

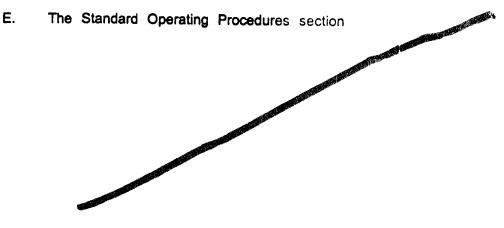
National Laboratory Certification Program

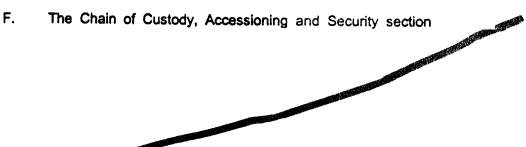
February 5, 1999

0083
Ms. Pat Pizzo
Dr. Leon Glass
Laboratory Specialists, Inc.
1101 Newton Street
Gretna, LA 70053

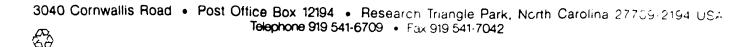
Dear Ms. Pizzo and Dr. Glass:

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. However, the following issues were raised:





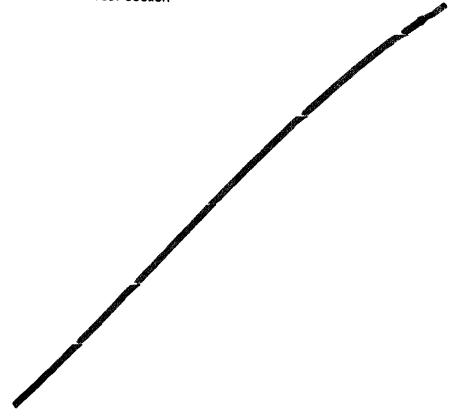
G. The Quality Control and Standards section



Ms. Pizzo and Dr. Glass February 5, 1999 Page 2 of 4

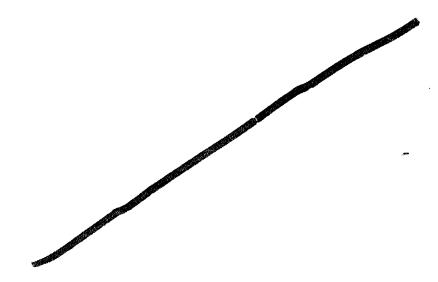


H. The Initial Test section

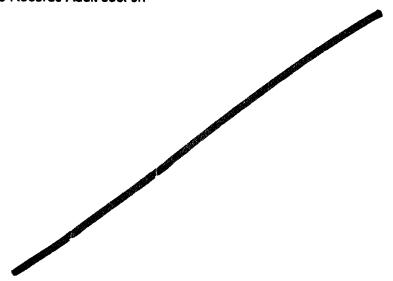


I. The Confirmatory Test section

Ms. Pizzo and Dr. Glass February 5, 1999 Page 3 of 4



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.

Ms. Pizzo and Dr. Glass February 5, 1999 Page 4 of 4

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

Sincerely,

Deborah J. Denson

NLCP Inspection Analyst

Enclosure

cc: Project Files/M15

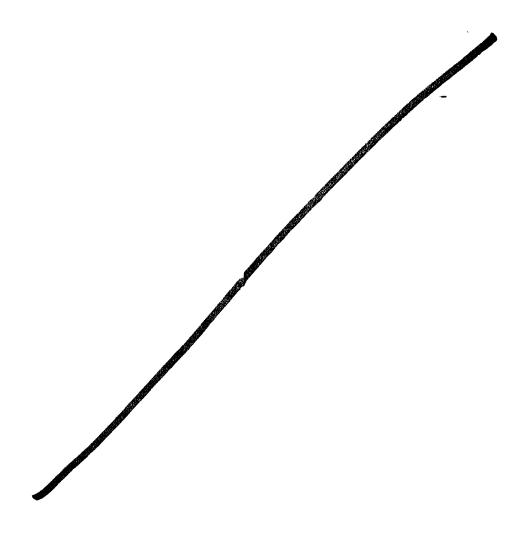
NATIONAL LABORATORY CERTIFICATION PROGRAM **Document Review and Critique** Laboratory I.D. Number: 0083 Document No. Final Laboratory: Laboratory Specialists, Inc. Location: Gretna, LA Document Reviewed: [] Application Form [XX] Inspection Report #M15 Date: 3 December 1998 [] Other ___ Status: [XX] Highly Acceptable] Acceptable [] Unacceptable 1 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:

