



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 20, 1998

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twelfth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the laboratory must clarify/correct the following issues raised:

A large, thin, curved line that starts from the left side of the page and curves upwards and to the right, ending near the top right corner. It appears to be a signature or a placeholder for a signature.

Dr. Grinstead
Page 2 of 3
11/20/98

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 Davier at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Dr. Grinstead
Page 3 of 3
11/20/98

Enclosure

cc: Project Files/M12



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0286
Document No. Final

Laboratory: Marshfield Laboratories

Location: Marshfield, WI

Document Reviewed: Application Form
 Inspection Report #M12 Date: 22 October 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. 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



RESEARCH TRIANGLE INSTITUTE

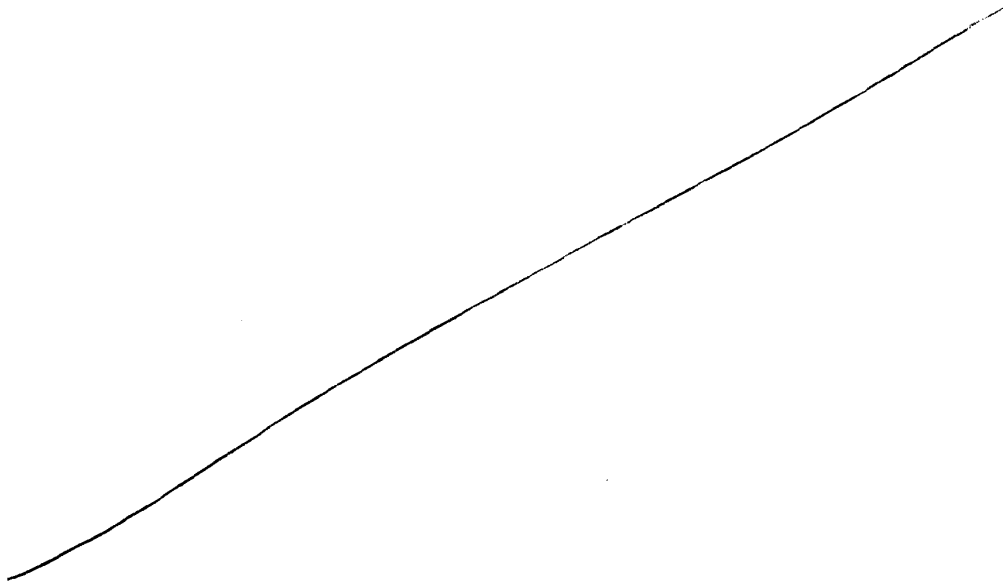
National Laboratory Certification Program

May 26, 1999

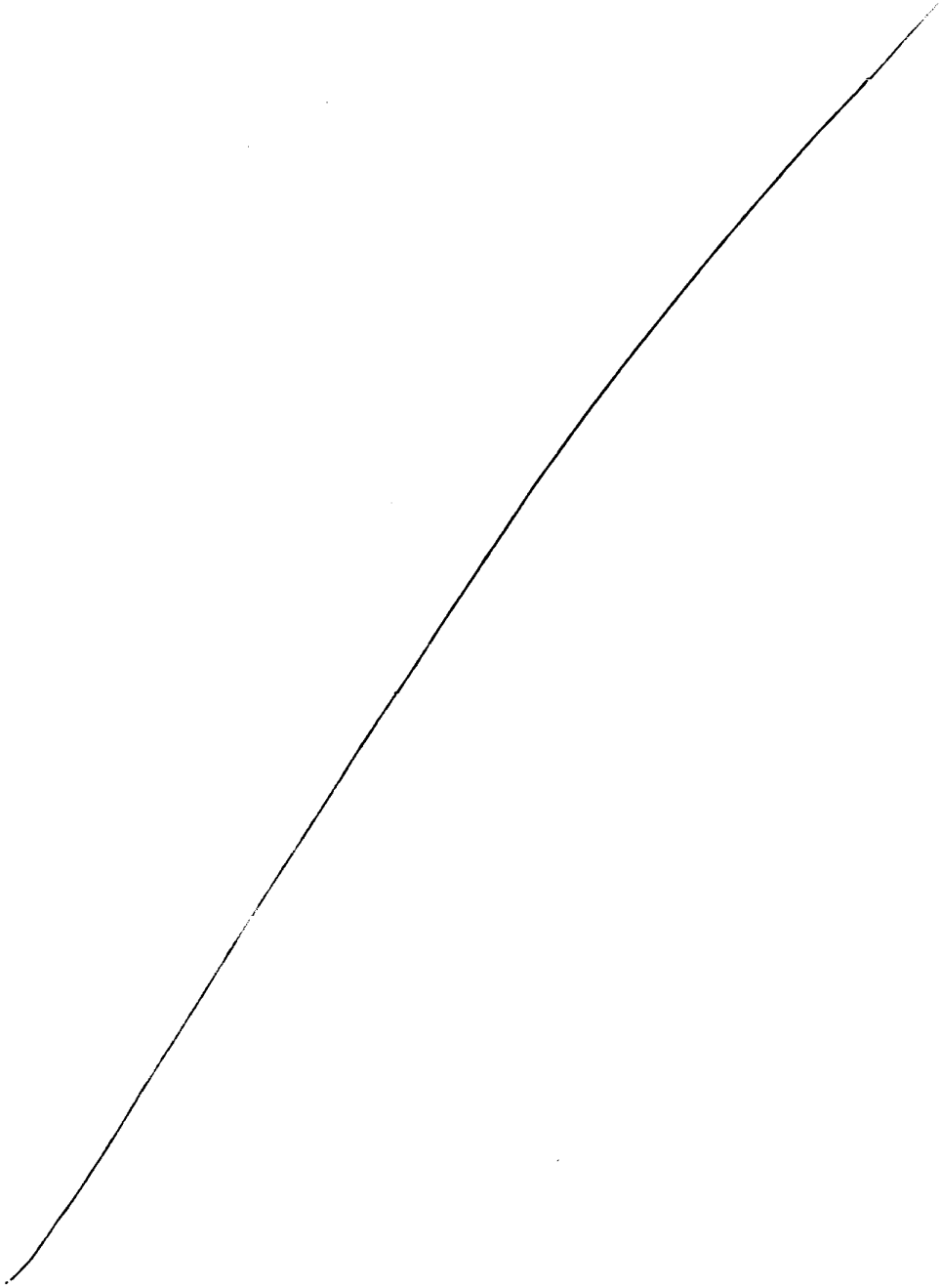
0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

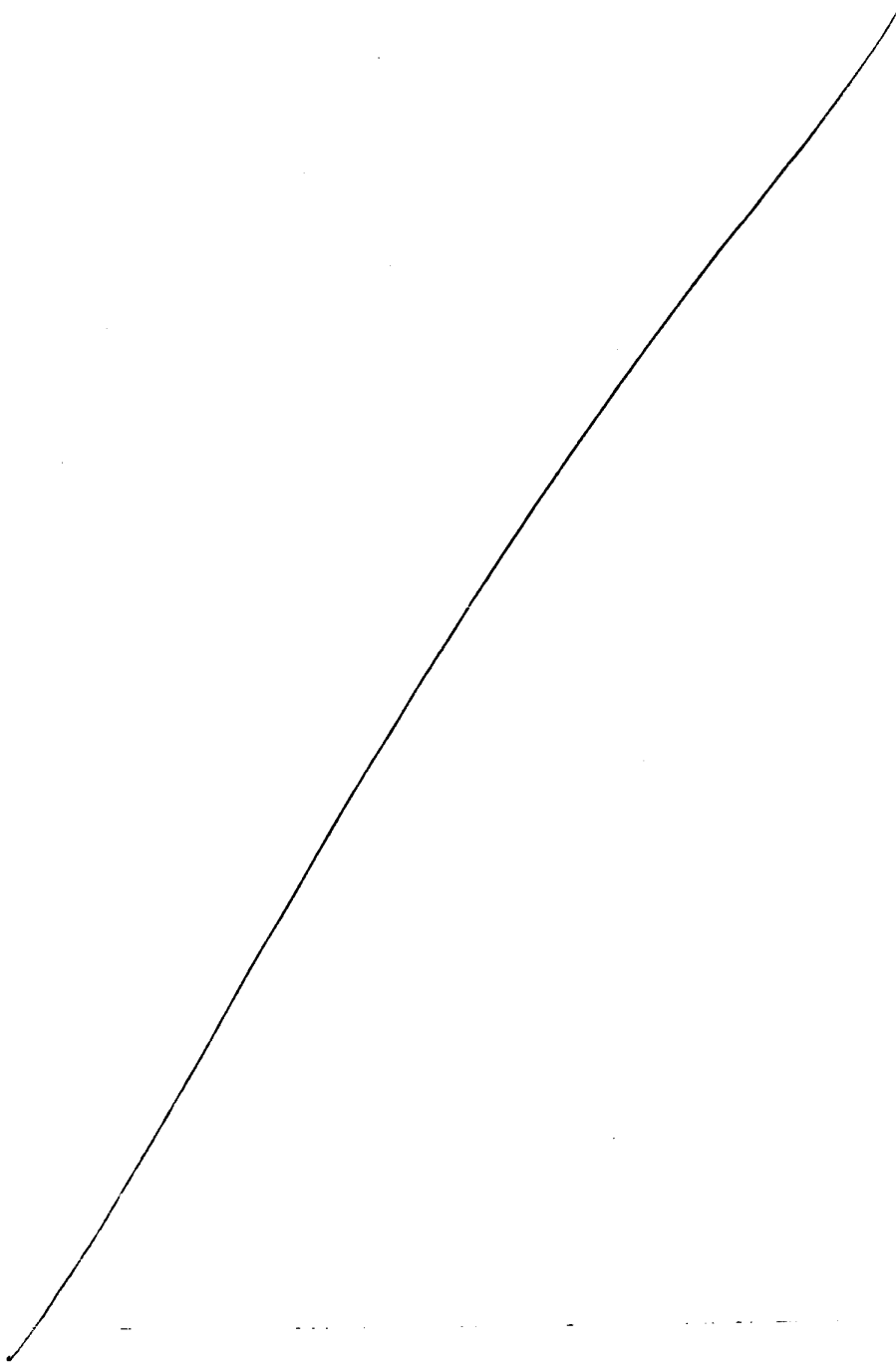
The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:



