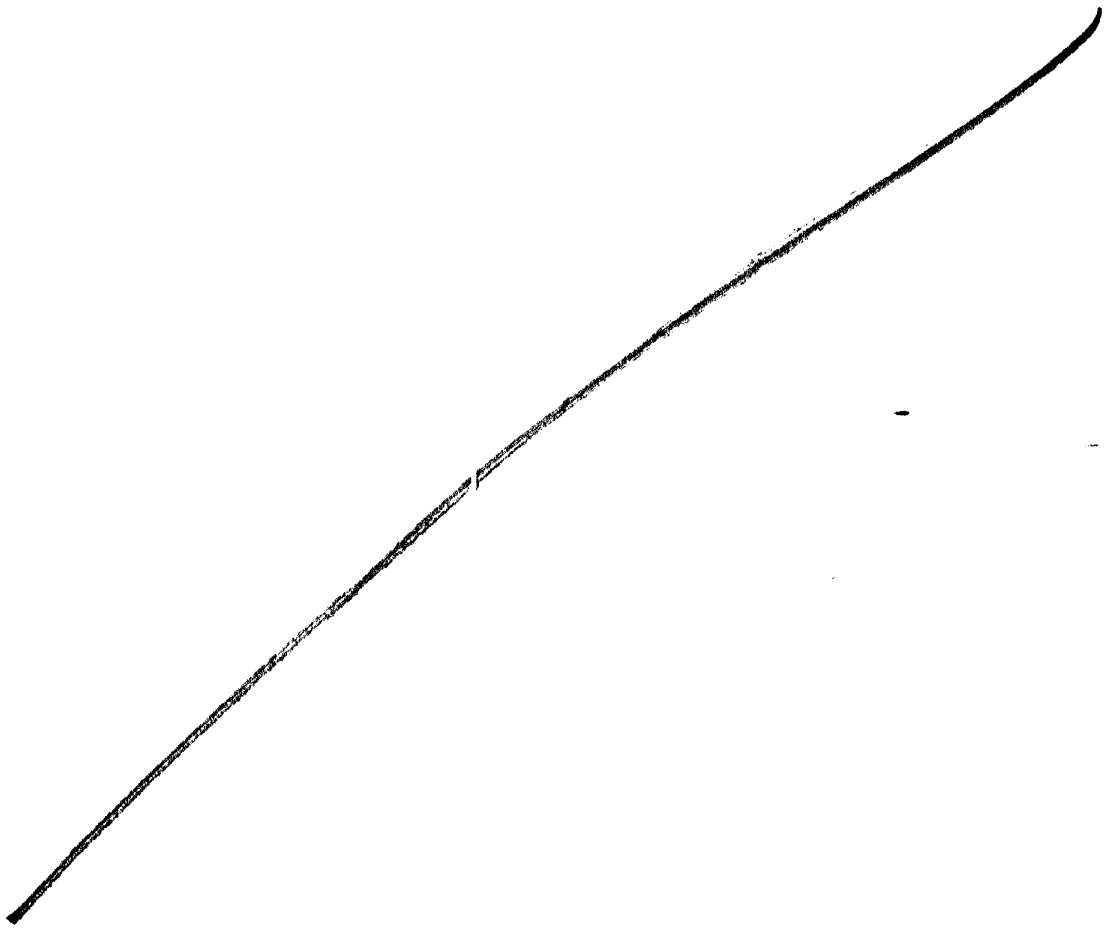


Section M. Equipment and Maintenance



Section N. Personnel





received
11/10/99 MRB

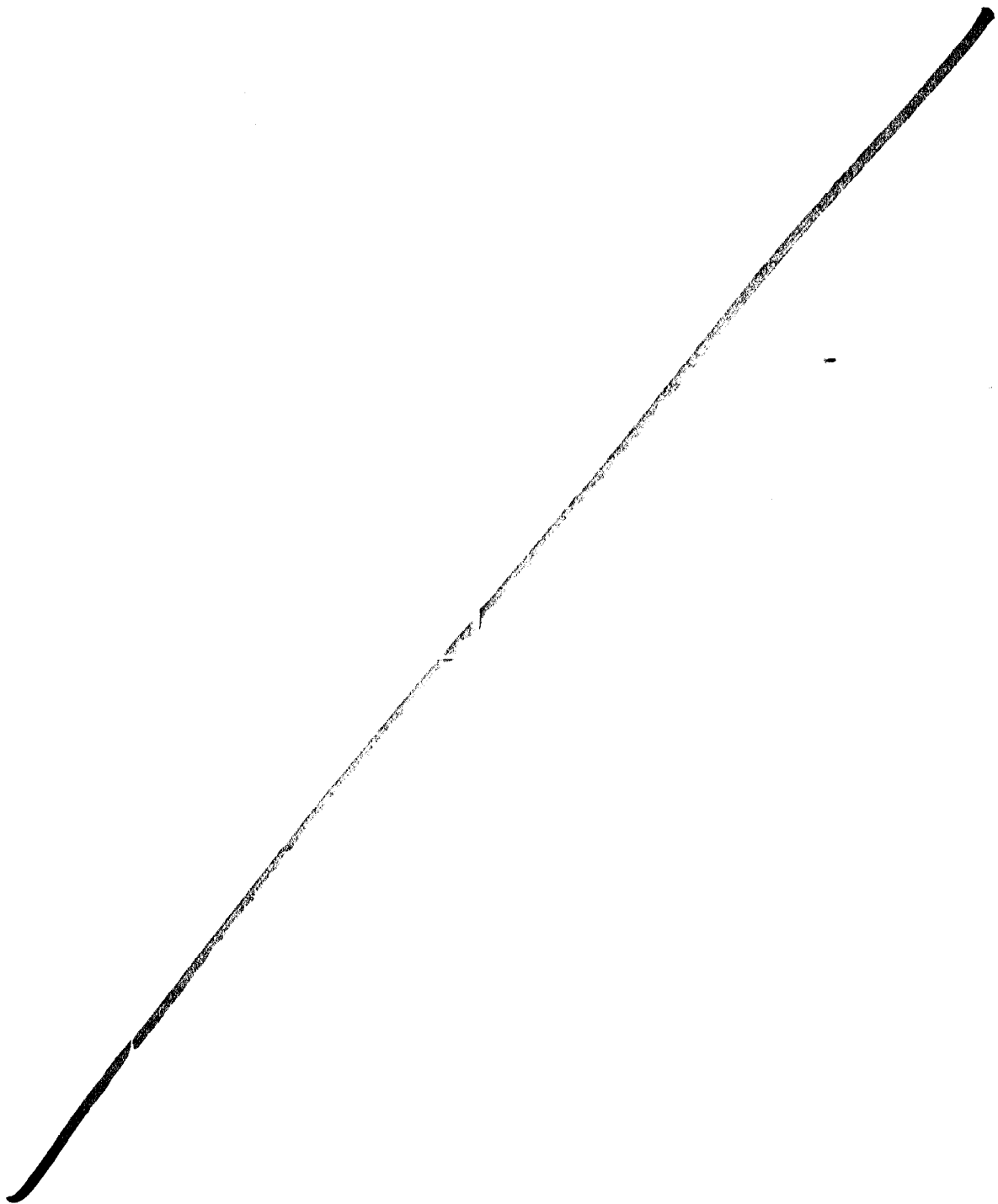
November 8, 1999

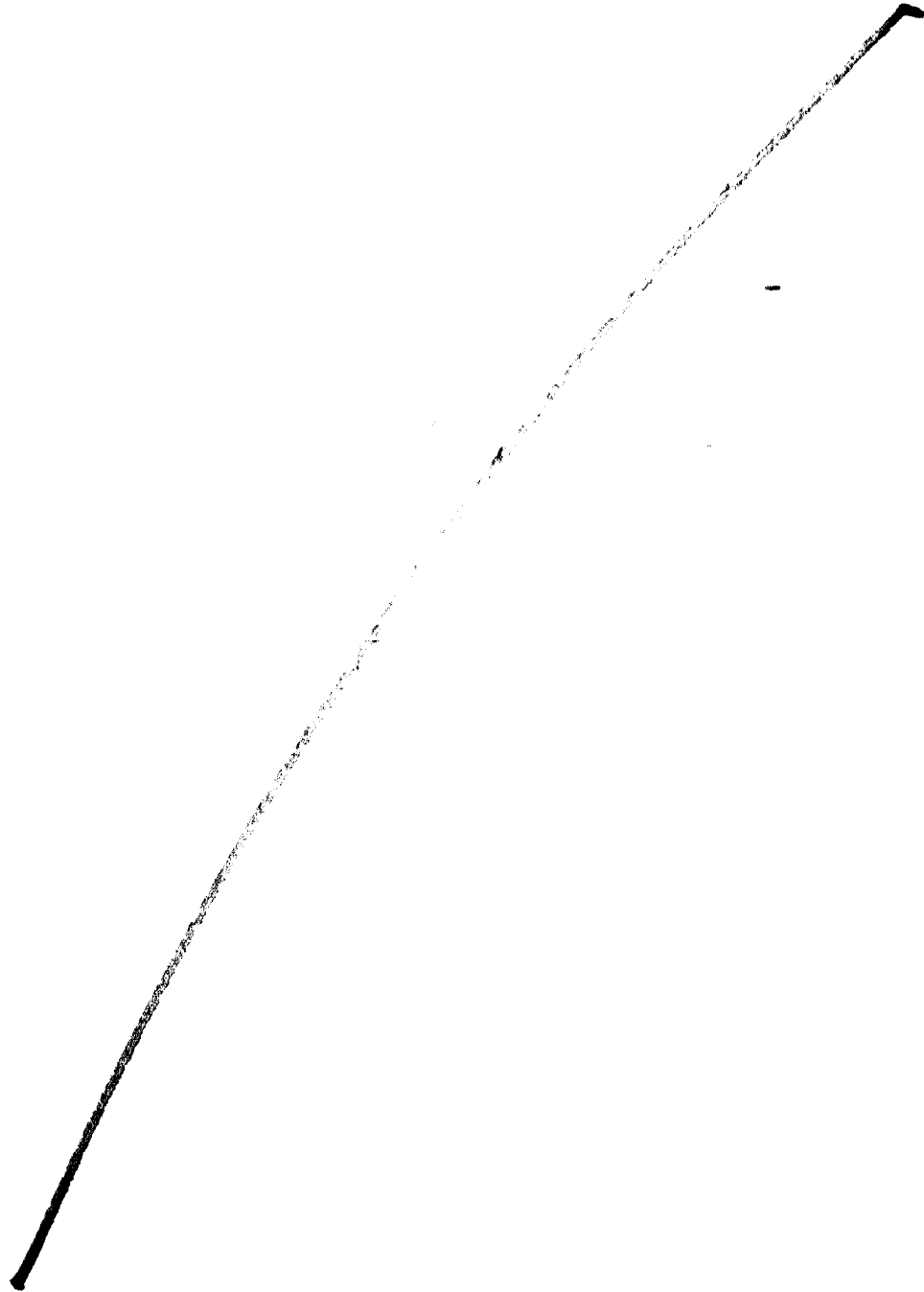
Michael R. Baylor, Ph.D.
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