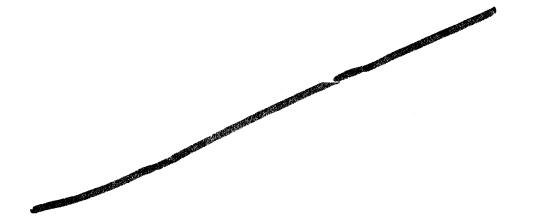
Section E. Standard Operating Procedures - Procedures Manual



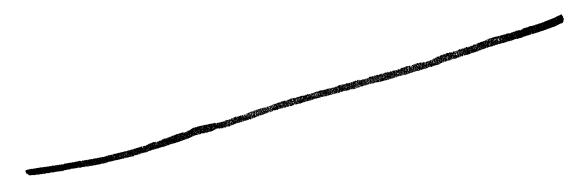
Section F. Chain-of-Custody. Accessioning and Se



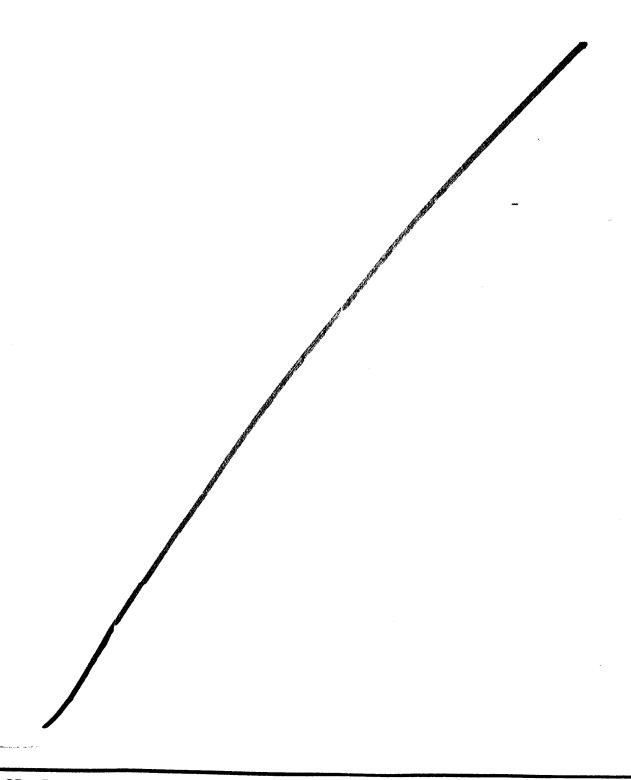
Section G. Quality Control and Standards



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



Section L. Laboratory Information Management System



Section M. Equipment and Maintenance



Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



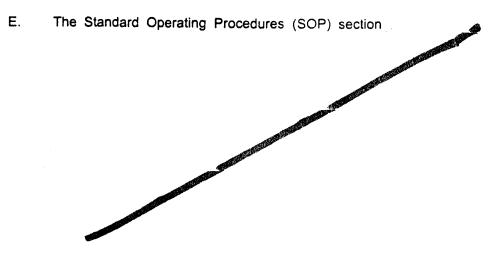
National Laboratory Certification Program

July 19, 1999

0083 Ms. Pat Pizzo Dr. Leon Glass Laboratory Specialists, Inc. 1101 Newton Street Gretna, LA 70053

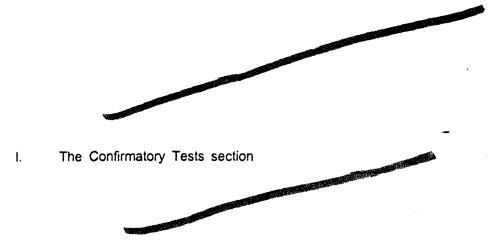
Dear Ms. Pizzo and Dr. Glass:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:



G. The Quality Control section

Ms. Pizzo and Dr. Glass Page 2 of 2 07/19/99



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 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: 0083 Document No. Final Laboratory: Laboratory Specialists, Inc. Location: Gretna, LA Document Reviewed:] Application Form [XX] Inspection Report #M16 Date: 3 June 1999] Other _____ Status: [XX] Acceptable] Highly Acceptable] Unacceptable] Failure