Dr. Grinstead
Page 2 of 4
05/26/99



Dr. Grinstead
Page 3 of 4
05/26/99



Dr. Grinstead
Page 4 of 4
05/26/99

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 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/M13

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0286
Document No. Final

Laboratory: Marshfield Laboratories, Forensic Toxicology Laboratory

Location: Marshfield, WI

Document Reviewed: Application Form
 Inspection Report #M13 Date: 8 April 1999
 Other _____

Status: Highly Acceptable 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. 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



**MARSHFIELD
LABORATORIES**

Forensic Toxicology

received
6/30/99 SDC

1000 North Oak Avenue
Marshfield, WI 54449-5795

715-389-3734
1-800-331-3734
Fax 715-389-3737

June 28, 1999

Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

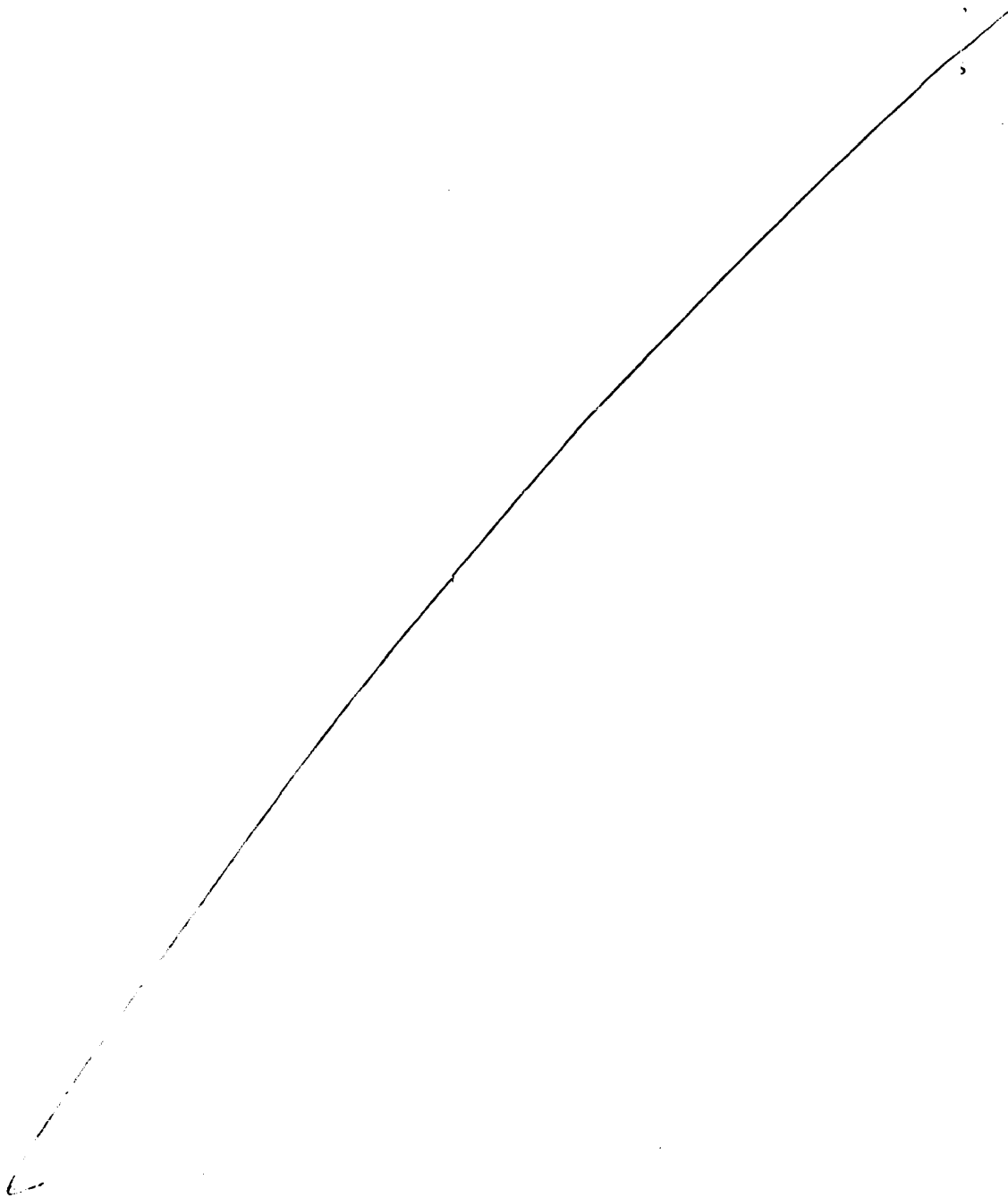
Dear Ms. Crumpton:

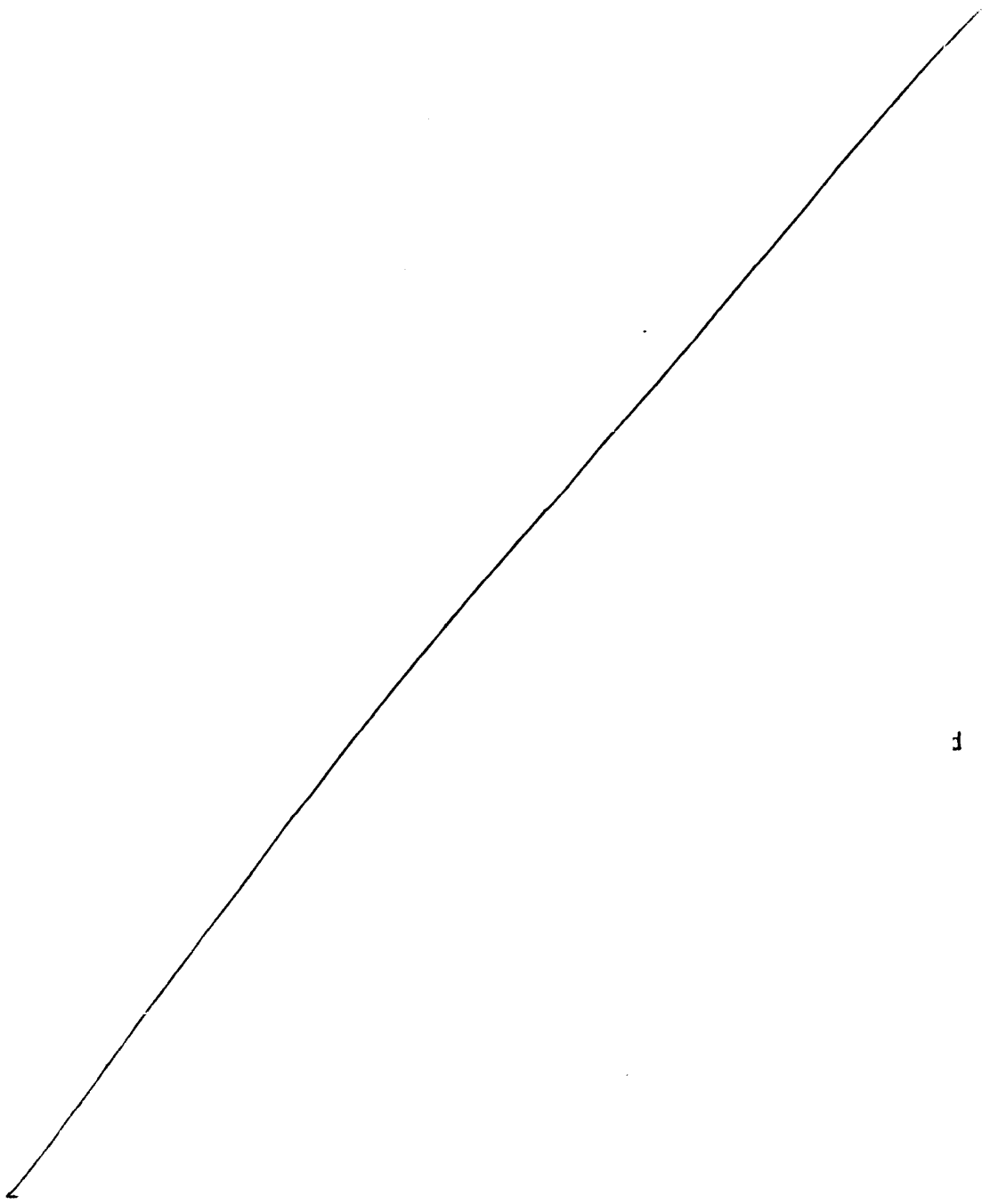
I have enclosed a reply to the critique of our thirteenth maintenance inspection, and documents and information requested by RTI. Please call if you need more information.