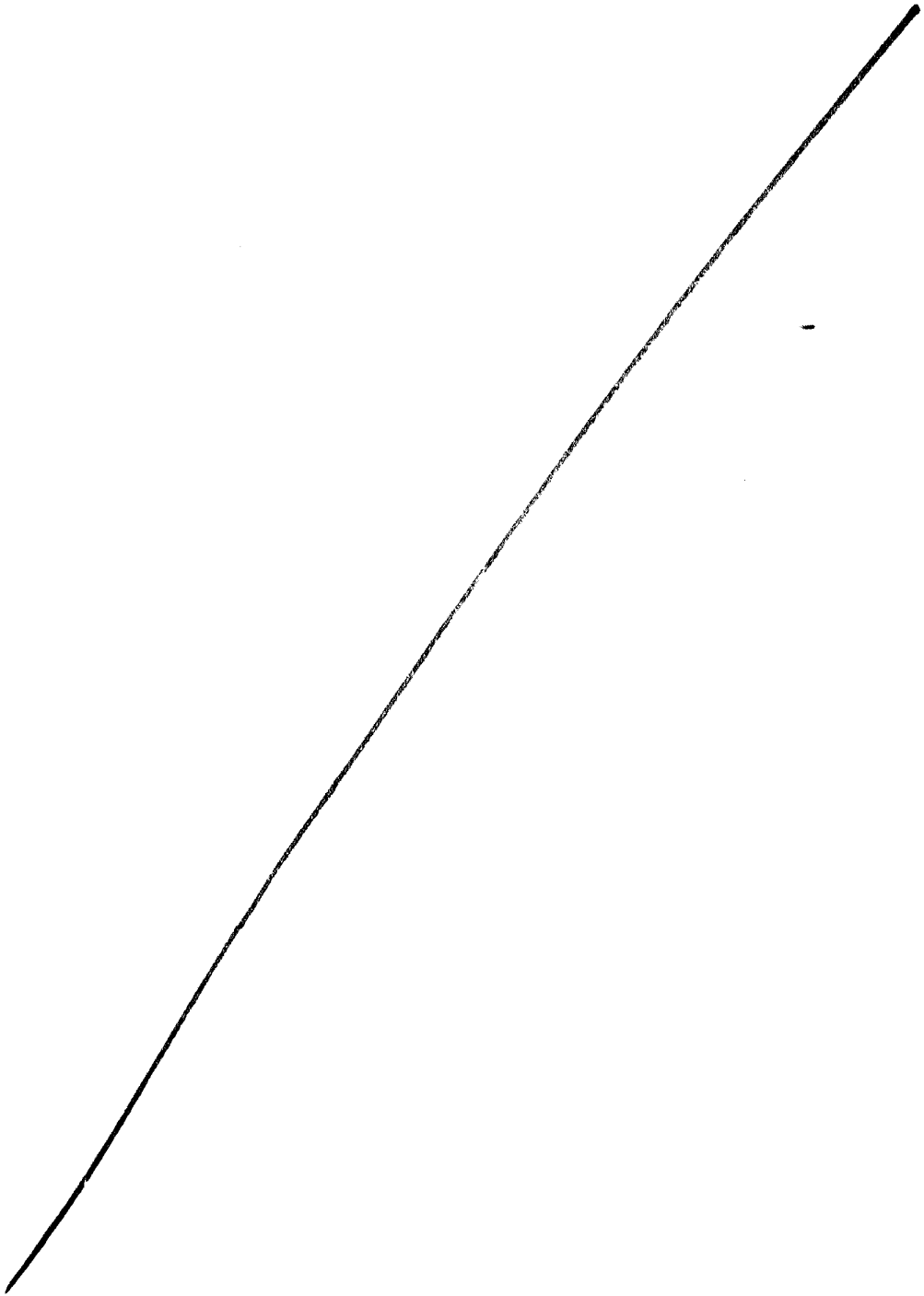
RE: Unilab ID#0135

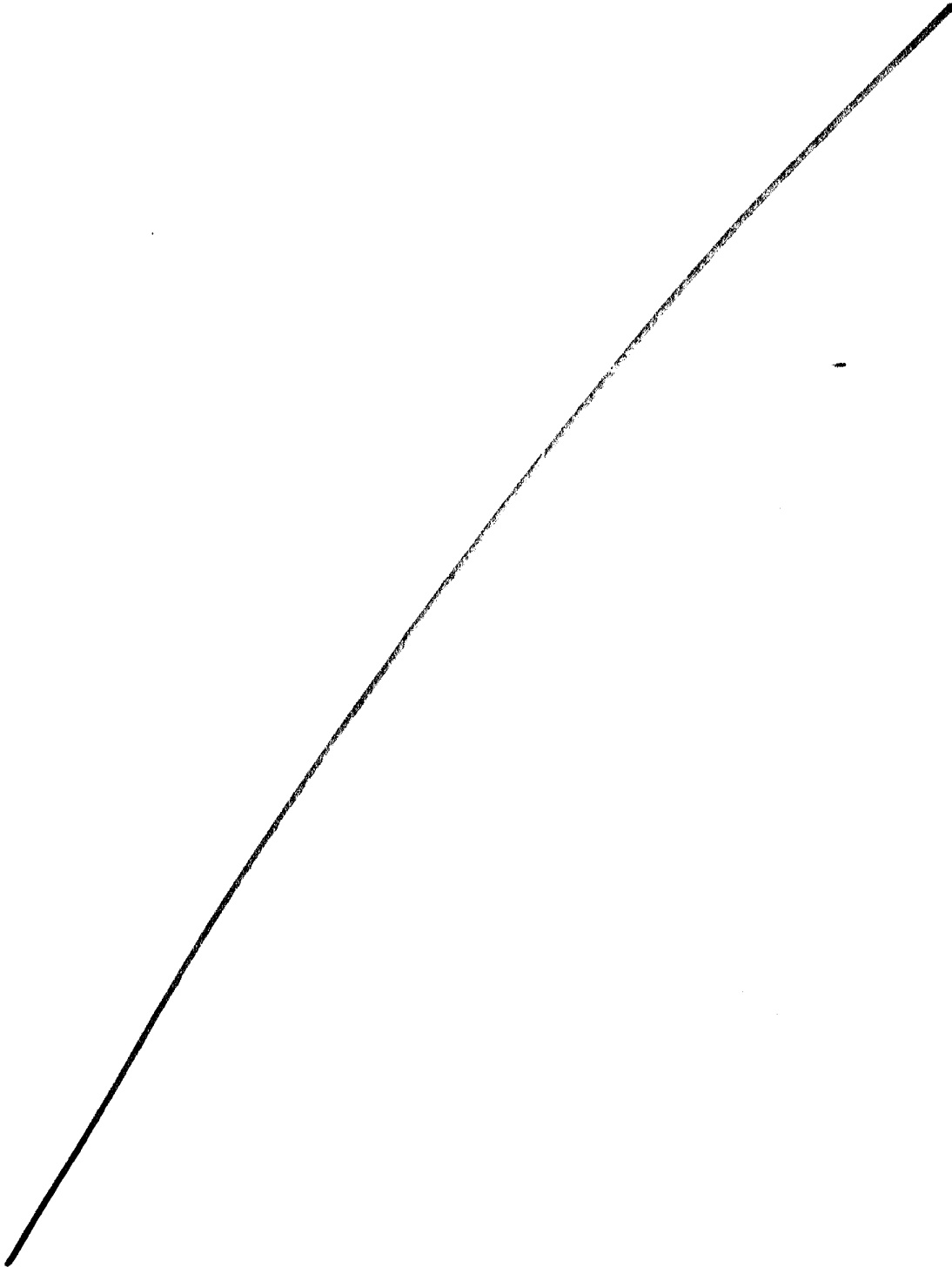
Dear Dr. Baylor:

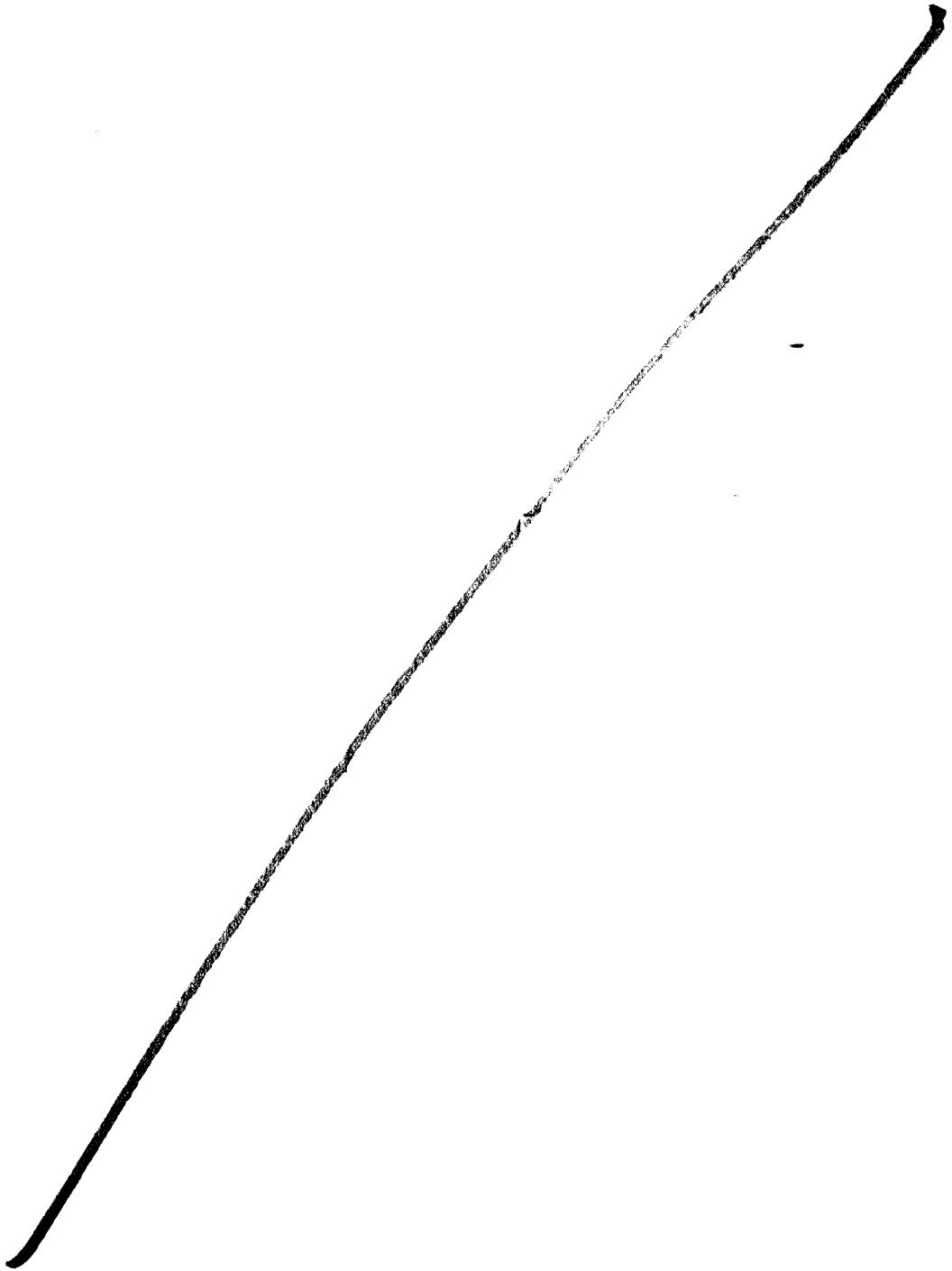
Regarding Unilab's (ID #0135) special inspection of September 15-17, 1999, by the three inspectors of the National Laboratory Certification Program (NLCP), we are responding with completion and documentation of all corrective actions listed in your critique letter of October 29, 1999:

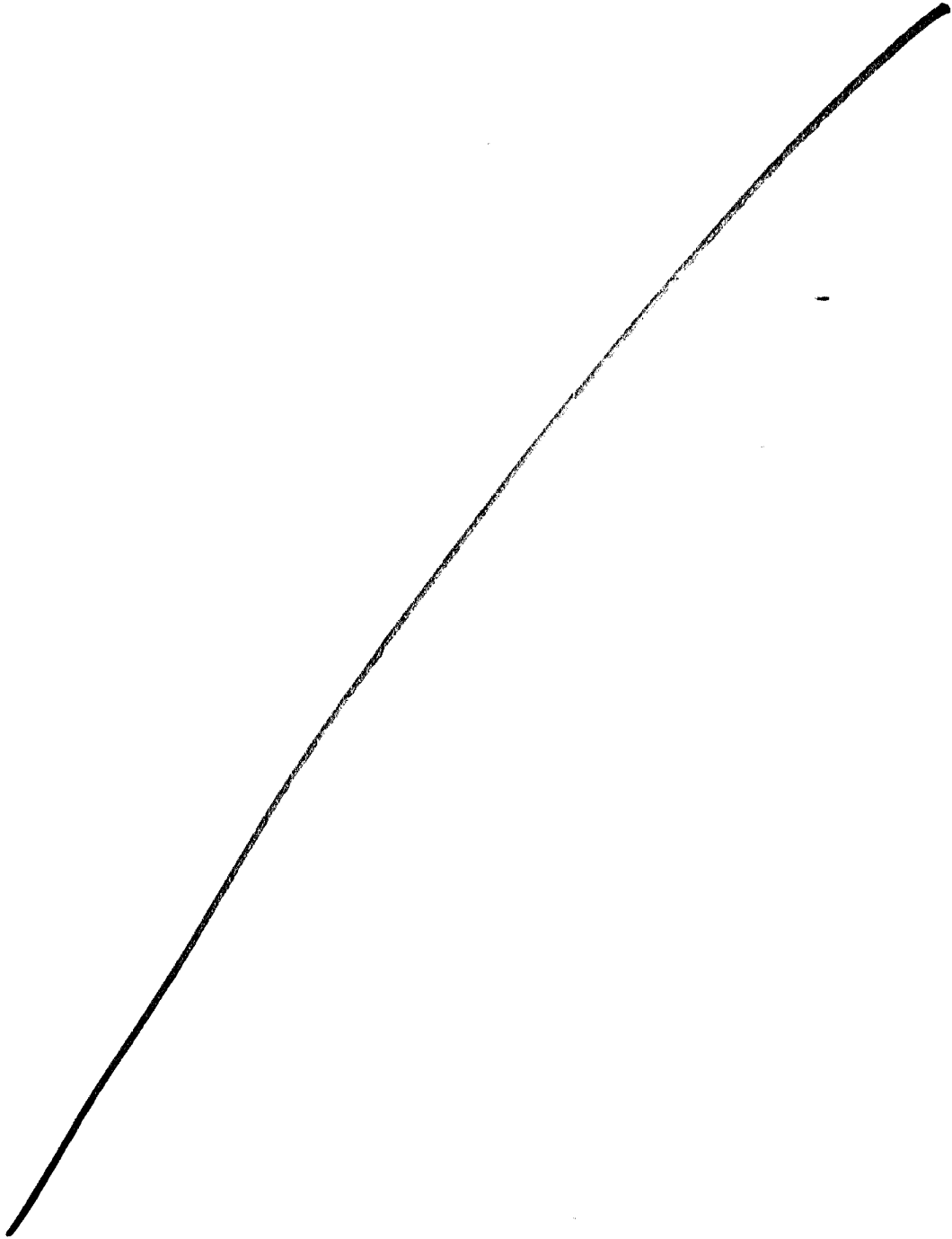


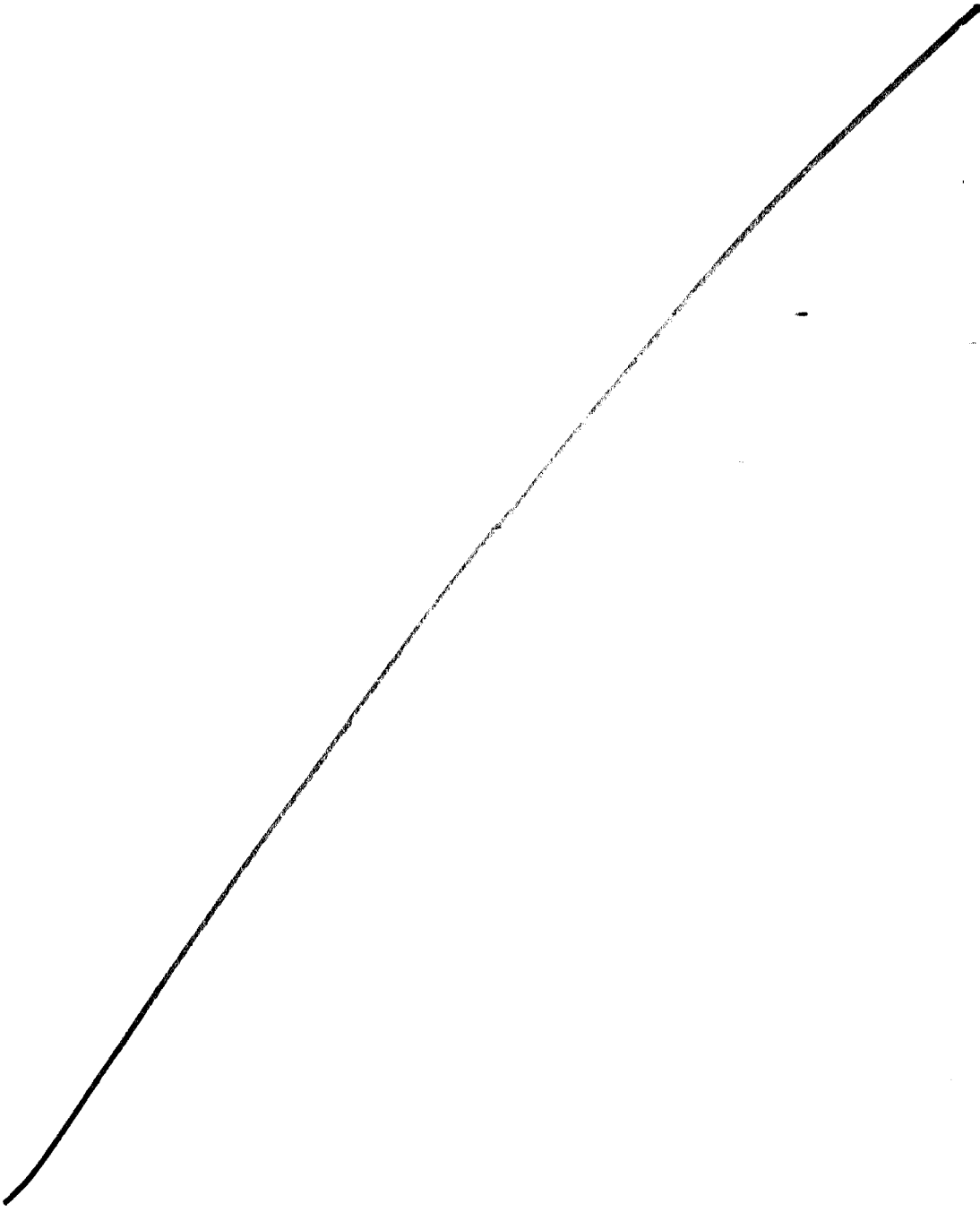


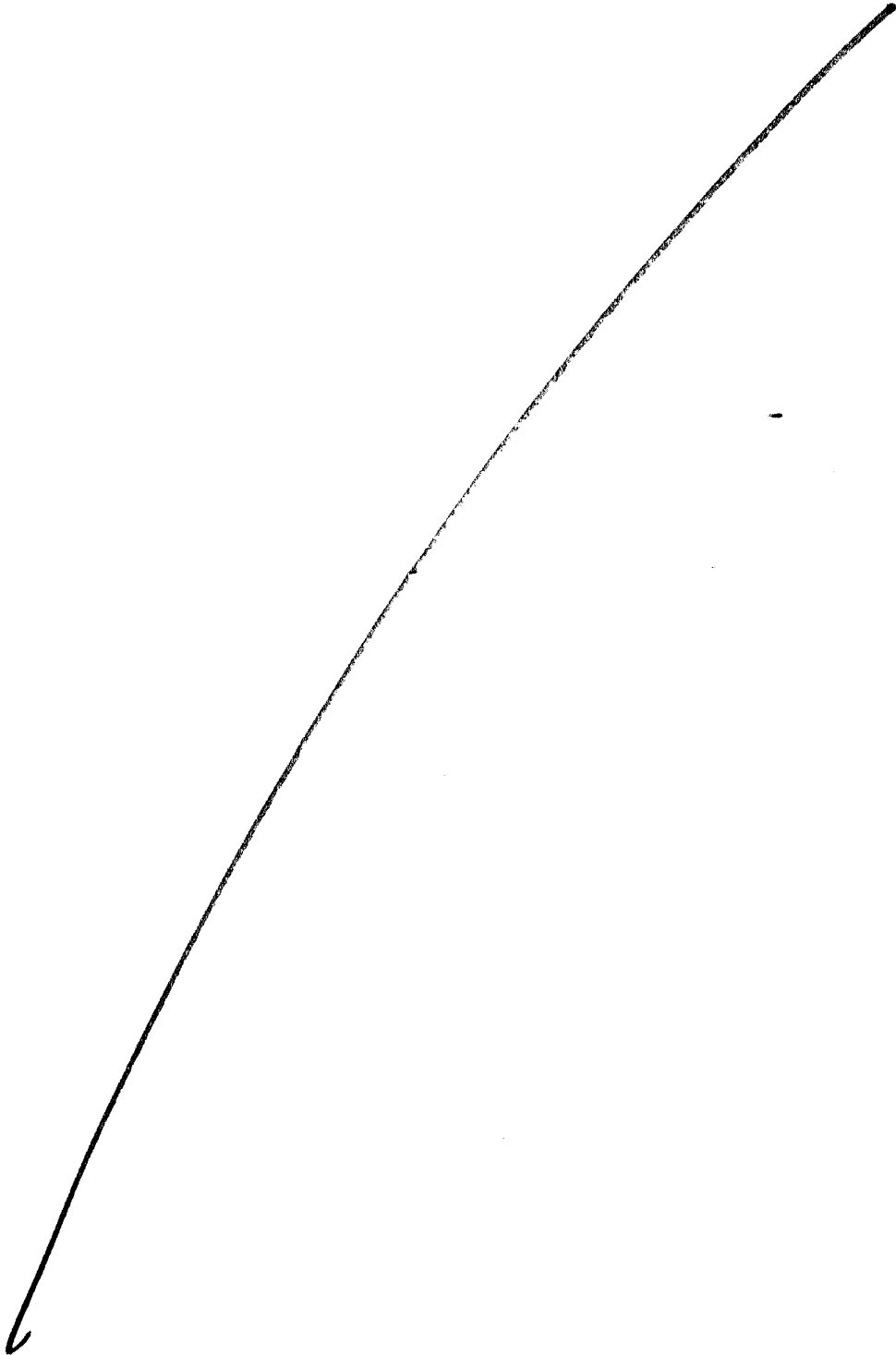


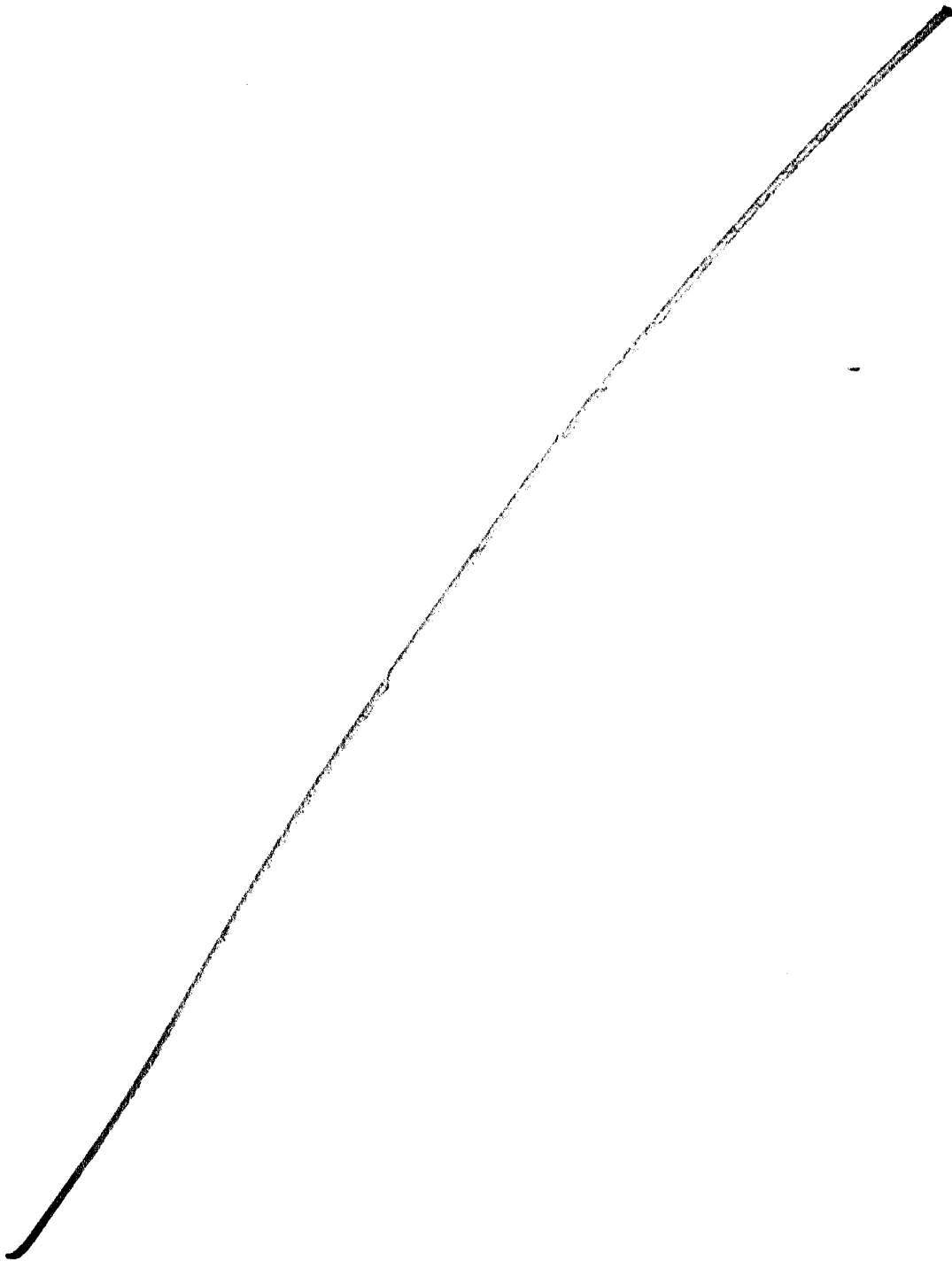