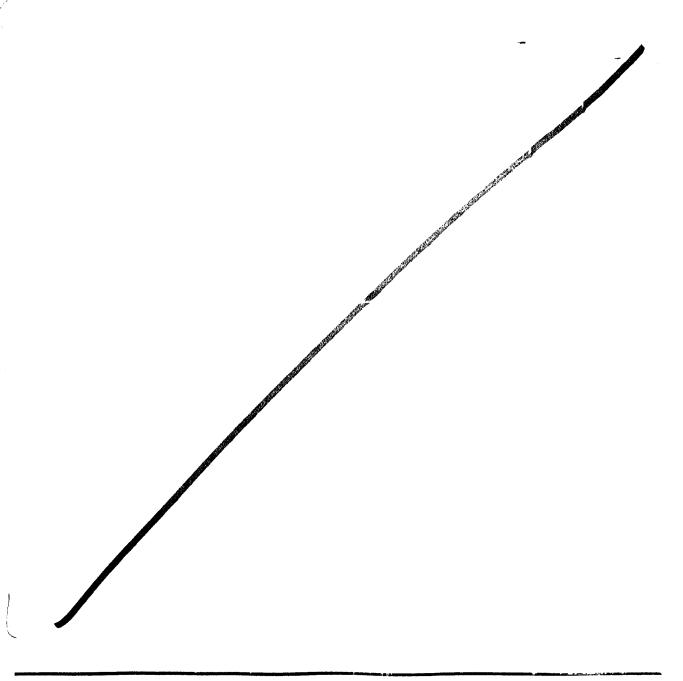
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

Ver. Final Lab ID# 0083

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



Ver. Final Lab ID# 0083 Section F. Chain-of-Custody, Accessioning, and Security Section G. Quality Control Section H. Initial Tests Section I. Confirmatory Tests NLCP • Research Triangle Institute

Page 3

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Mainter

Section N. Personnel



Laboratory Specialists, Inc.

A wholly owned subsidiary of Laboratory Specialists of America, Inc. (NASDAQ, LABZ)

H11 Newton Street Gretna, LA 70053 (504) 361-8989

August 4, 1999

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

RE: 16th Maintenance Inspection

Dear Ms. Crumpton:

Enclosed is Laboratory Specialists, Inc.'s response to the critique of the 16th maintenance inspection. Also, included is the documentation to demonstrate corrective actions have been implemented to address the issues raised.

Sincerely

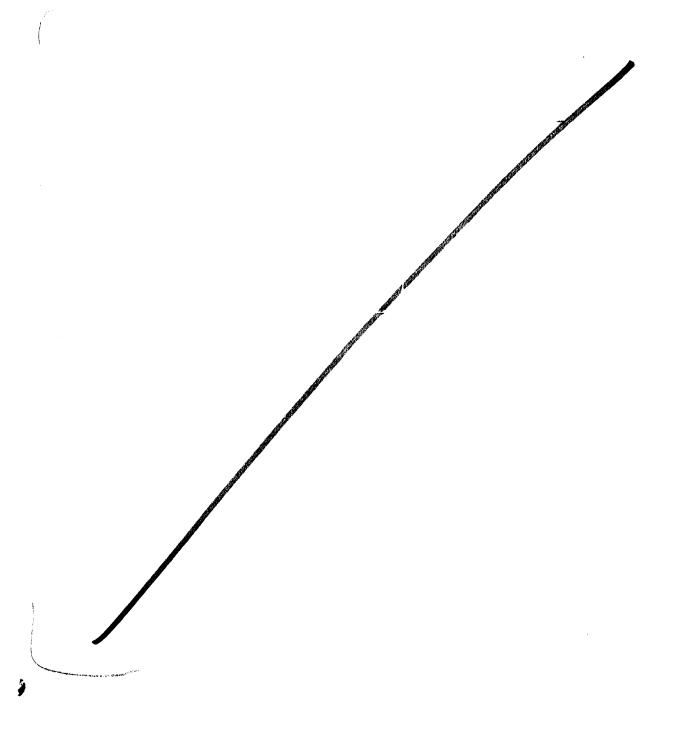
Pat Pizzo, B.S., BCFE Vice President/Production Director of Toxicology