Sincerely,

Greg Grinstead

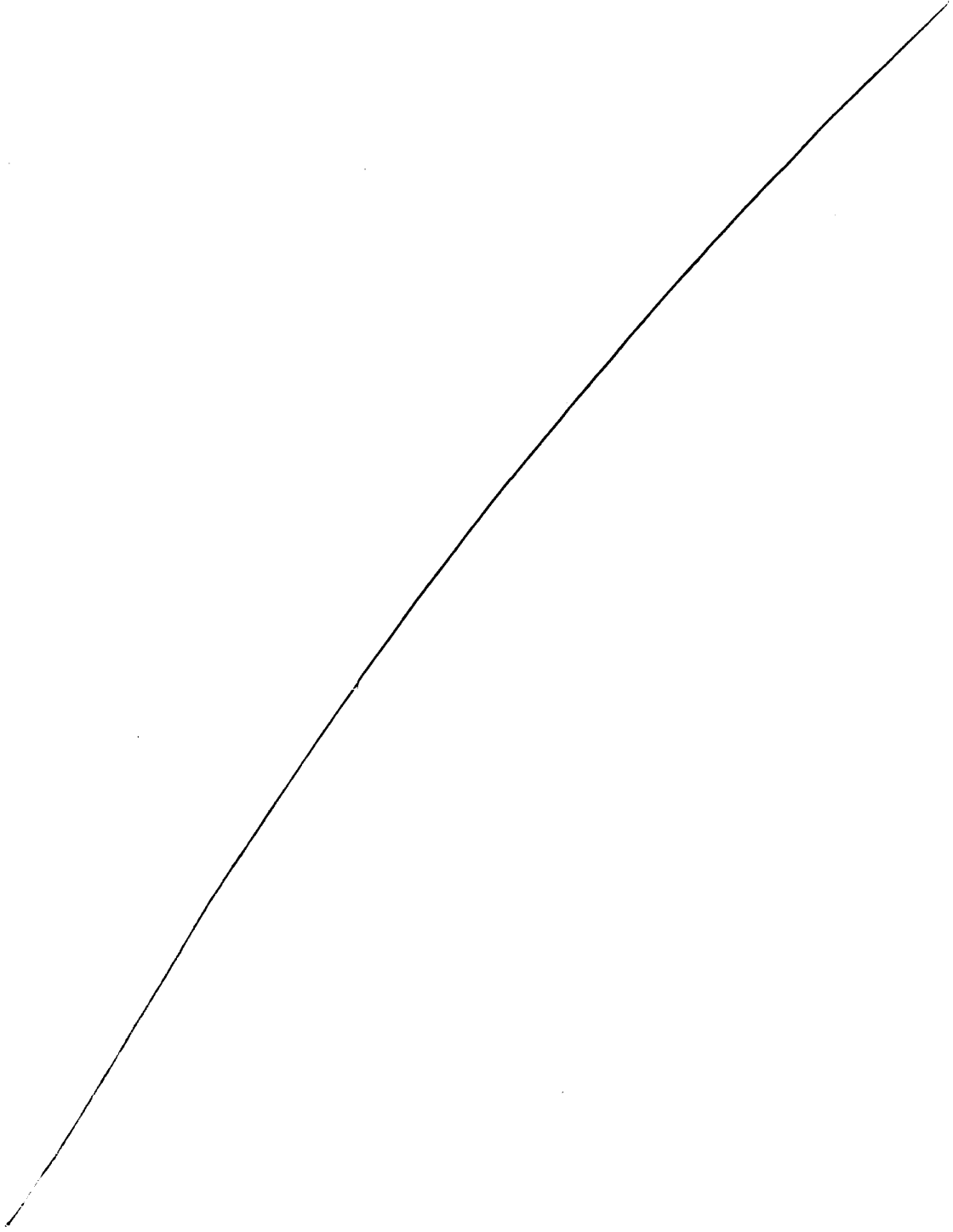
Greg Grinstead, Ph.D.
Director & Responsible Person, Forensic Toxicology Laboratory