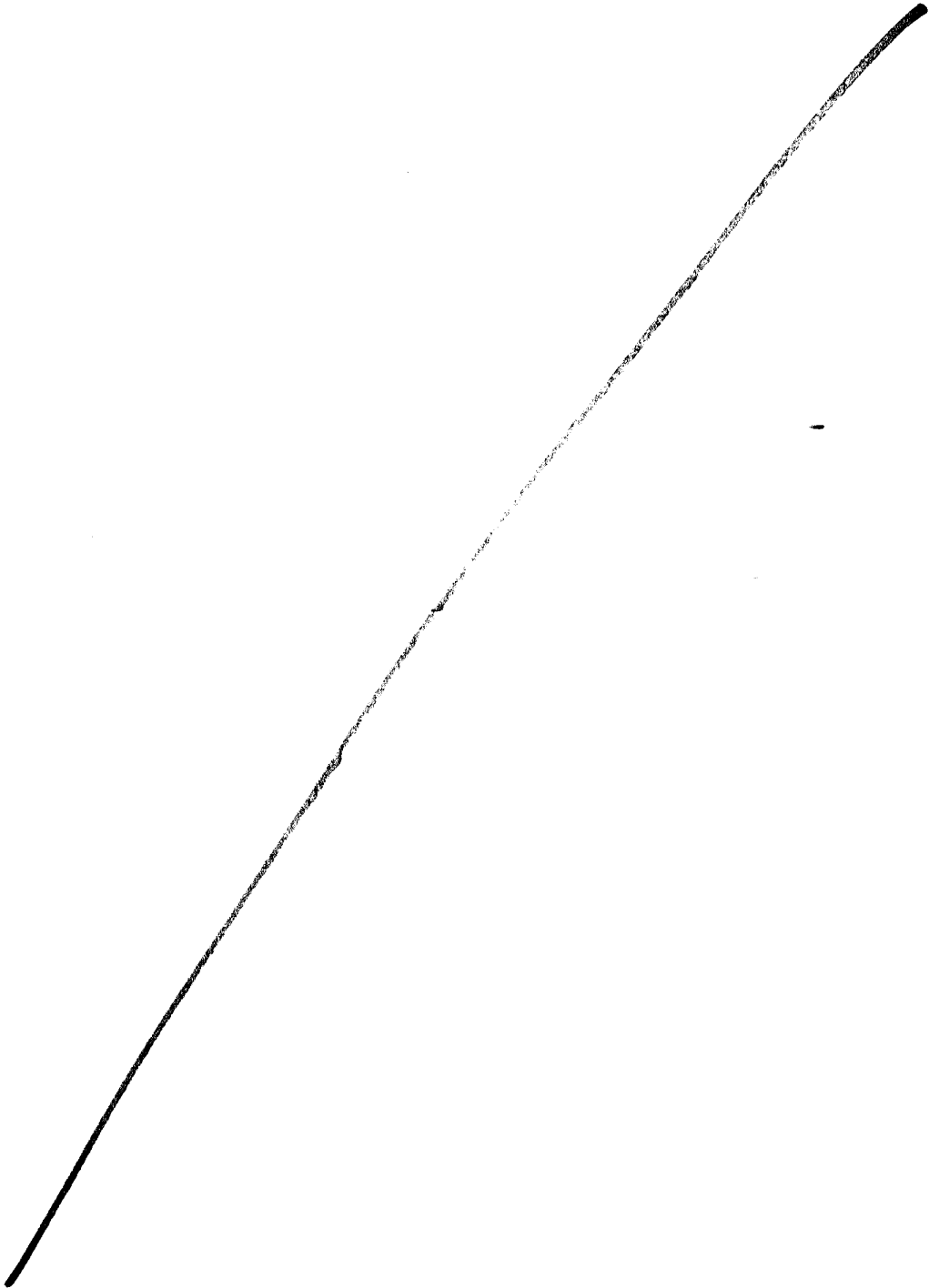




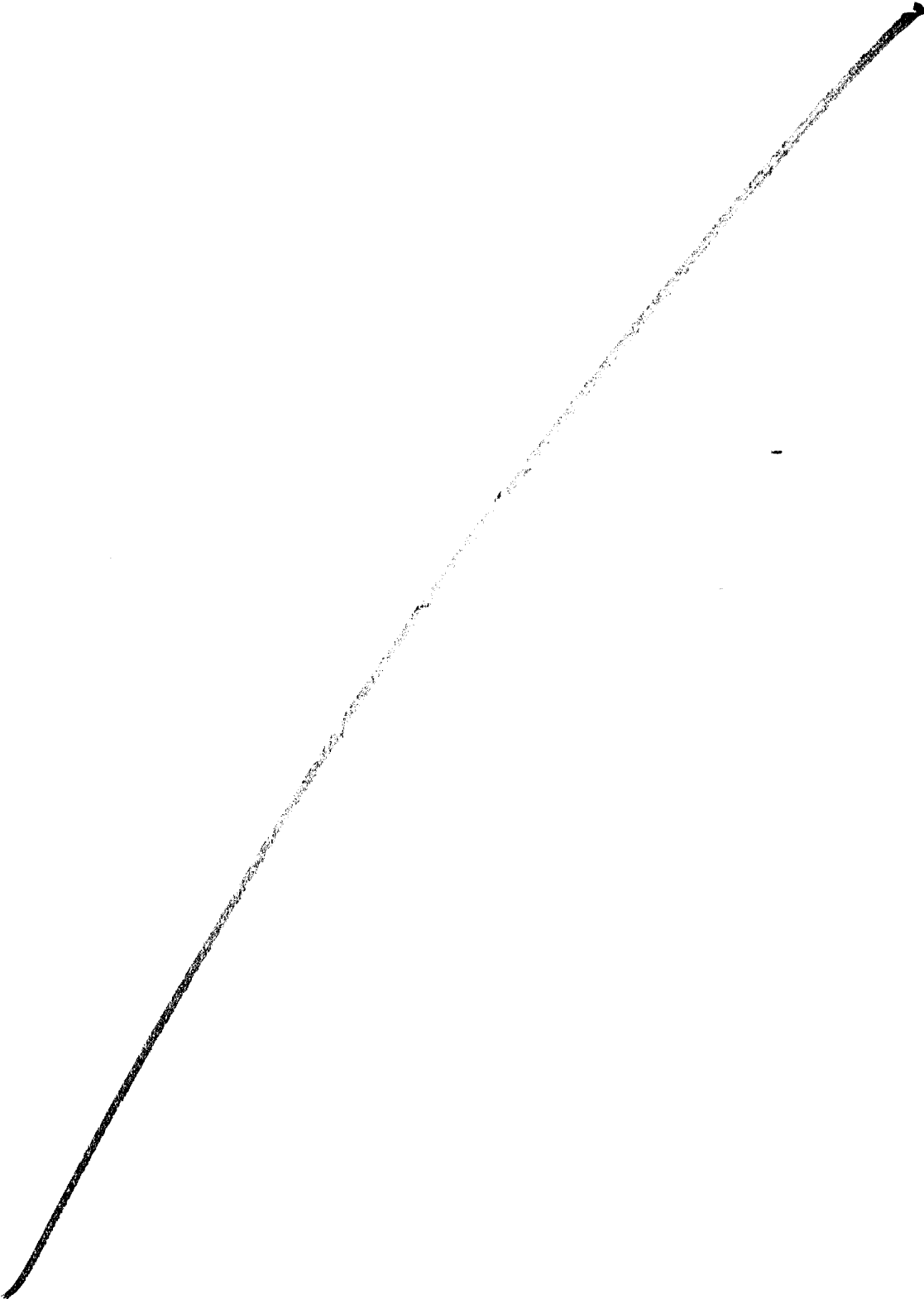


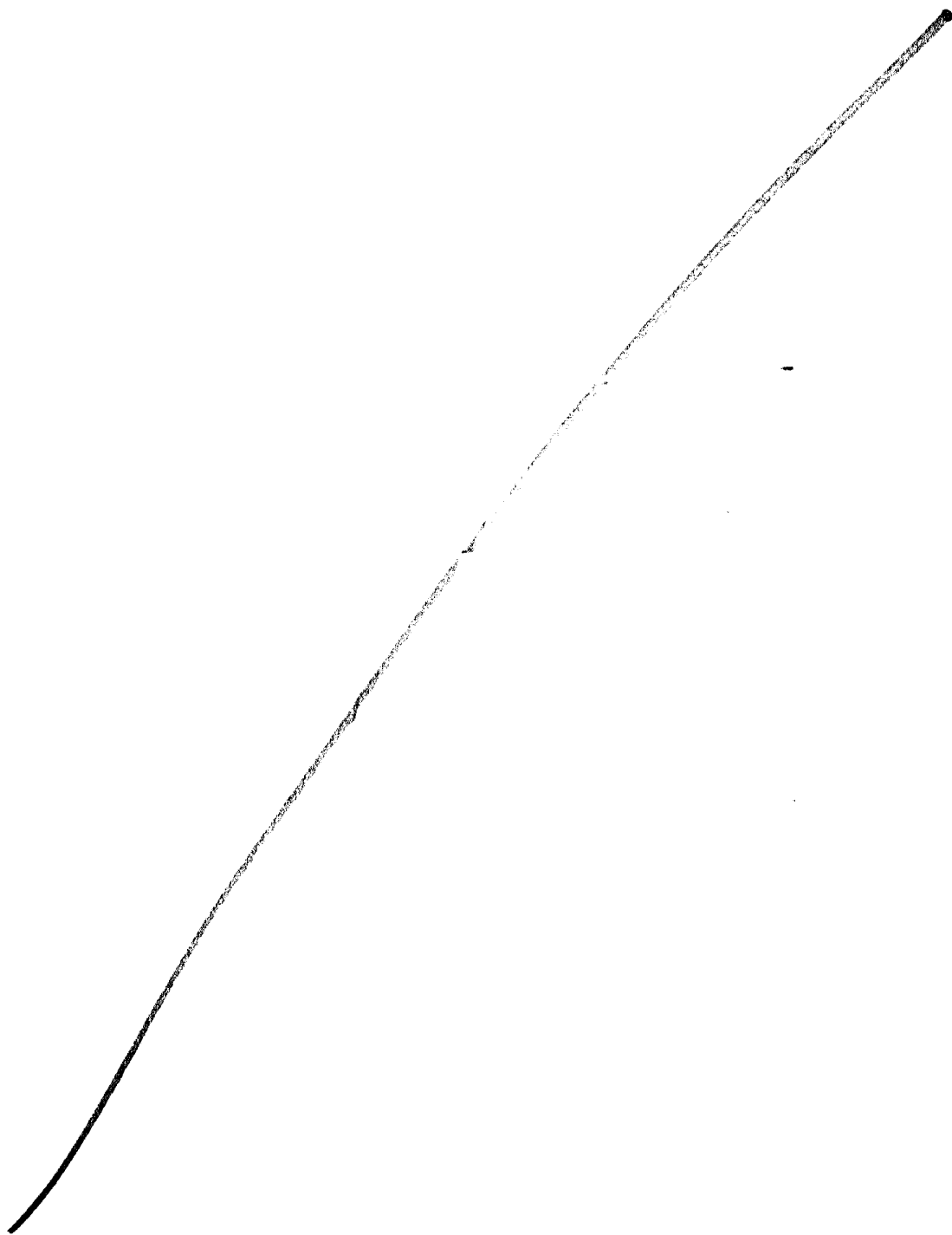


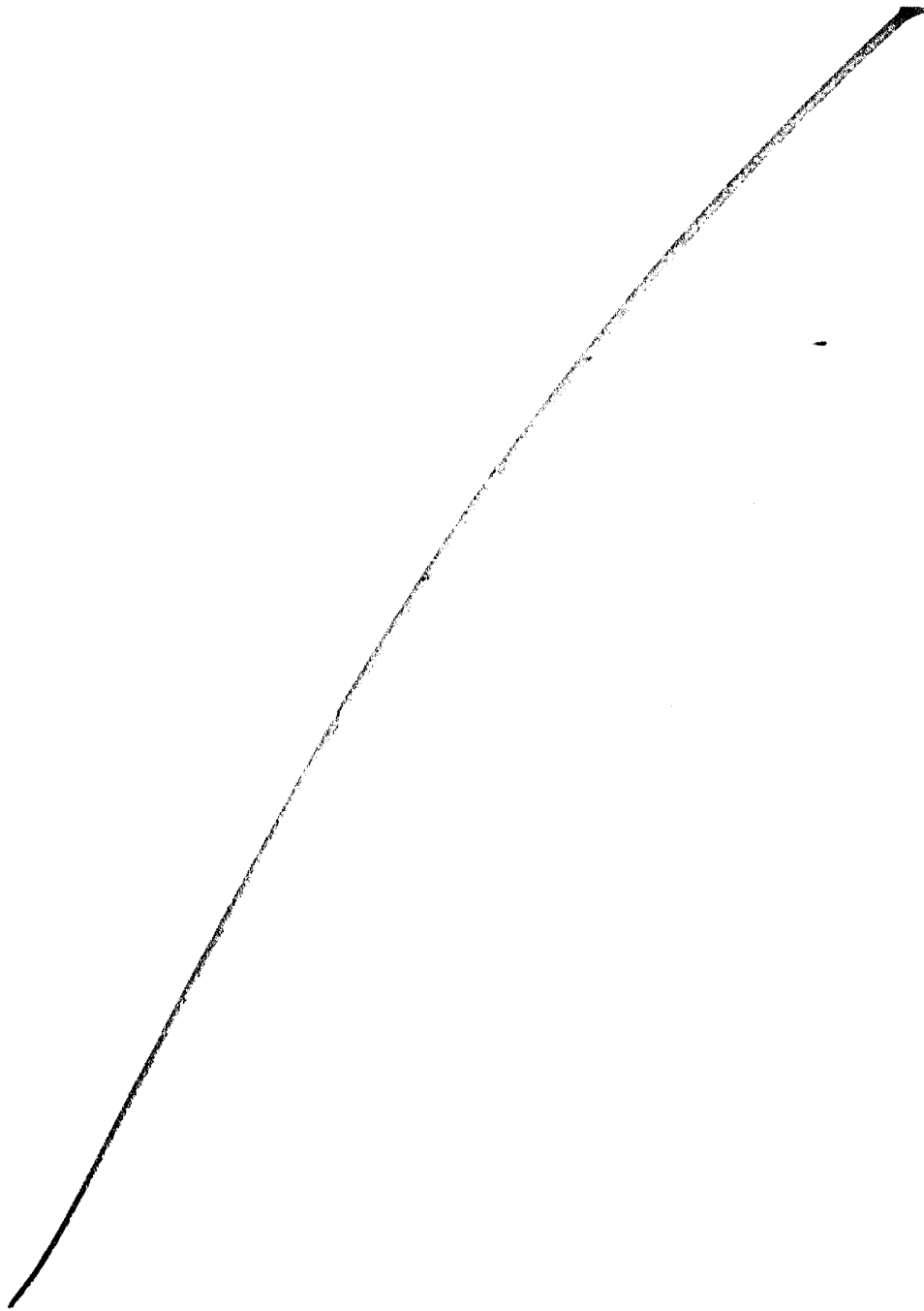