PP/bb

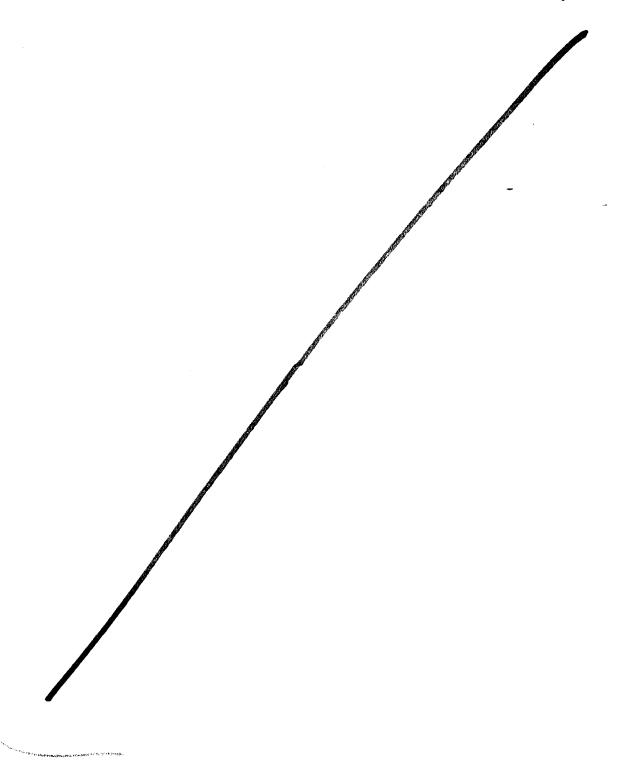
Enclosure

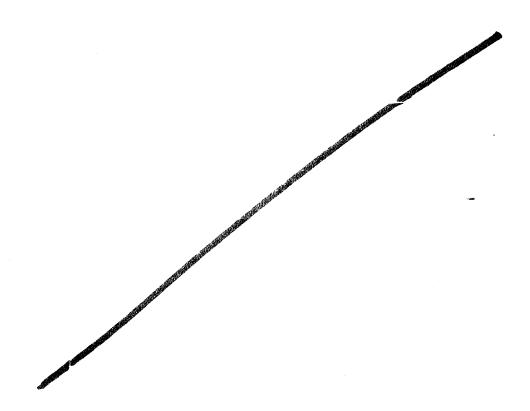
RESPONSE TO CRITIQUE OF 16TH MAINTENANCE INSPECTION JUNE 1999

Section E. Standard Operating Procedures - Procedures Manual

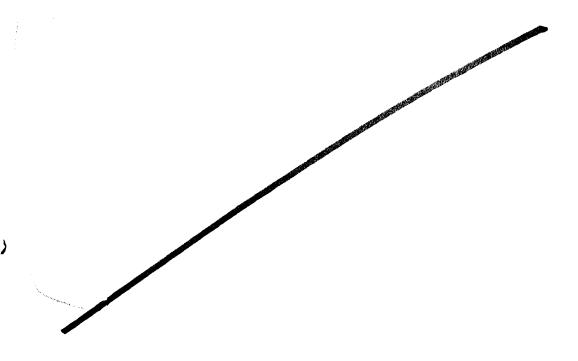


Page 2 August 3, 1999 Response/16th Maintenance Inspection

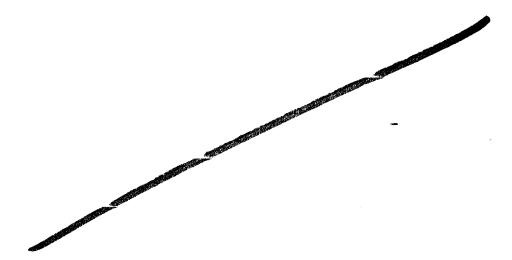




Section F. Chain of Custody, Accessioning, and Security



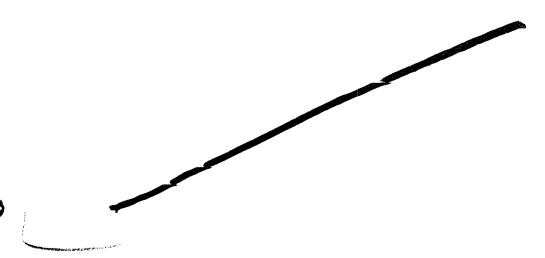
Page 4 August 3, 1999 Response/16th Maintenance Inspection



Section H. Initial Tests



Section I. Confirmatory Tests



Section M. Equipment and Maintenance Response/16th Maintenance Inspection Section N. Personnel