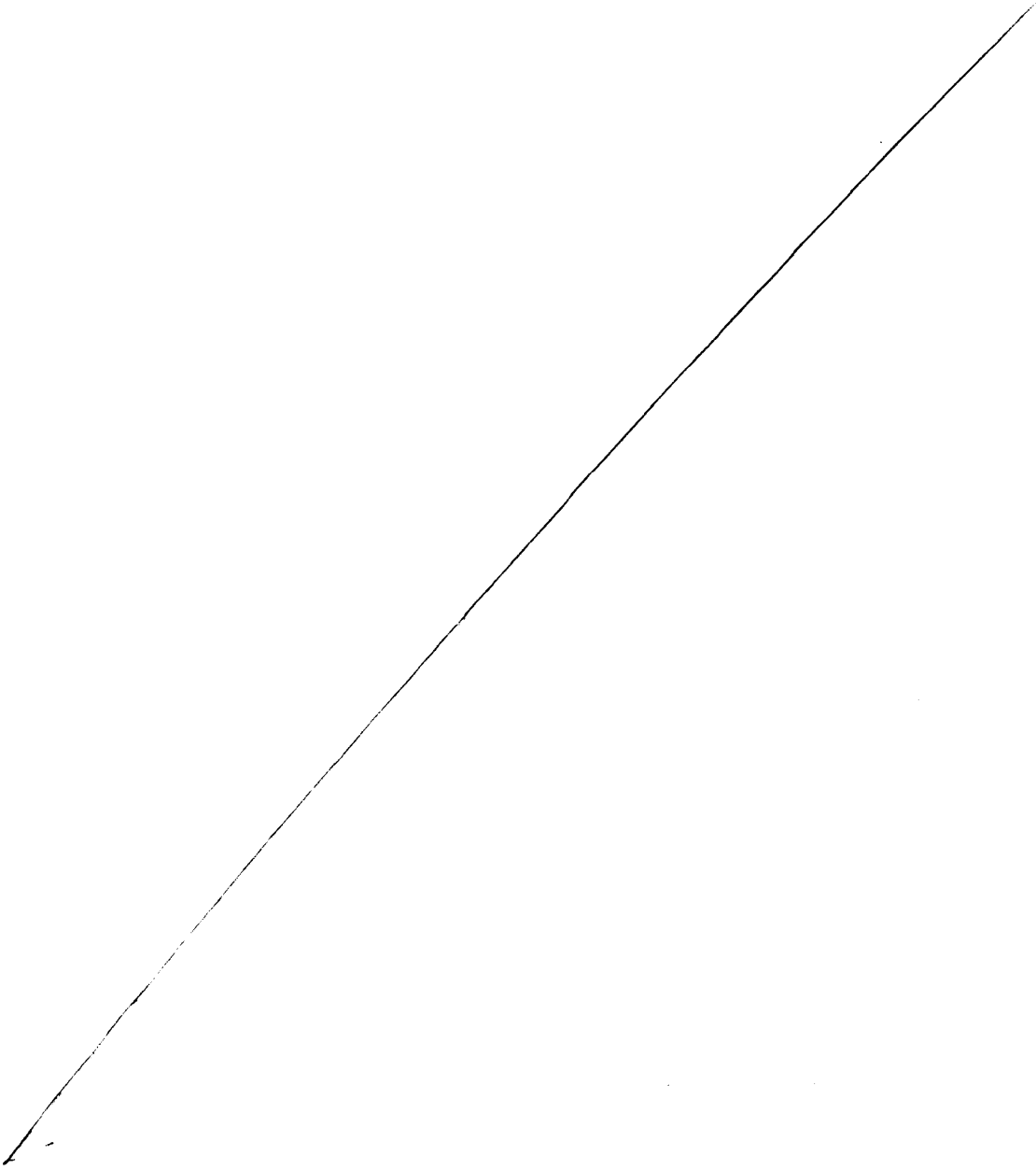


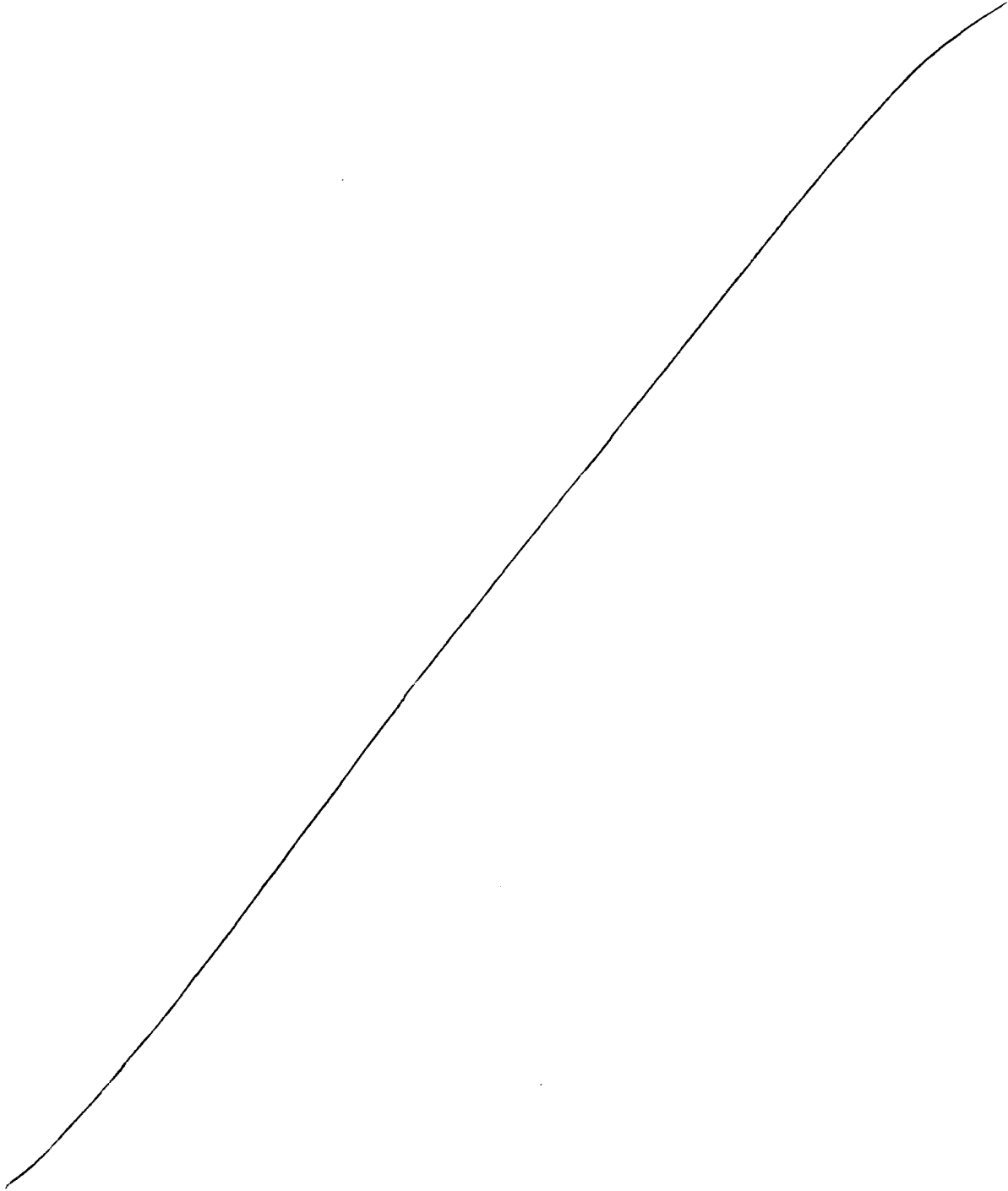


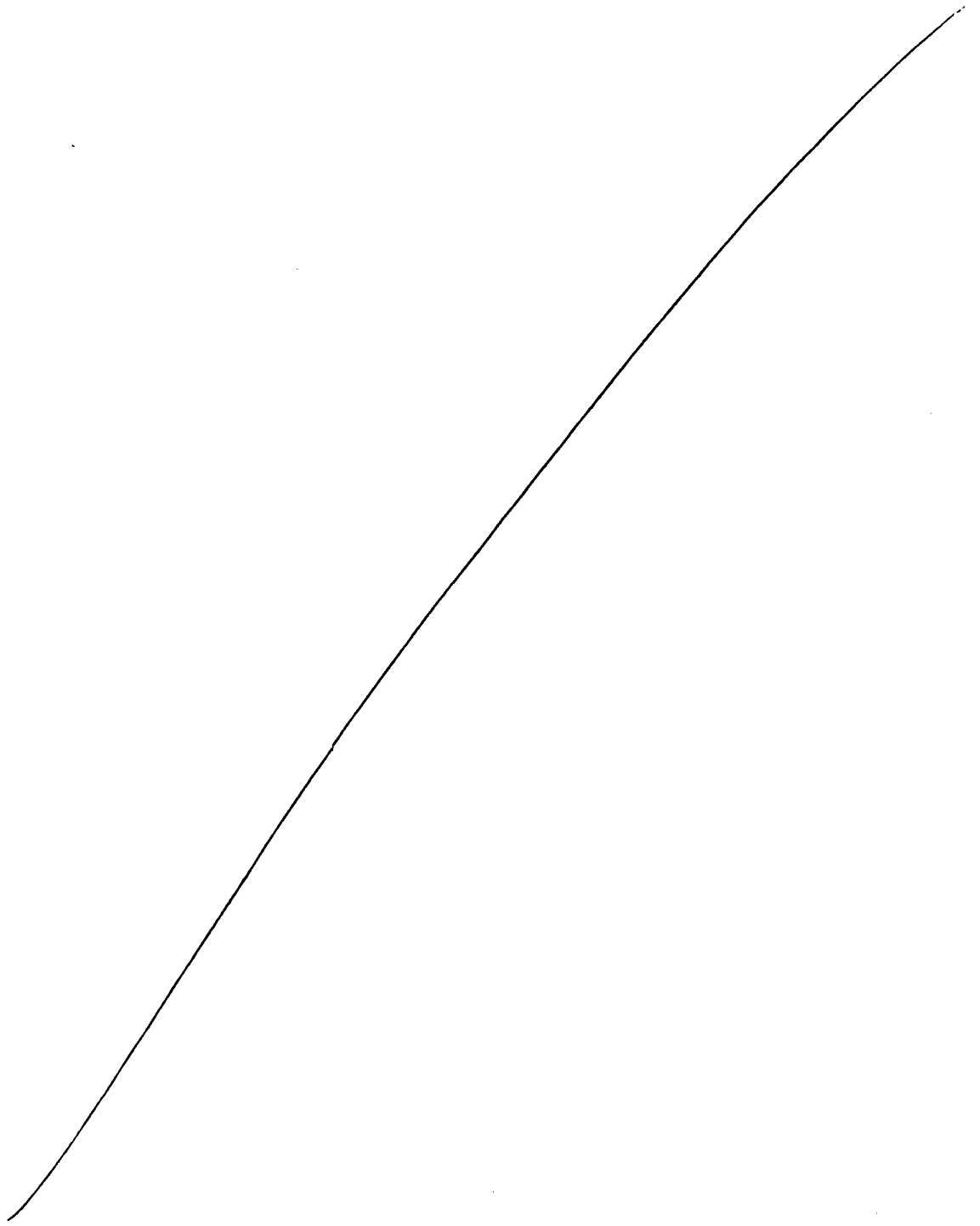
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RESEARCH TRIANGLE INSTITUTE

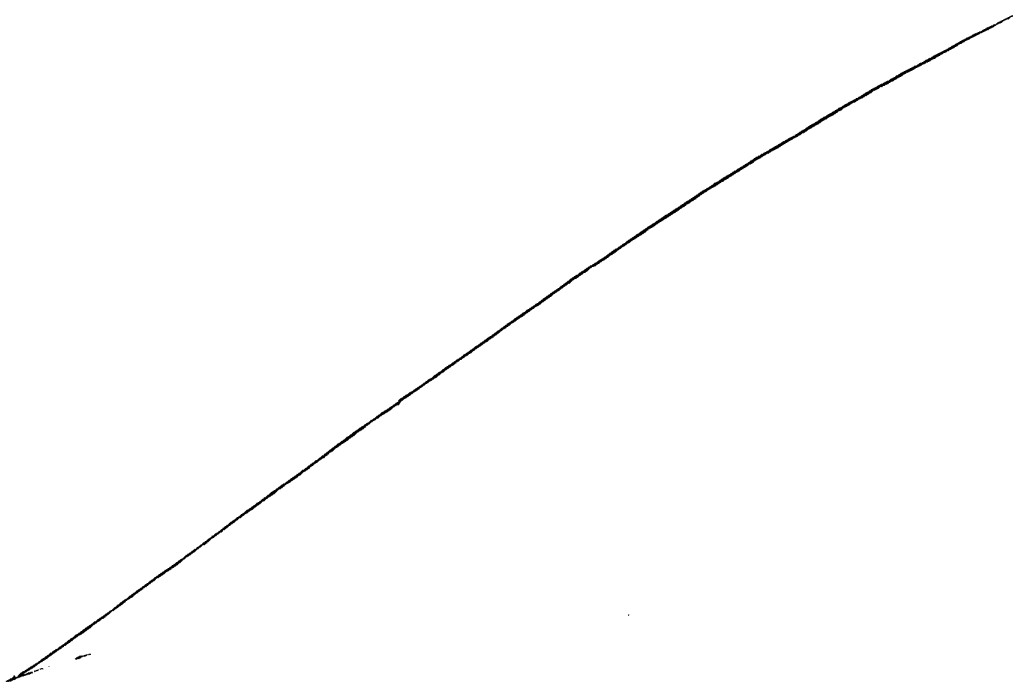
National Laboratory Certification Program

July 8, 1999

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

We have reviewed the material provided in your correspondence of June 28, 1999, submitted in response to issues raised during the thirteenth maintenance inspection of your laboratory as outlined in our correspondence of May 26, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. The following is a summary of remaining issues:



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. at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M13

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 15, 1999

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

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,

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

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M14



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0286
Document No. Final

Laboratory: Marshfield Laboratories

Location: Marshfield, WI

Document Reviewed: Application Form
 Inspection Report #M14 Date: 7 October 1999
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 24, 2000

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

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'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.