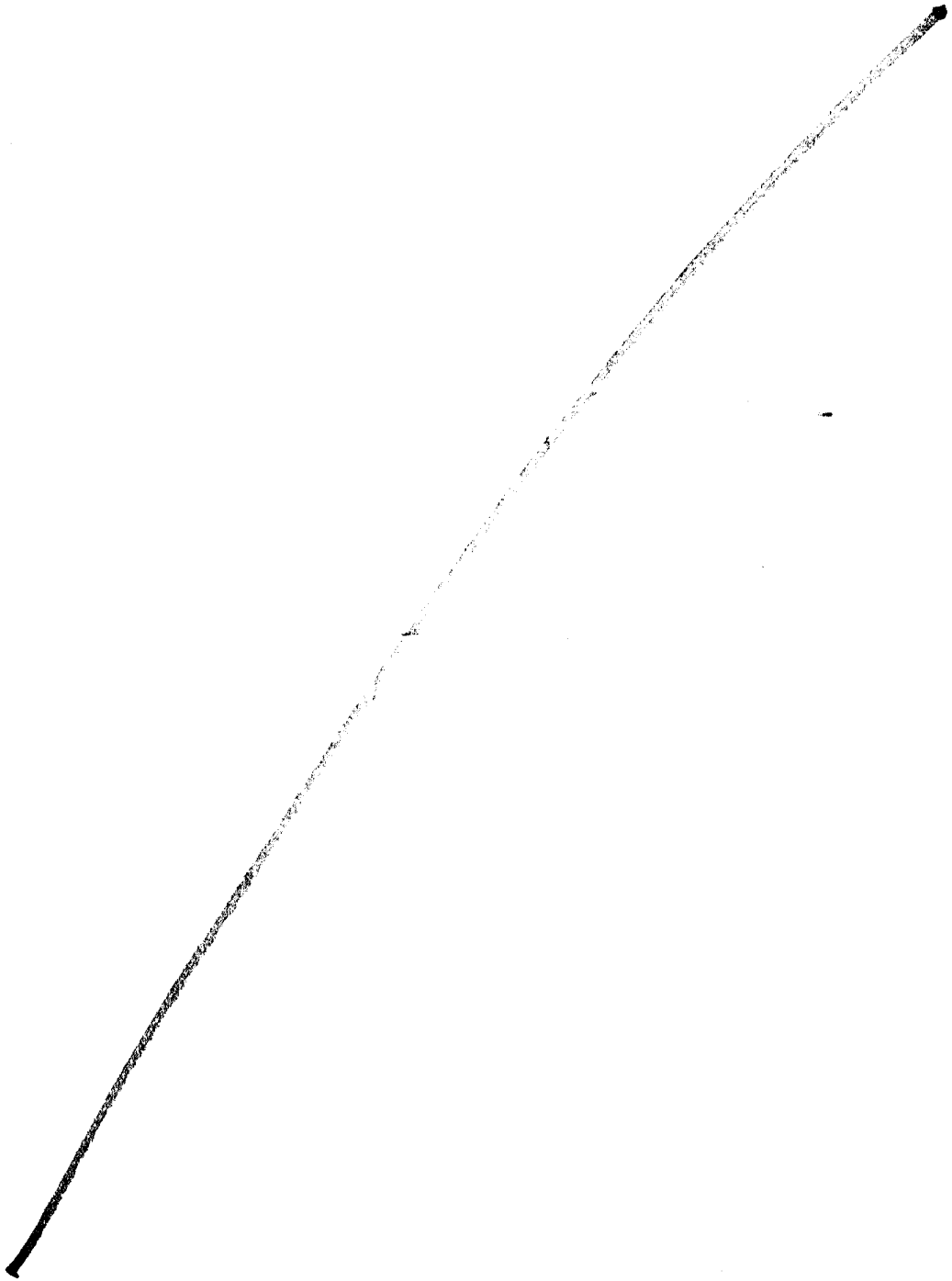


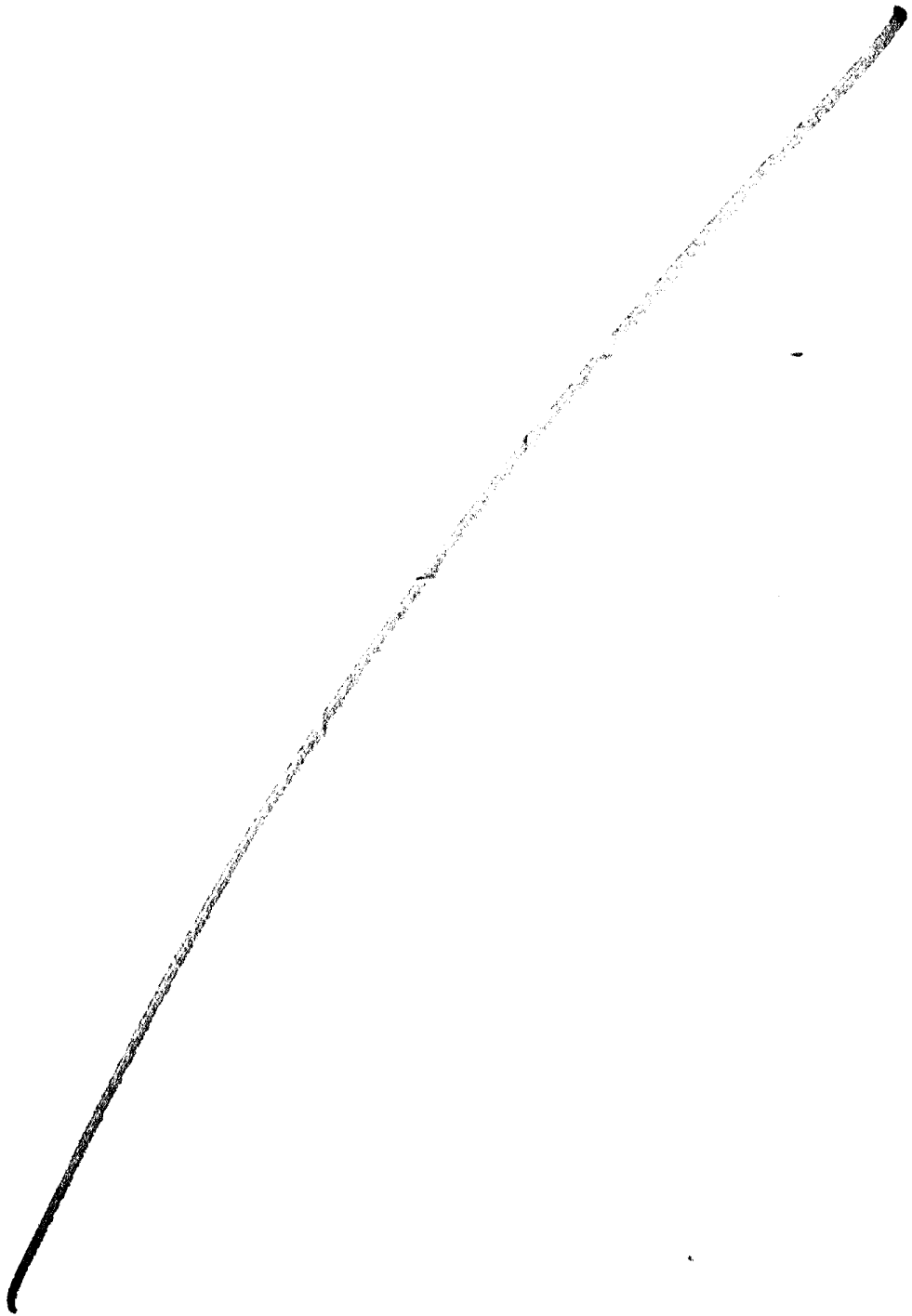


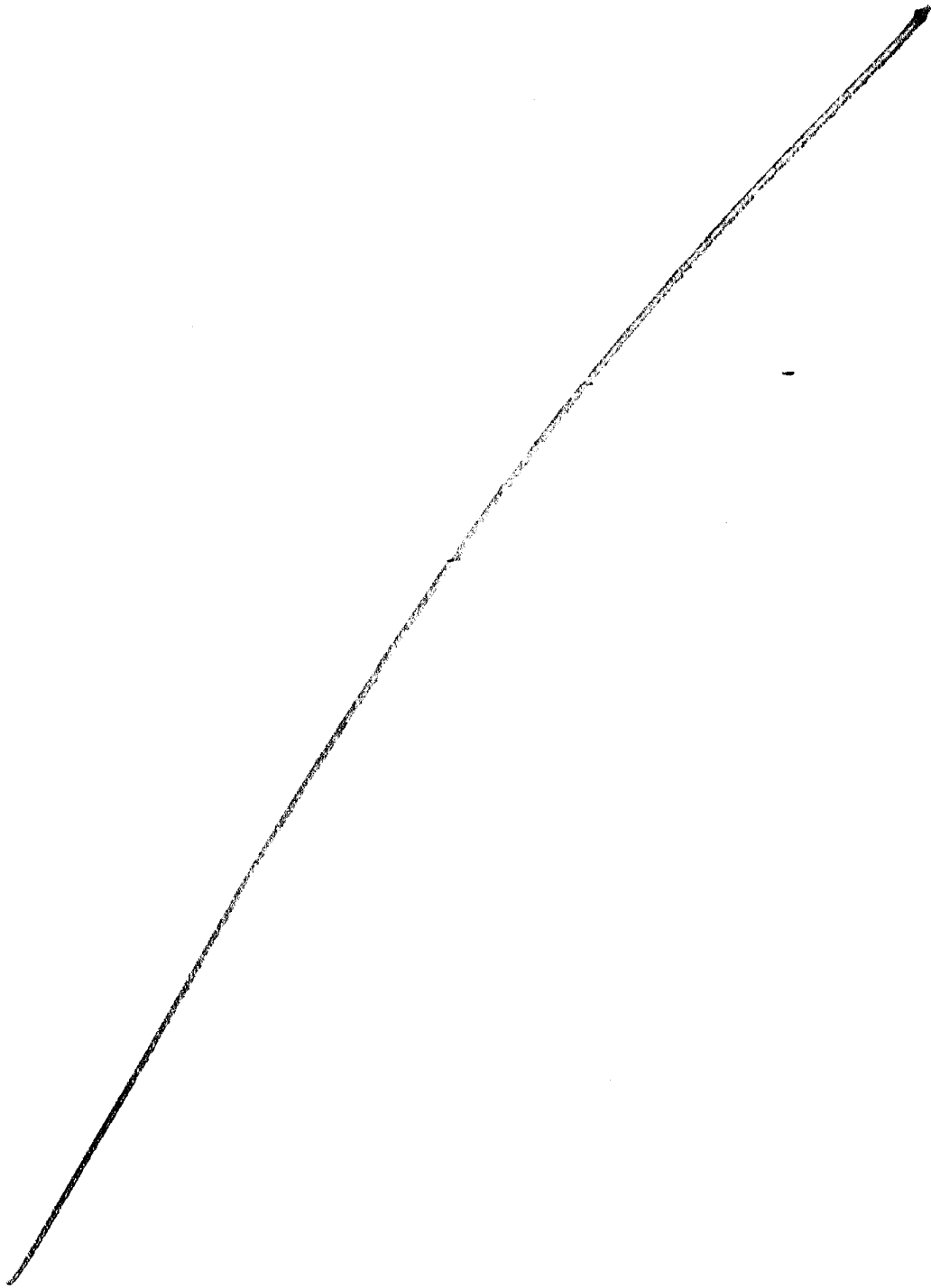












Sincerely,

Andrew J. Fischinger Ph.D