1



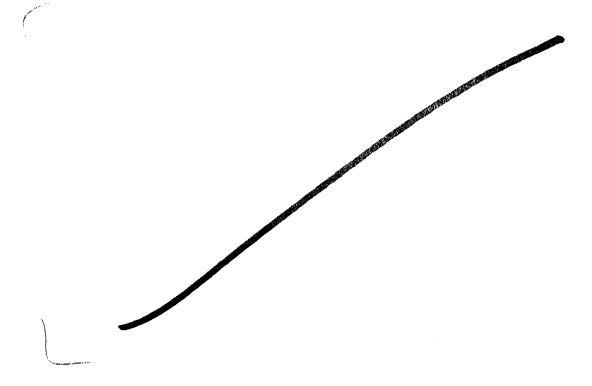
National Laboratory Certification Program

August 16, 1999

0083
Ms. Pat Pizzo
Dr. Leon Glass
Laboratory Specialists, Inc.
1101 Newton Street
Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

We have reviewed the material provided in your correspondence of August 4, 1999, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of July 19, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following issues were raised during our review of the submitted material:



Ms. Pizzo Dr. Glass Page 2 of 2 08/16/99

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.

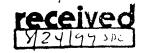
Sincerely,

Susan Crumpton

NLCP Inspection Analyst

cc: Dr. Michael Baylor

Project Files/M16



Laboratory Specialists, Inc.

A wholly owned subsidiary of Laboratory Specialists of America, Inc. (NASDAQ: LABZ)

1111 Newton Street Gretna, LA 70053 (504) 361-8989

August 23, 1999

John Mitchell, Ph.D. NLCP Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709

RE: RTI Letter Dated August 16, 1999 16th Maintenance Inspection

Dear Dr. Mitchell:

I have enclosed additional material in response to the letter from RTI dated August 16, 1999. This material should demonstrate that the appropriate corrective actions have been completed by LSI. Also enclosed is the check in the amount of \$1200.00 for remedial action.

Sincerely,

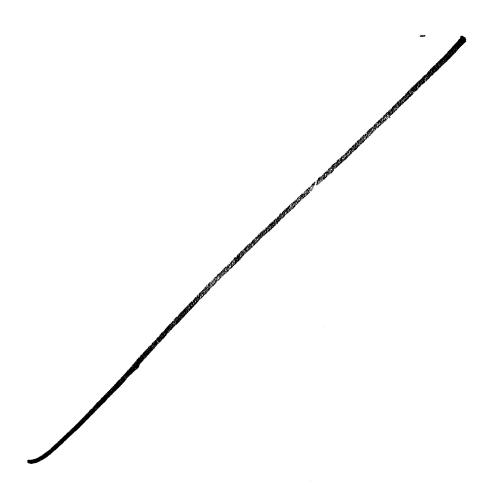
Pat Pizzo, B.S., BCFE Vice President/Production Director of Toxicology

PP/bb

Enclosure

1111 Newton Street Gretna, LA 70053 (504) 361-8989

RESPONSE TO RTI LETTER DATED AUGUST 16, 1999





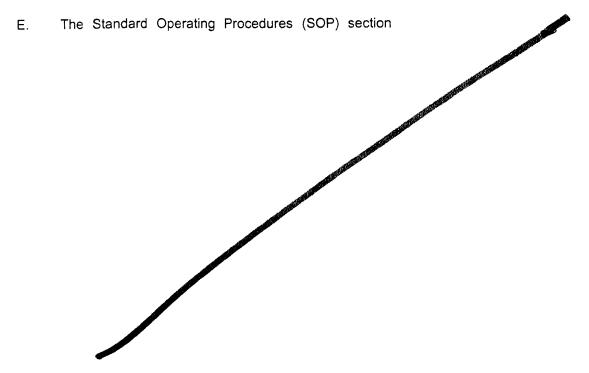
National Laboratory Certification Program

January 13, 2000

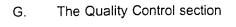
0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

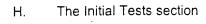
Dear Ms. Pizzo and Dr. Glass:

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.



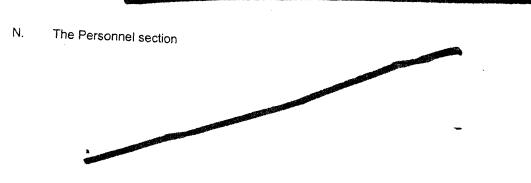






I. The Confirmatory Tests section

J. The Records 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

NLCP Inspection Analyst

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0083 Document No. Final

Laboratory:

Kroll Laboratory Specialists, Inc.