Dr. Grinstead
Page 2 of 2
05/24/00

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 Technical Analyst

Enclosure

cc: Project Files/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0286
Document No. Final

Laboratory: Marshfield Laboratories

Location: Marshfield, WI

Document Reviewed: Application Form
 Inspection Report #M15 Date: 6 April 2000
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control

Section H. Initial Tests

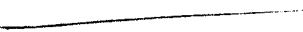
Section I. Confirmatory Tests

Section J. Records Audit

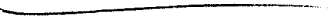
Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 8, 2000

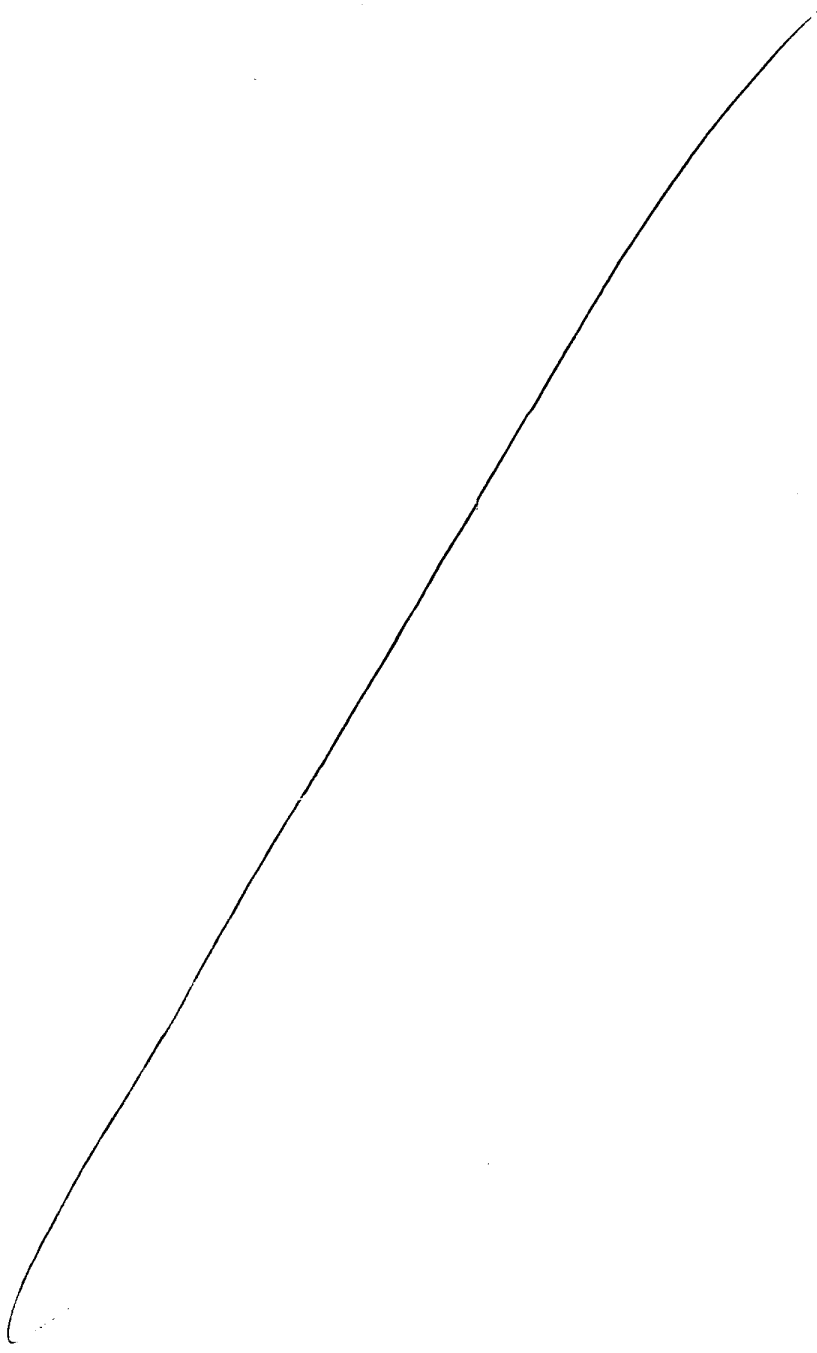
0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

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 take steps to correct the following issues raised:



Dr. Grinstead
Page 2 of 3
12/08/00



Dr. Grinstead
Page 3 of 3
12/08/00

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 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 Technical Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0286
Document No. Final

Laboratory: Marshfield Laboratories

Location: Marshfield, WI

Document Reviewed: Application Form
 Inspection Report #M16 Date: 12 October 2000
 Other _____

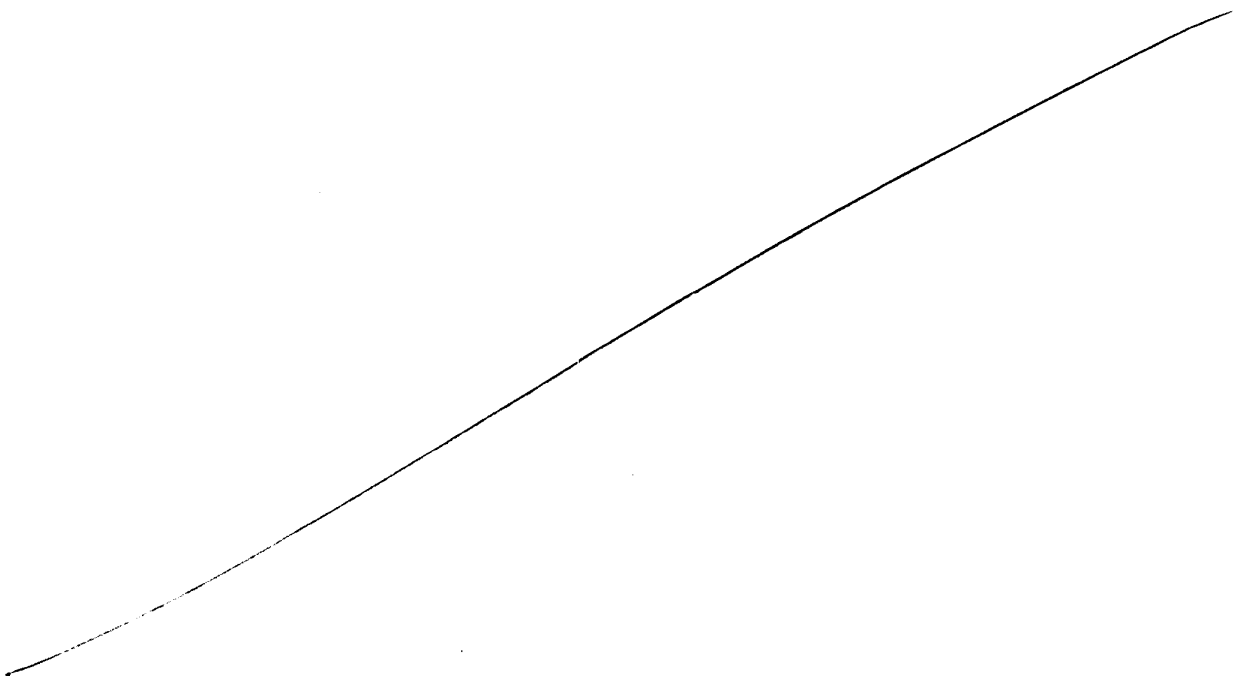
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



**MARSHFIELD
LABORATORIES**

Forensic Toxicology

received
1/17/01 SDC

1000 North Oak Avenue
Marshfield, WI 54449-5795

715-389-3734
1-800-331-3734
Fax 715-389-3737

January 8, 2001

Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

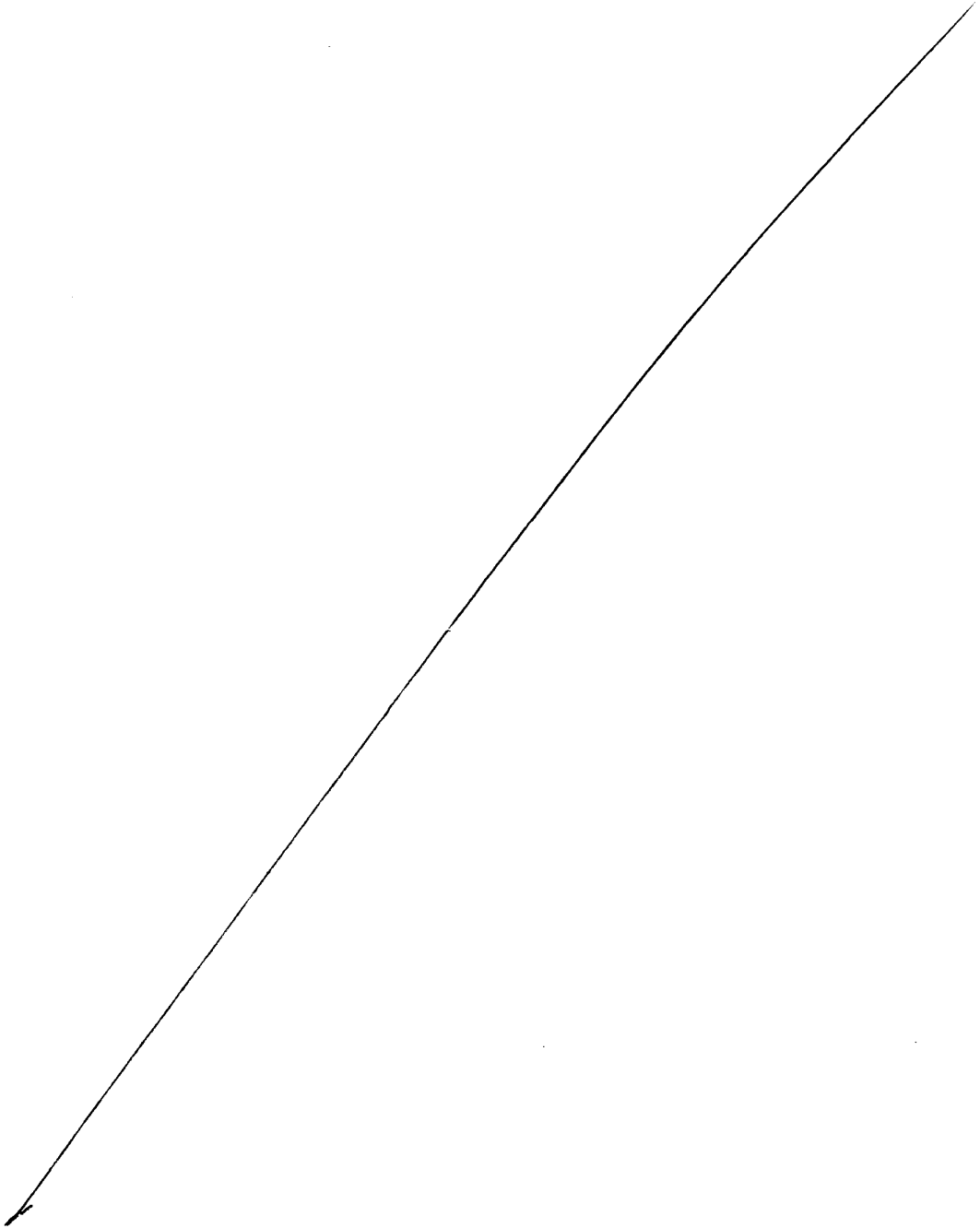
I have enclosed a reply to the critique of our laboratory's sixteenth maintenance inspection conducted under the National Laboratory Certification Program (NLCP). I was asked to submit information to demonstrate that corrective actions have been implemented to address the issues raised. In most cases, required SOP changes are to be reviewed at the next inspection. Please contact me if further clarification is necessary or if the corrective actions are not acceptable.