Andrew J. Fischinger Ph.D
Responsible Person Lab. 0135

RESEARCH TRIANGLE INSTITUTE



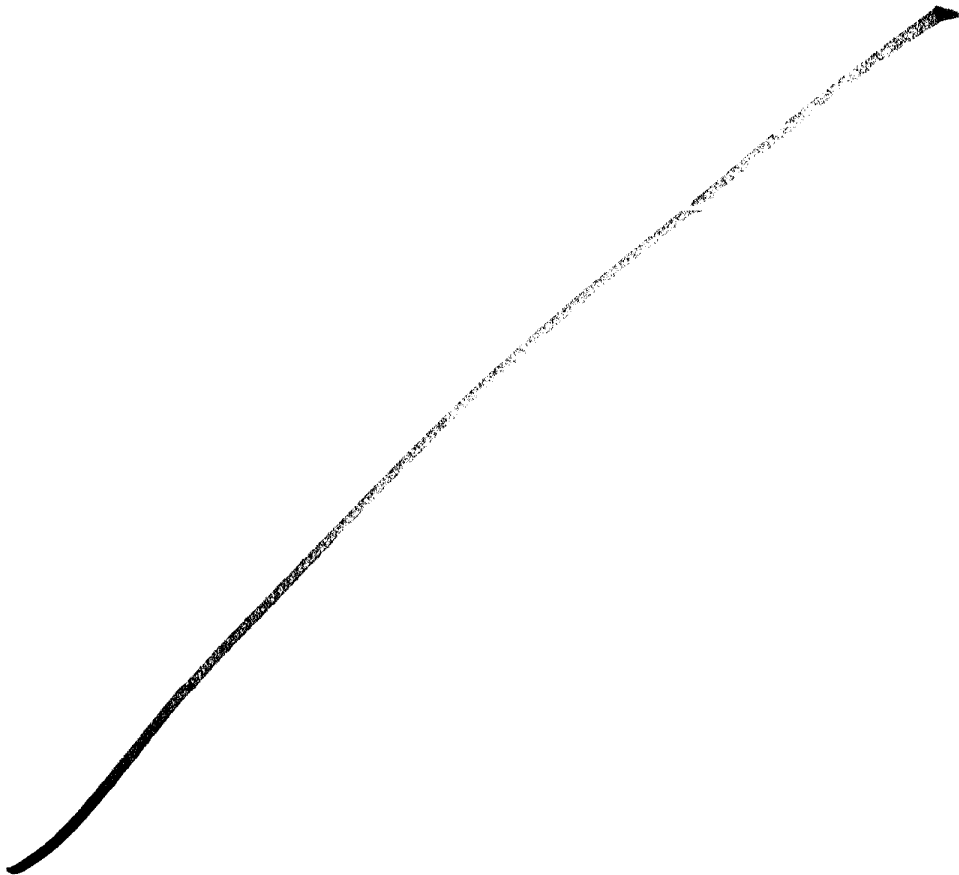
National Laboratory Certification Program