Location:

Gretna, LA

Document Reviewed:

[] Application Form

[XX] Inspection Report #M17 [] Other _____

Date: 2 December 1999

Status:

[XX] Highly Acceptable

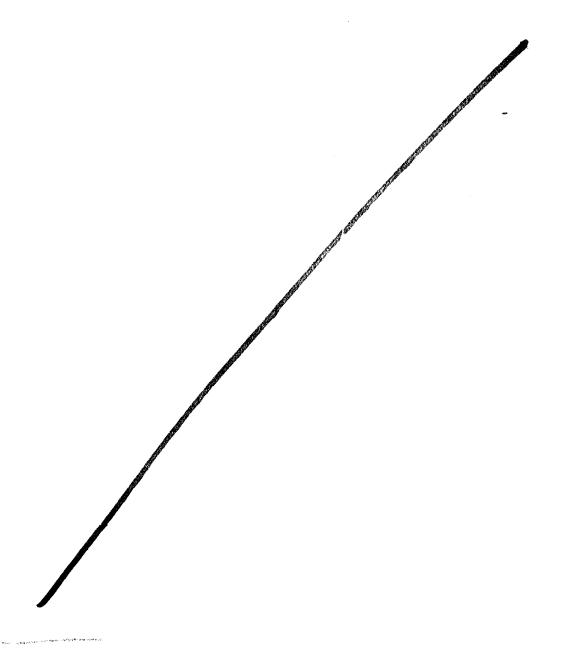
1 Acceptable] Failure [] Unacceptable

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

Ver. Final Lab ID# 0083

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



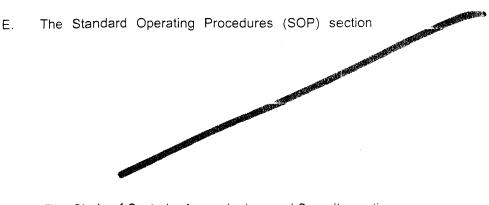
National Laboratory Certification Program

July 17, 2000

0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

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.

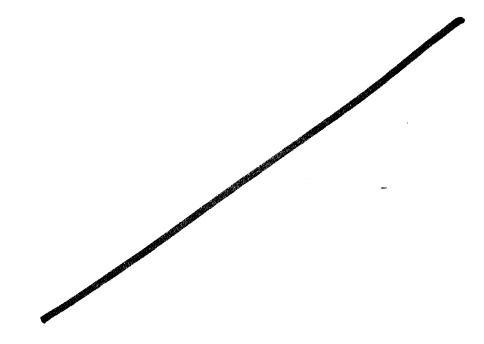


F. The Chain of Custody, Accessioning, and Security section

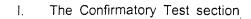


G. The Quality Control section



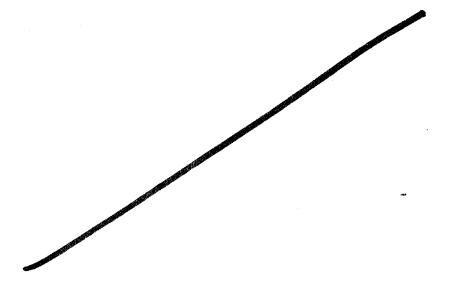


H. The Initial Tests section



J. The Records Audit section

Ms. Pizzo Dr. Glass July 17, 2000 Page 3 of 3



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 R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson NLCP Technical Analyst

Debrah J Denson

Enclosure

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0083

Document No. Final

Laboratory: Kroll Laboratory Specialists, Inc.

Location: Gretna, LA

Status:

Document Reviewed: [] Application Form

[XX] Inspection Report #M18

Date: 1 June 2000

[] Other ____

[XX] Highly Acceptable
[] Unacceptable

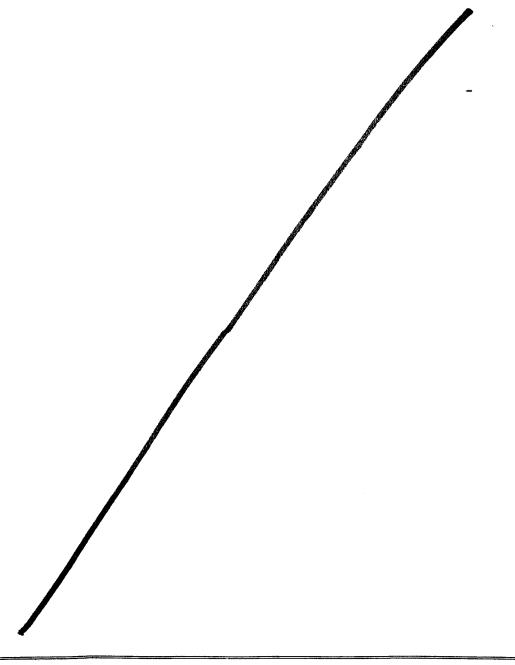
able [] Acceptable [] Failure

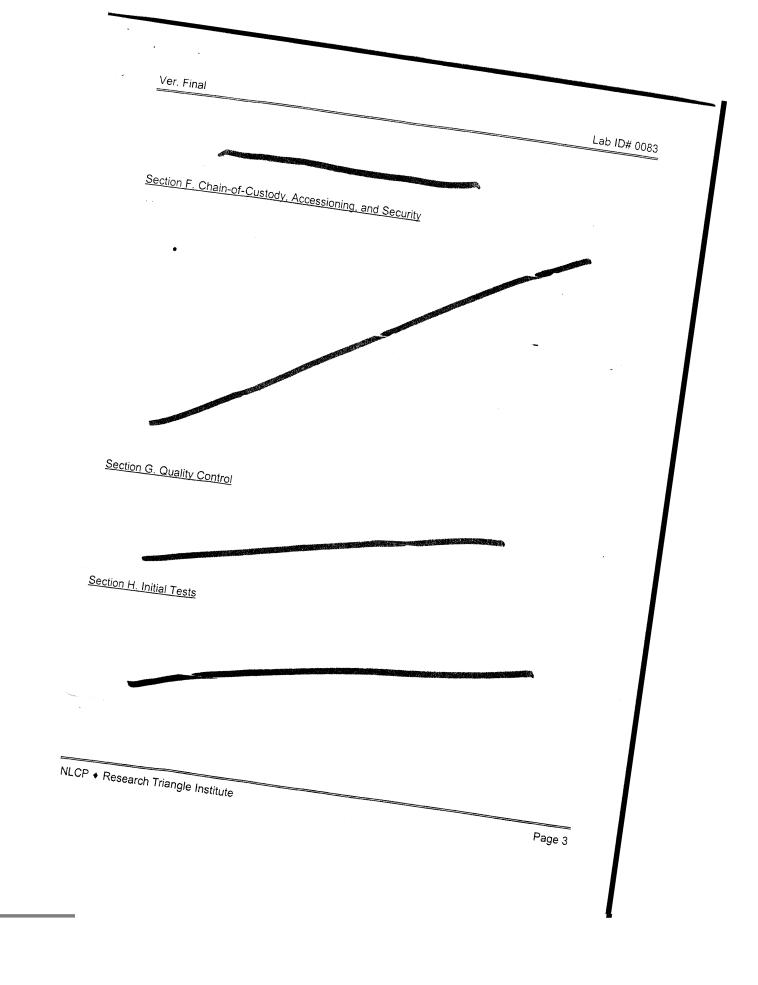
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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 I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



1111 Newton Street Gretna, LA 70053

Tel: (800) 433-3823 (504) 361-8989 Fax: (504) 361-1530

August 3, 2000

John Mitchell, Ph.D. National Laboratory Certification Program Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709

RE: Eighteenth Maintenance Inspection

Dear Dr. Mitchell:

Attached is Kroll Laboratory Specialists, Inc.'s response to the critique of the maintenance inspection. If you require additional information, please contact us immediately.

Sincerely,

Pat Pizzo, B.S., BCFE

V.P. Production/Director of Toxicology

PP/bb

Attachment





1111 Newton Street Gretna, LA 70053

Tel: (504) 361-8989 Fax: (504) 361-1530 Toll Free: (800) 433-3823

krollworldwide.com

RESPONSE TO CRITIQUE OF EIGHTEENTH MAINTENANCE INSPECTION JUNE 2000

RESPONSE TO CRITIQUE OF INSPECTION JUNE 2000

Section E. Standard Operating Procedures – Procedures Manual

PAGE 2 RESPONSE TO CRITIQUE/JUNE 2000

PAGE 3 RESPONSE TO CRITIQUE/JUNE 2000

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

PAGE 4 RESPONSE TO CRITIQUE/JUNE 2000

Section G. Quality Control

PAGE 5 RESPONSE TO CRITIQUE/JUNE 2000

	RESI ONSE TO CRITIQUE/JUNE 2000
Section H. Initial Tests	
	·

Section I. Confirmatory Tests

PAGE 6 RESPONSE TO CRITIQUE/JUNE 2000

Section J. Records Audit





National Laboratory Certification Program

August 14, 2000

0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

We have reviewed the material provided in your undated, unsigned correspondence received August 04, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of July 17, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been initiated to address a majority of the issues raised. The following is a reverse material submitted:

Ms. Pizzo Dr. Glass August 14, 2000 Page 2 of 3 Ms. Pizzo Dr. Glass August 14, 2000 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 continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Michael R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,

Deborah J. Denson

NLCP Technical Analyst

cc:

Project Files/M18

Dr. Donna Bush (SAMHSA)

Dr. Walt Vogi (SAMHSA)





1111 Newton Street Gretna, LA 70053

Tel: (800) 433-3823 (504) 361-8989 Fax: (504) 361-1530

August 17, 2000

Deborah Denson National Laboratory Certification Program Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709

RE: Letter Dated August 14, 2000

Dear Ms. Denson:

Please excuse the omission of the cover letter. It was not included in your copy. I have copy to be added to the original response.



Page 2 August 17, 2000 Ms. Denson

Sincerely,

Pat Pizzo, B.S., BCFE

V.P. Production/Director of Toxicology

PP/bb

Attachments

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

August 22, 2000

0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

We have reviewed the material provided in your correspondence of August 17, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of August 14, 2000. The laboratory submitted information to further clarify issues raised during the inspection. It appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.



Ms. Pizzo Dr. Glass August 22, 2000 Page 2 of 2

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Michael R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,

Deborah J. Denson NLCP Technical Analyst

cc: Project Files/M18



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 8, 2001

0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet most of the minimum technical criteria. However, the laboratory must take steps to correct the following issues raised:

E. The Standard Operating Procedures (SOP) section acceptable. The following issues were raised:

Ms. Pizzo Dr. Glass Page 2 of 3 02/08/01

inspection.

8. The laboratory's signature page was incomplete. The laboratory must take steps to address this issue, to document the signature and initials of all staff working with regulated specimens. This will be reviewed at the next inspection.

The Chain of Custody, Accessioning, and Security section

L. The Certification and Reporting section

the section of the property of the section of the s

Ms. Pizzo Dr. Glass Page 3 of 3 02/08/01

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

CP Technical Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0083

Document No. Final

Laboratory: Kroll Laboratory Specialists, Inc.

Location: Gretna, LA

Document Reviewed: [] Application Form

[XX] Inspection Report #M19 Date: 7 December 2000

Status: [XX] Appeared to meet most of the minimum technical criteria

] Appeared to meet a number of the minimum technical criteria] Failed to meet a number of the minimum technical criteria

Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

Ver. Final Lab ID# 0083

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

Section E. Standard Operating Procedures - Procedures Manual

Ver. Final	Lab ID# 0083
Section F. Chain-of-Custody, Accessioning, and Security	
	V
	~
	-
Section G. Quality Control and Quality Assurance	

1 /	Final
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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 (LIMS)

Section N. Personnel



1111 Newton Street Gretna, LA 70053

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February 28, 2001

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

RE: Nineteenth Maintenance Inspection

Dear Ms. Crumpton:

Attached is Kroll Laboratory Specialists, Inc.'s response to the critique of the nineteenth maintenance inspection. If you require additional information, please contact us.

Sincerely,

Pat Pizzo, B.S., BCFE

V.P. Production/Director of Toxicology

PP/bb

Attachments

RESPONSE TO CRITIQUE OF DECEMBER 2001 INSPECTION

Section E. Standard Operating Procedures – Procedures Manual

PAGE 2 OF 5 RESPONSE TO CRITIQUE DECEMBER 2000 INSPECTION

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

PAGE 3 OF 5 RESPONSE TO CRITIQUE DECEMBER 2000 INSPECTION

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section L. Certification and Reporting

PAGE 5 OF 5 RESPONSE TO CRITIQUE DECEMBER 2000 INSPECTION



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 12, 2001

0083 Ms. Pat Pizzo Dr. Leon Glass Kroll Laboratory Specialists, Inc. 1111 Newton Street Gretna, LA 70053

Dear Ms. Pizzo and Dr. Glass:

We have reviewed the material provided in your correspondence of February 28, 2001, submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of February 8, 2001. 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:

Ms. Pizzo Dr. Glass Page 2 of 3 03/12/01

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Ms. Pizzo Dr. Glass

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. The laboratory must take corrective action to address issues outlined in this correspondence. 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 Technical Analyst

cc: Dr. Michael Baylor Project Files/0083