Sincerely,

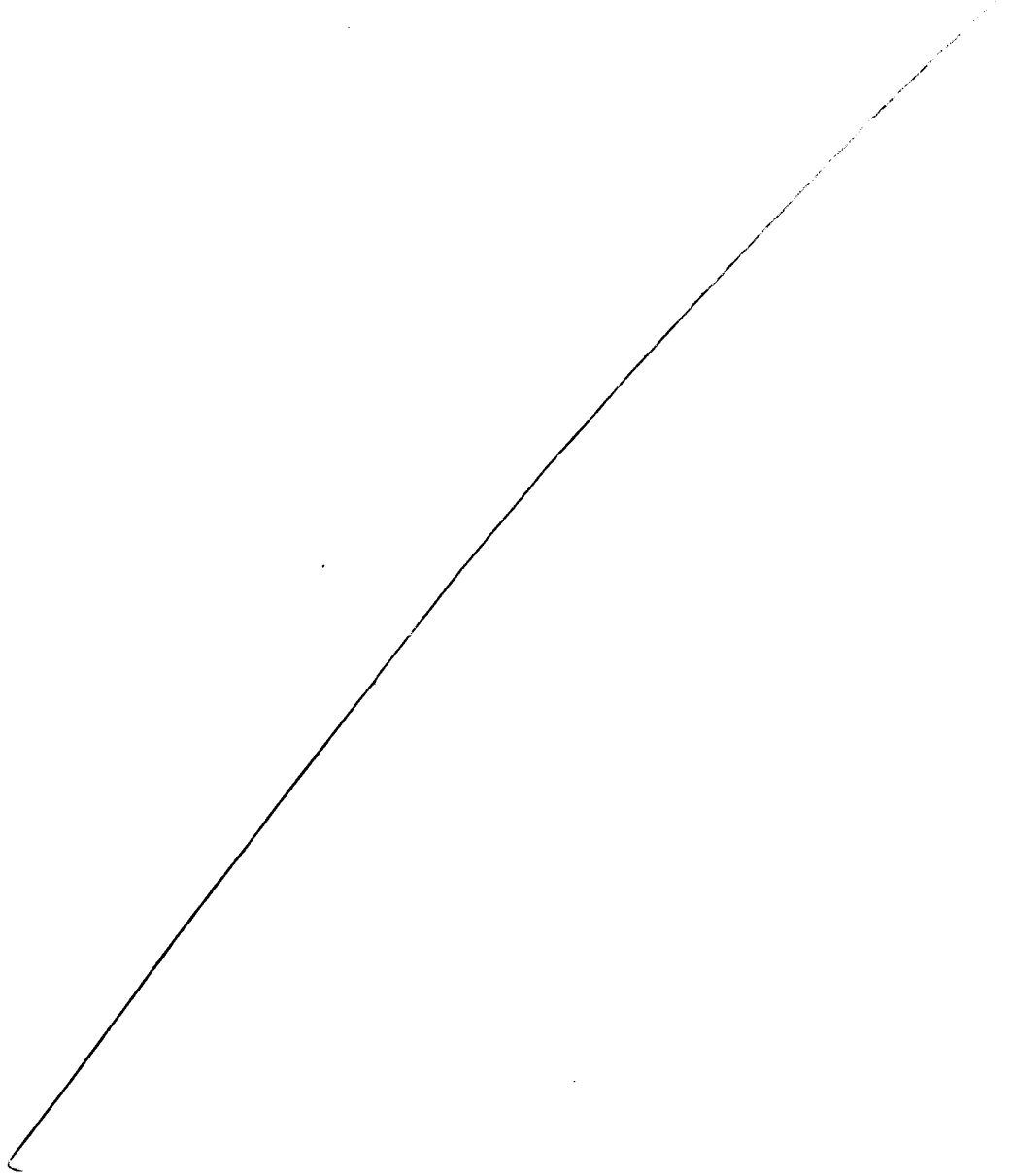
Greg Grinstead

Greg Grinstead, Ph.D.
Director & Responsible Person, Forensic Toxicology Laboratory

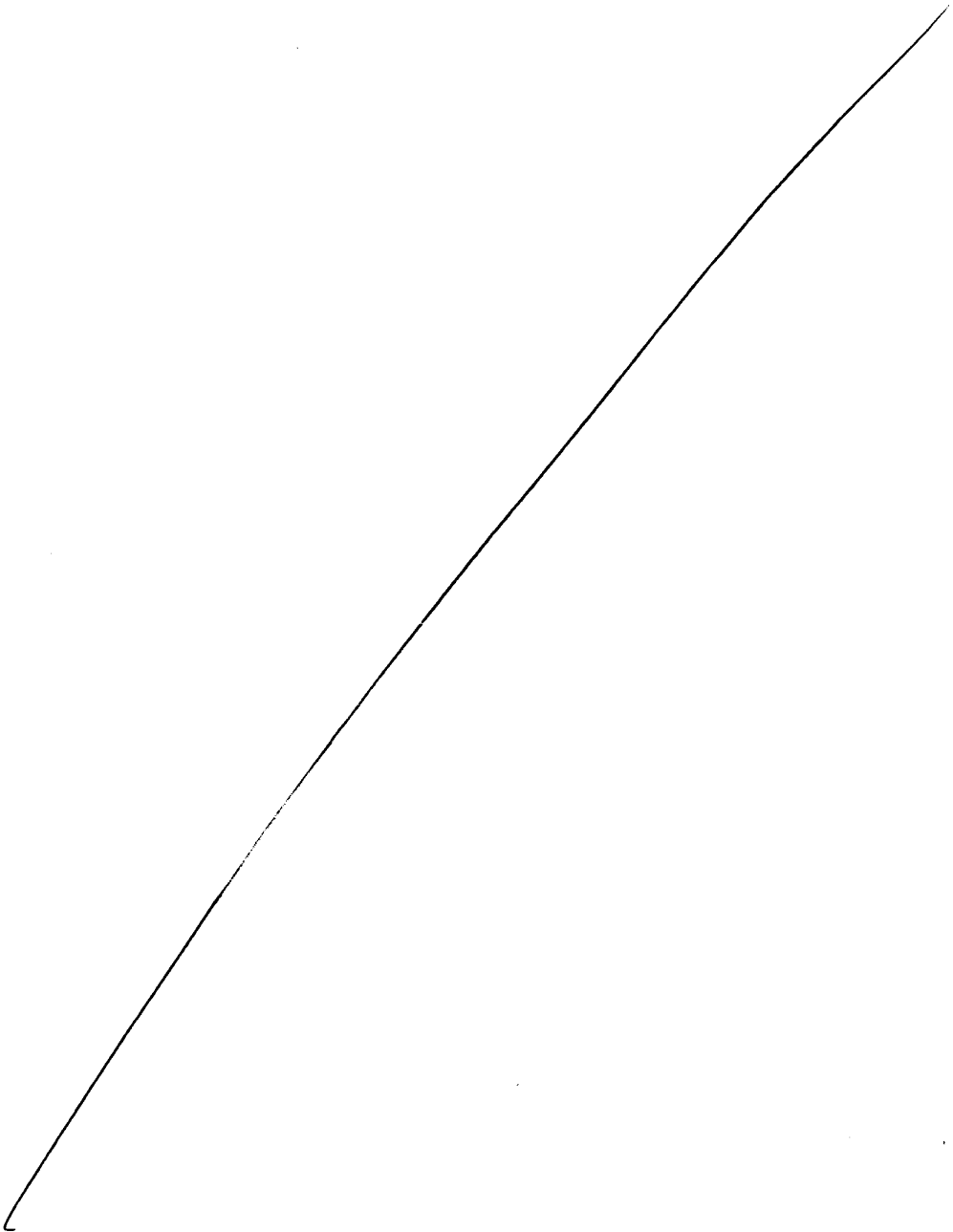
Section E (SOP)