November 18, 1999

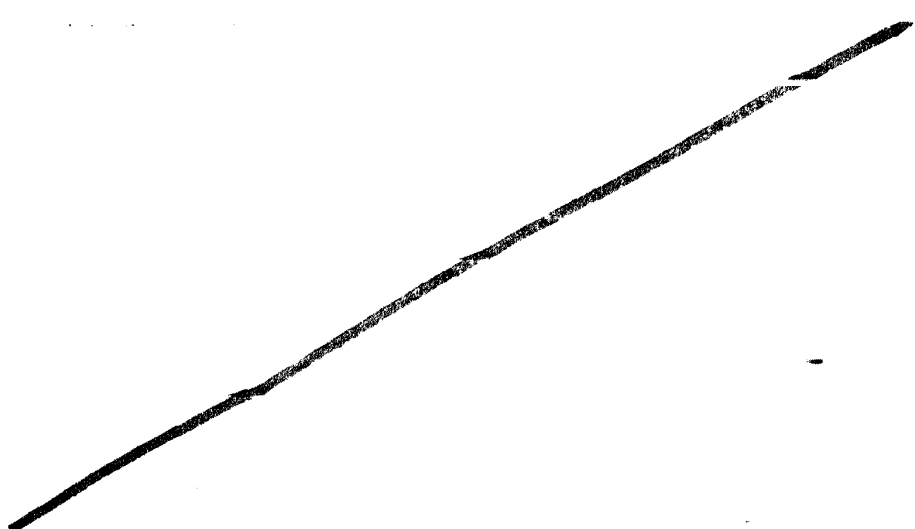
0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of November 08, 1999, provided in response to the deficiencies cited during the Special inspection of your laboratory as outlined in our correspondence of October 29, 1999. The plan to clarify and/or correct the deficiencies noted was found acceptable. However, the following procedures require additional clarification and correction (listed in accordance with the laboratory's submission):

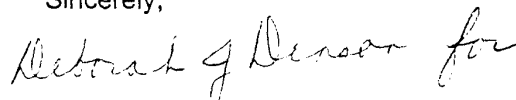


Dr. Fishinger
November 18, 1999
Page 2 of 2



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 Deborah Denson at (919) 541-7265.

Sincerely,



Dr. Michael R. Baylor, Ph.D
Sr. Forensic Toxicologist

cc: Project Files/SP



UNILAB

received
01/03/2000 DD

Michael R. Baylor, Ph.D.
Sr. Forensic Toxicologist
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road, P.O. BOX 12194
Research Triangle Park, NC 27709-2194 USA

P. 1 of 4.

RE: Lab #0135

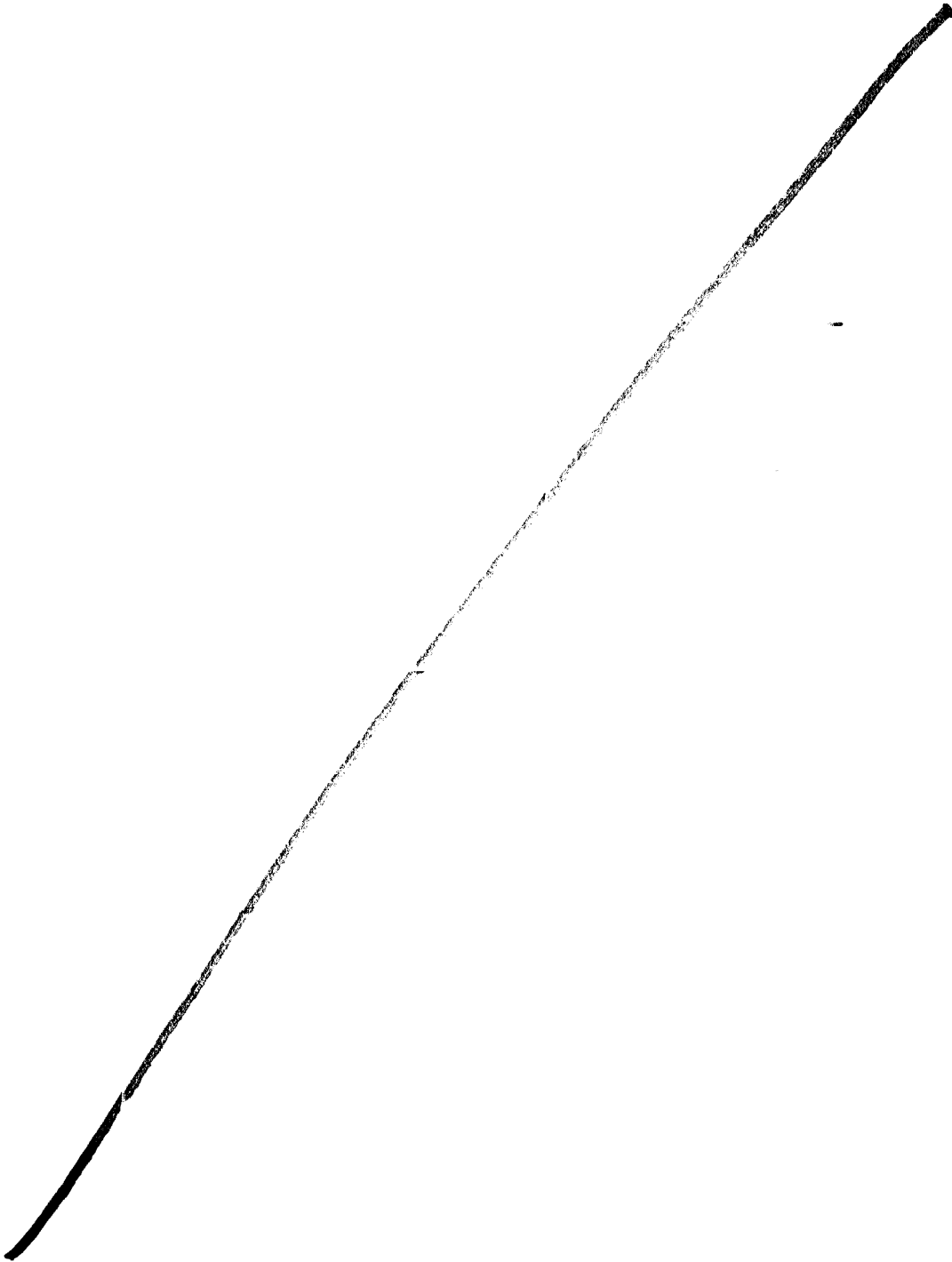
Dec. 27, 1999

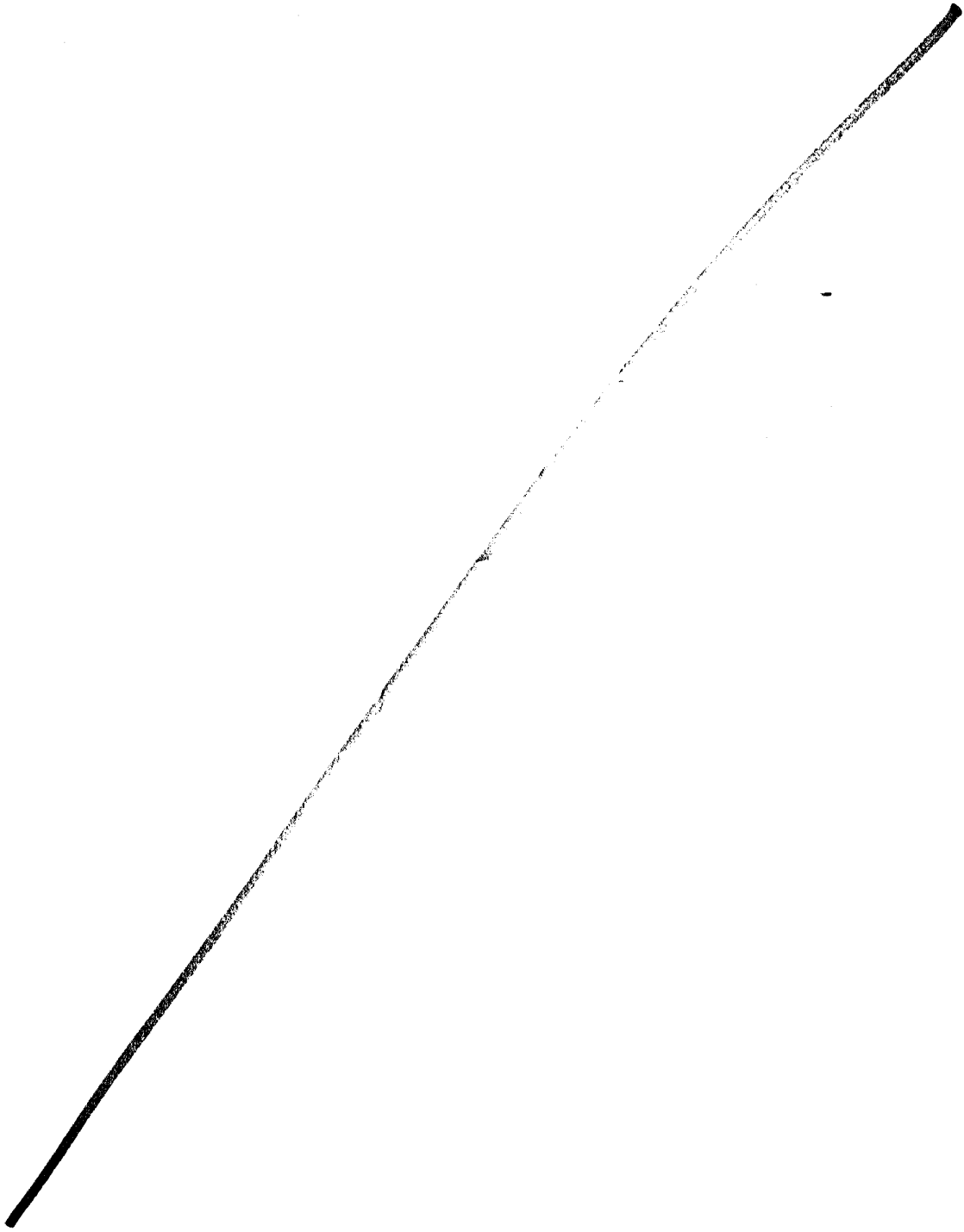
Dear Dr. Baylor:

As we discussed previously via phone conference on 12/23/99 with Ken Davis, I am submitting the completed final responses for E2a, E2e, E5a, E8c, E8c, G26b, and N6 corrective actions as detailed in your response of 11/18/99 to our corrective action responses of 11/8/99 to our fifteenth maintenance and special inspection.

Unilab Corporation

18408 Oxnard Street • Tarzana, California 91356 • Tel. 818 996-7300





Sincerely,

Andrew J. Fischinger Ph.D.