Section F: Chain of Custody, Accessioning, and Security



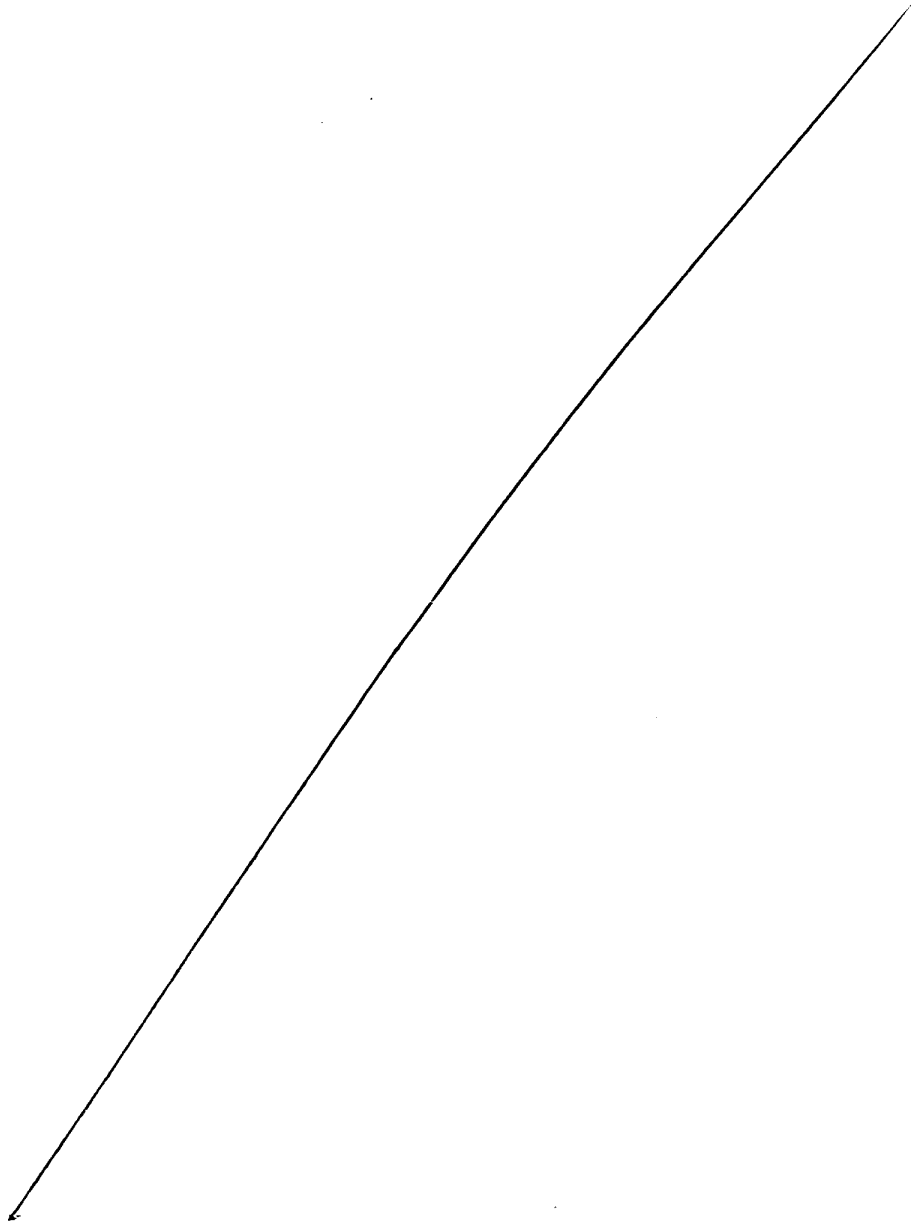
Section G. Quality Control

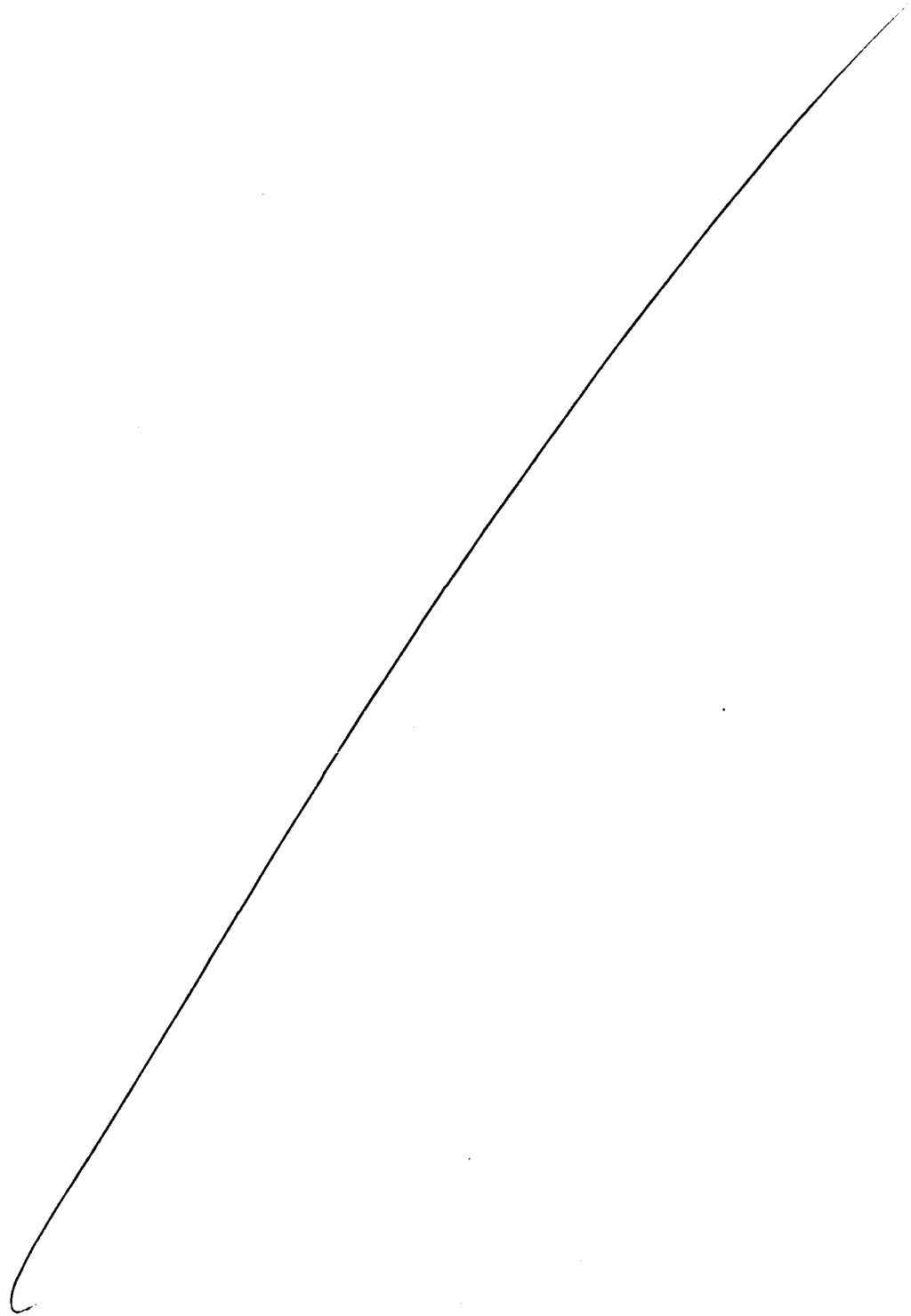




Section H. Initial Tests

Section J: Records Audit









RESEARCH TRIANGLE INSTITUTE

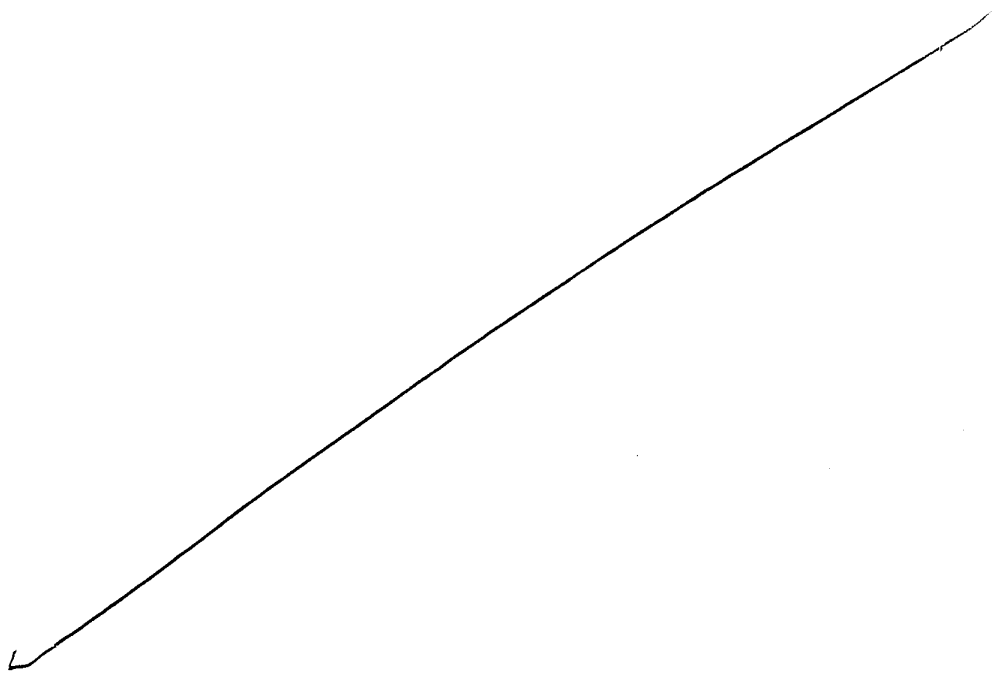
National Laboratory Certification Program