Andrew J. Fischinger, Ph.D., M.T.(ASCP)
Responsible Person (Lab. #0135)

RESEARCH TRIANGLE INSTITUTE



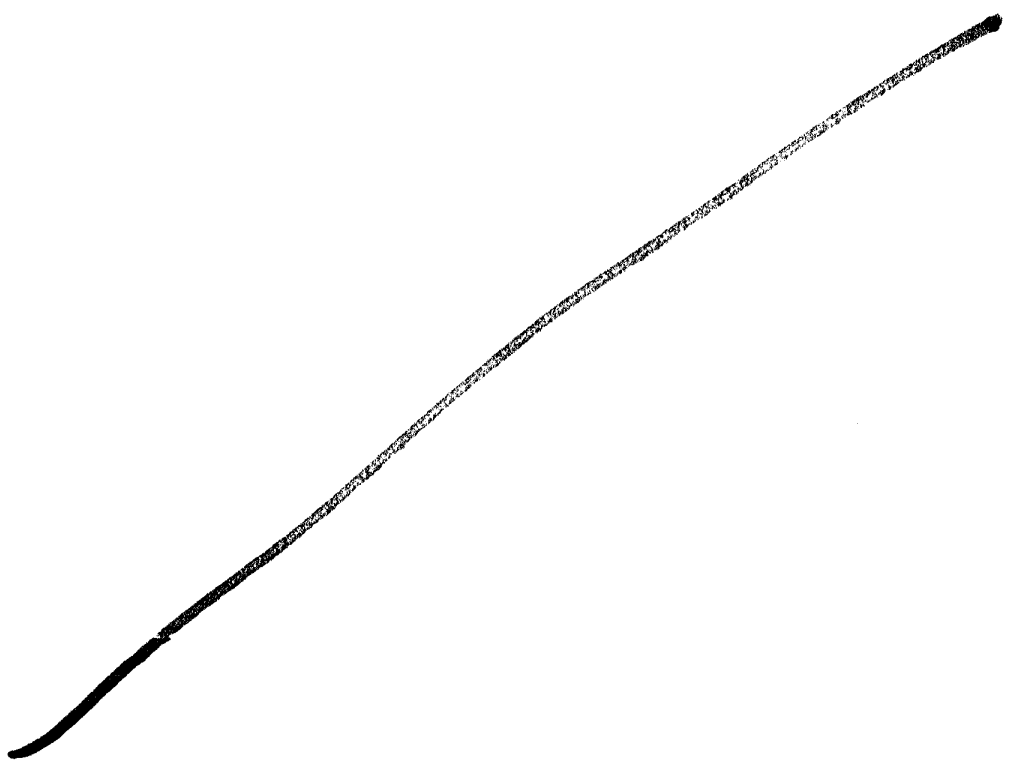
National Laboratory Certification Program

January 10, 2000


0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:

We have reviewed the material provided in your correspondence of December 27, 1999, submitted in response to deficiencies cited during the special inspection of your laboratory as outlined in our correspondence of November 18, 1999. 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:



Dr. Fishinger
January 10, 2000
Page 2 of 2



Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory 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/SP



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 24, 2000

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:


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. 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

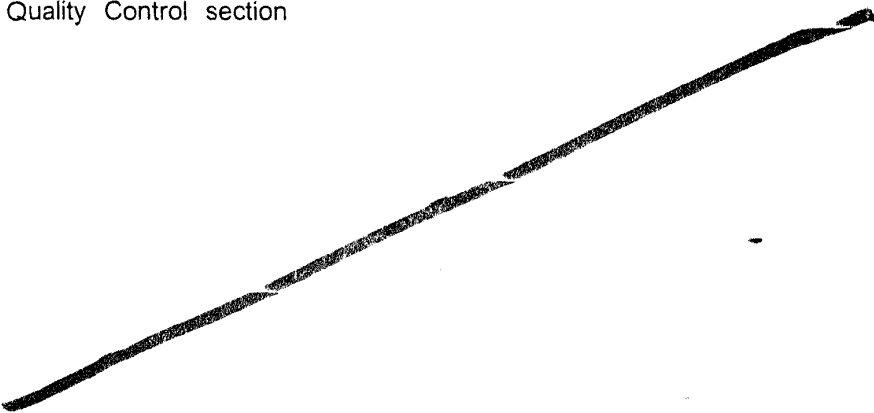


F. The Chain of Custody, Accessioning, and Security section





G. The Quality Control section



J. The Records Audit section



Dr. Fischinger
Page 3 of 3
02/24/00

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UNILAB

Location: Tarzana, CA

Document Reviewed: Application Form
 Inspection Report #M16 Date: 13 January 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



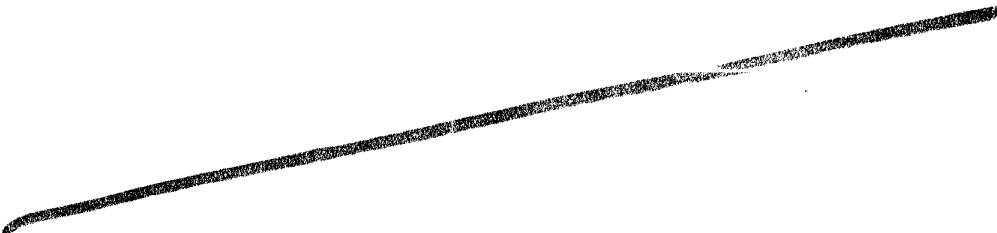
Section G. Quality Control



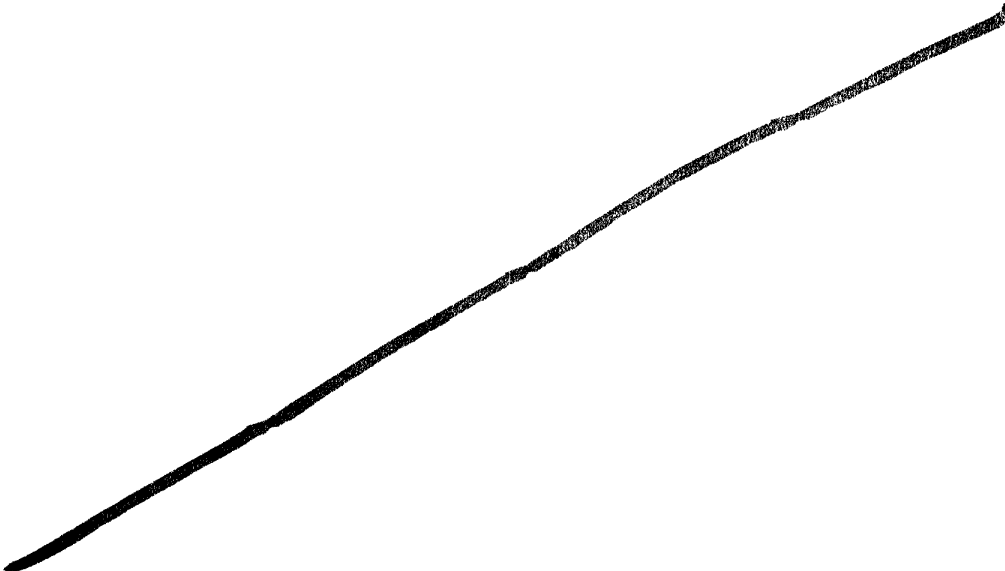
Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 8, 2000

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356


Dear Dr. Fischinger:

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. 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

[Redacted]

J. The Records Audit section


[Redacted]

Dr. Fischinger
September 8, 2000
Page 3 of 3

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,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UNILAB

Location: Tarzana, CA

Document Reviewed: Application Form
 Inspection Report #M17 Date: 13 July 2000
 Other _____

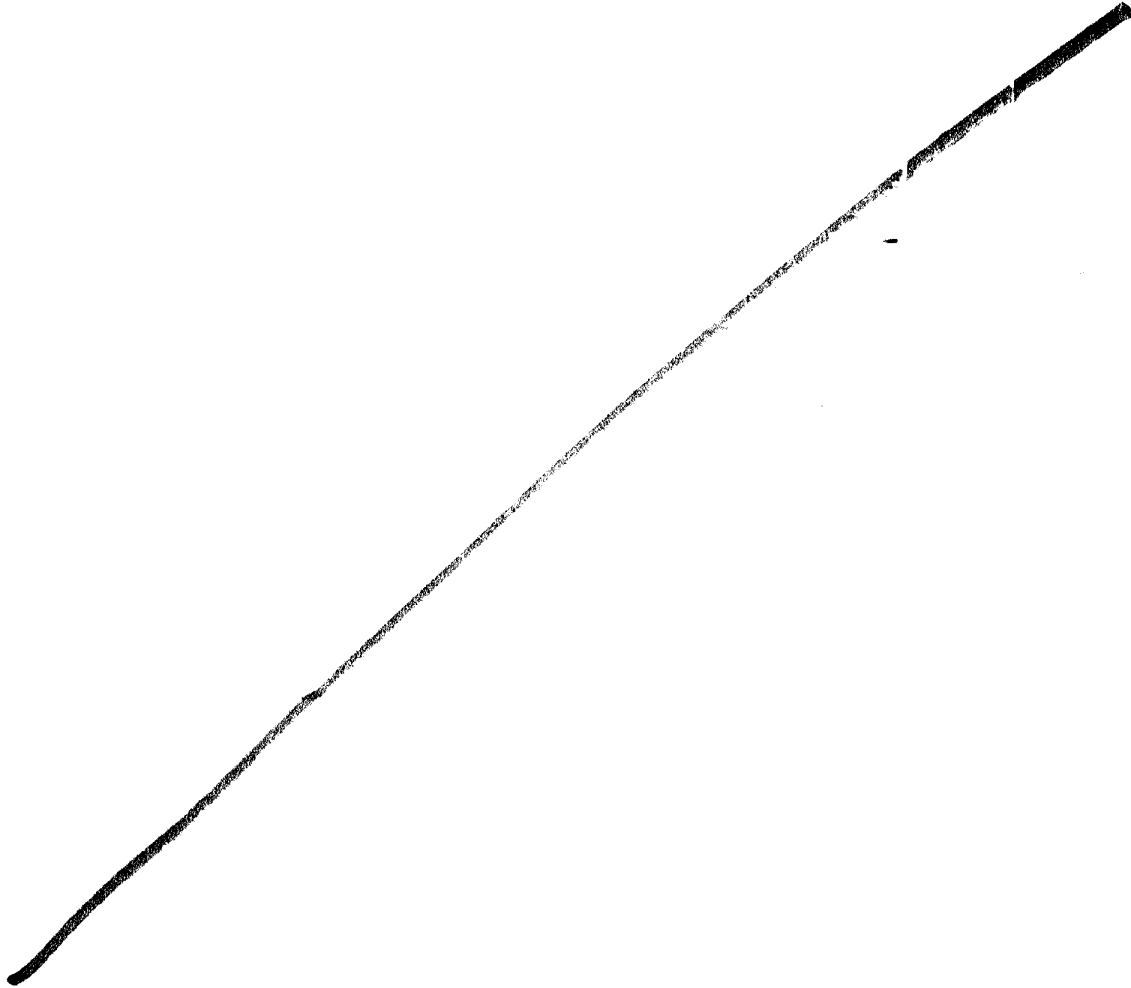
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

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]