January 29, 2001

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

We have reviewed the material provided in your correspondence of January 8, 2001, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of December 8, 2000. 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:



Dr. Grinstead
Page 2 of 2
01/29/01

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 Technical Analyst

cc: Dr. Michael Baylor
Project Files/M16



**MARSHFIELD
LABORATORIES**

Forensic Toxicology

received
2/12/01 SDC

1000 North Oak Avenue
Marshfield, WI 54449-5795

715-389-3734
1-800-331-3734
Fax 715-389-3737

February 8, 2001

Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

I am replying to your letter of January 29, 2001 regarding the sixteenth maintenance inspection of our laboratory. I hope to finally resolve the remaining issues from that inspection. The story so far is:

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{

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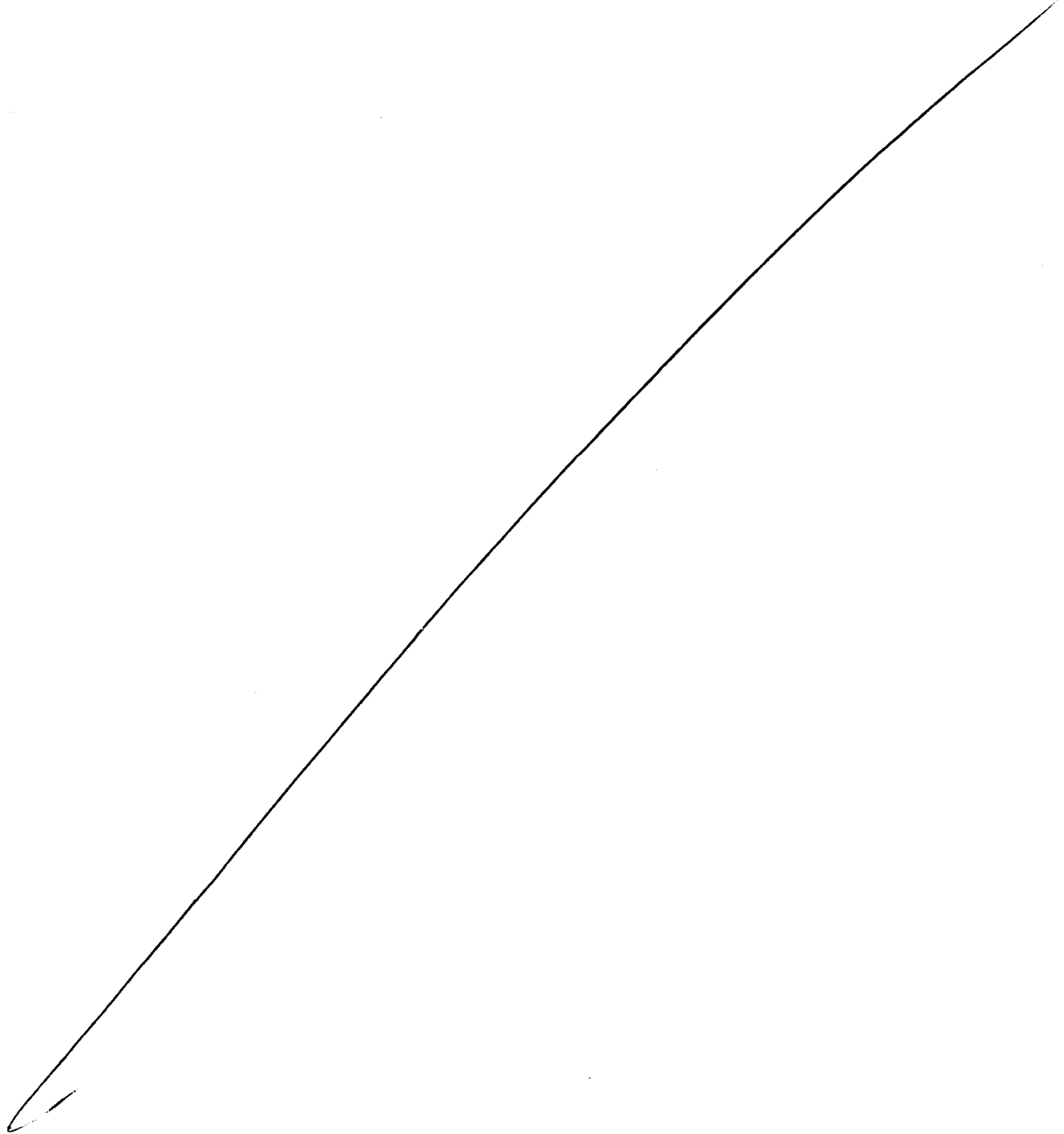
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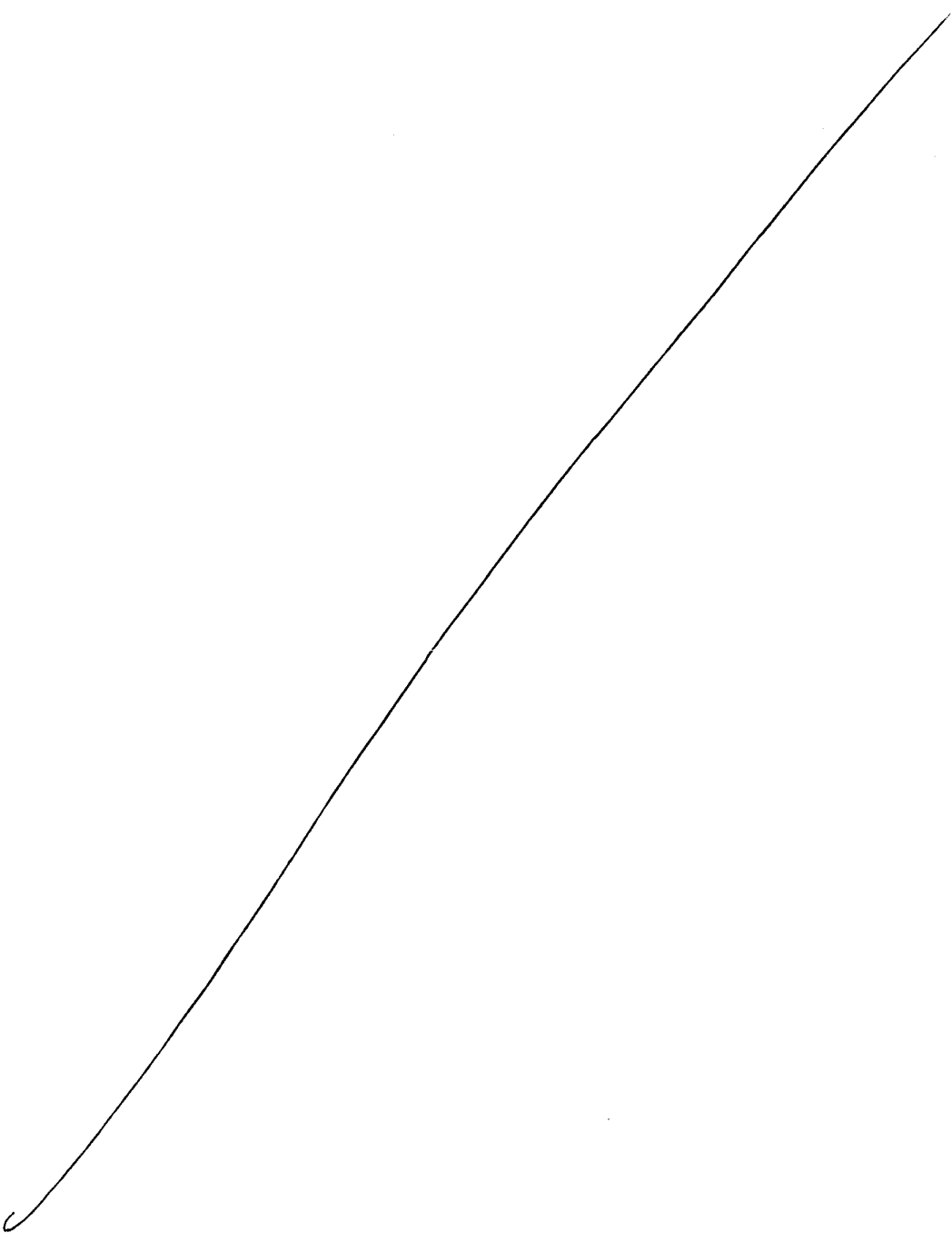
Sincerely,

Greg Grinstead

Greg Grinstead, Ph.D.
Director & Responsible Person, Forensic Toxicology Laboratory

Quality Control





February 16, 2001

0286
Dr. Gregory F. Grinstead
Marshfield Laboratories
Forensic Toxicology Laboratory
1000 N. Oak Avenue
Marshfield, WI 54449

Dear Dr. Grinstead:

We have reviewed the material provided in your correspondence of February 8, 2001, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of January 29, 2001. 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 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 Technical Analyst

cc: Dr. Michael Baylor
Project Files/0286

