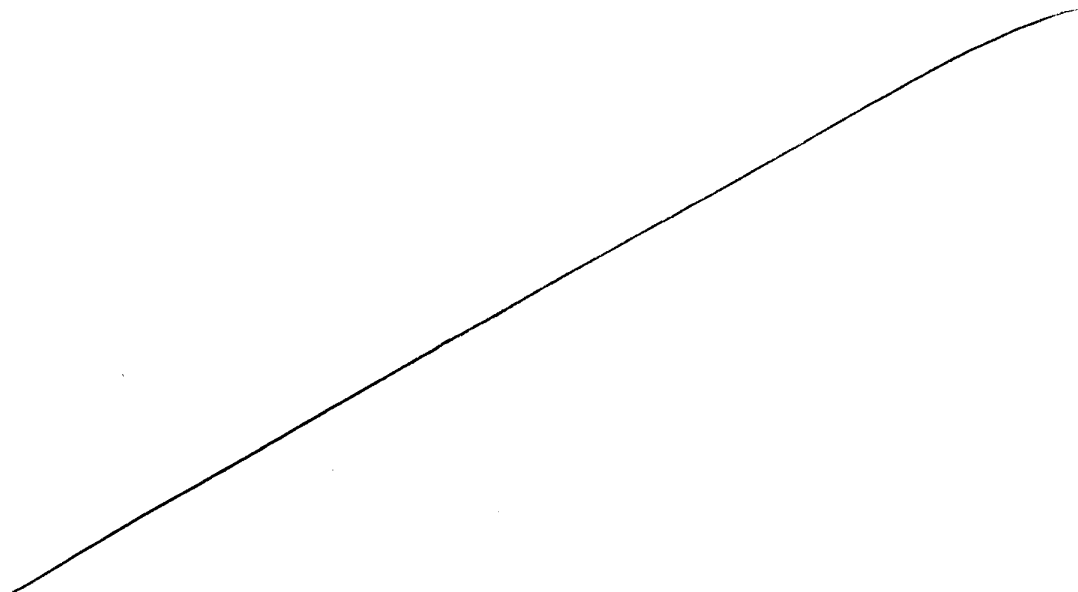


February 26, 1999

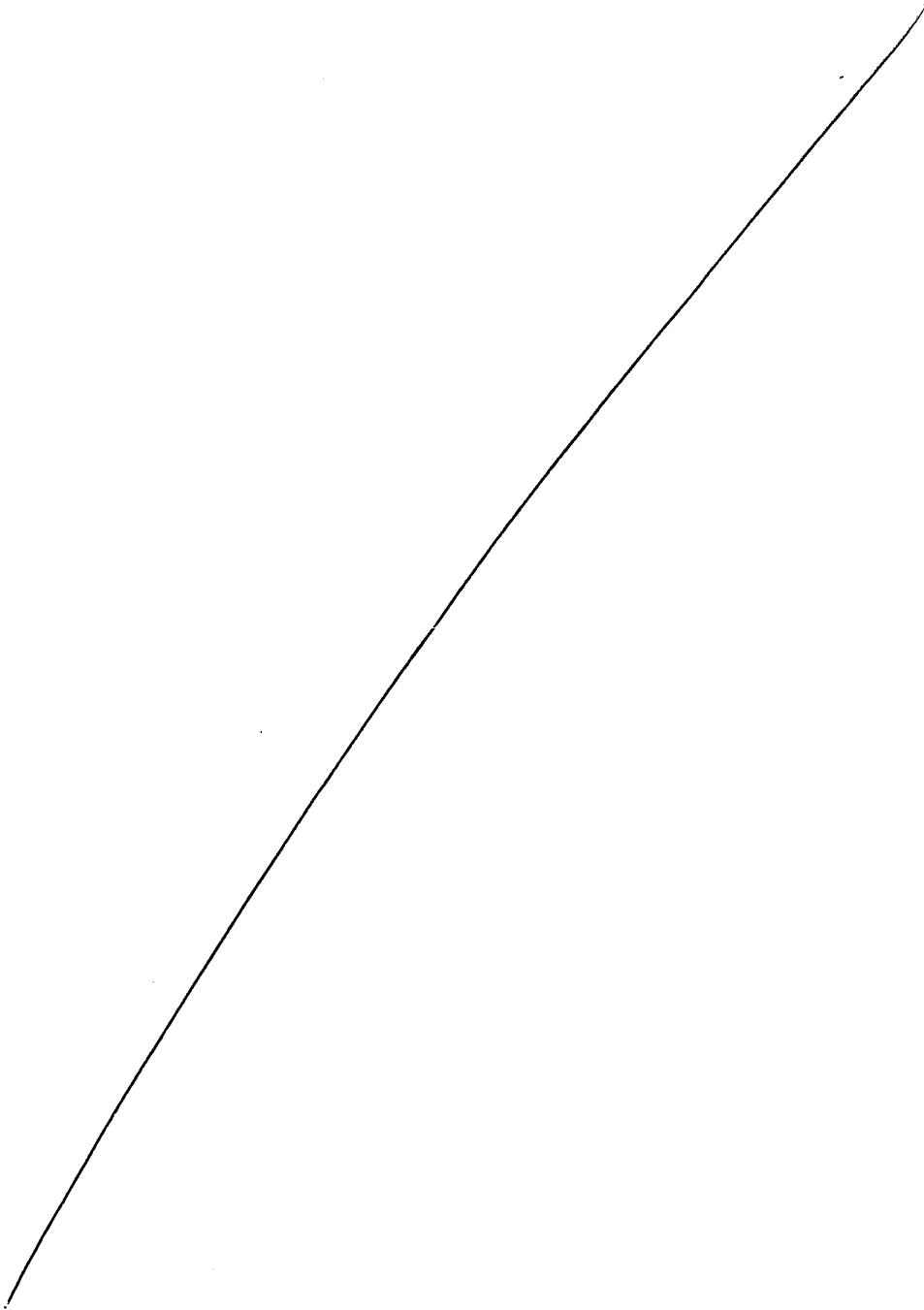
0608
Dr. Anthony Okorodudu
University of Texas Medical Branch Toxicology Lab
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Okorodudu:

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



Dr. Okorodudu
Page 2 of 3
02/26/99



Dr. Okorodudu
Page 3 of 3
02/26/99

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 described above. 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 your 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 of the 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/M4

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0608
Document No. Final

Laboratory: UTMB Pathology-Toxicology Laboratory

Location: Galveston, TX

Document Reviewed: Application Form
 Inspection Report #M4 Date: 21 January 1999
 Other _____

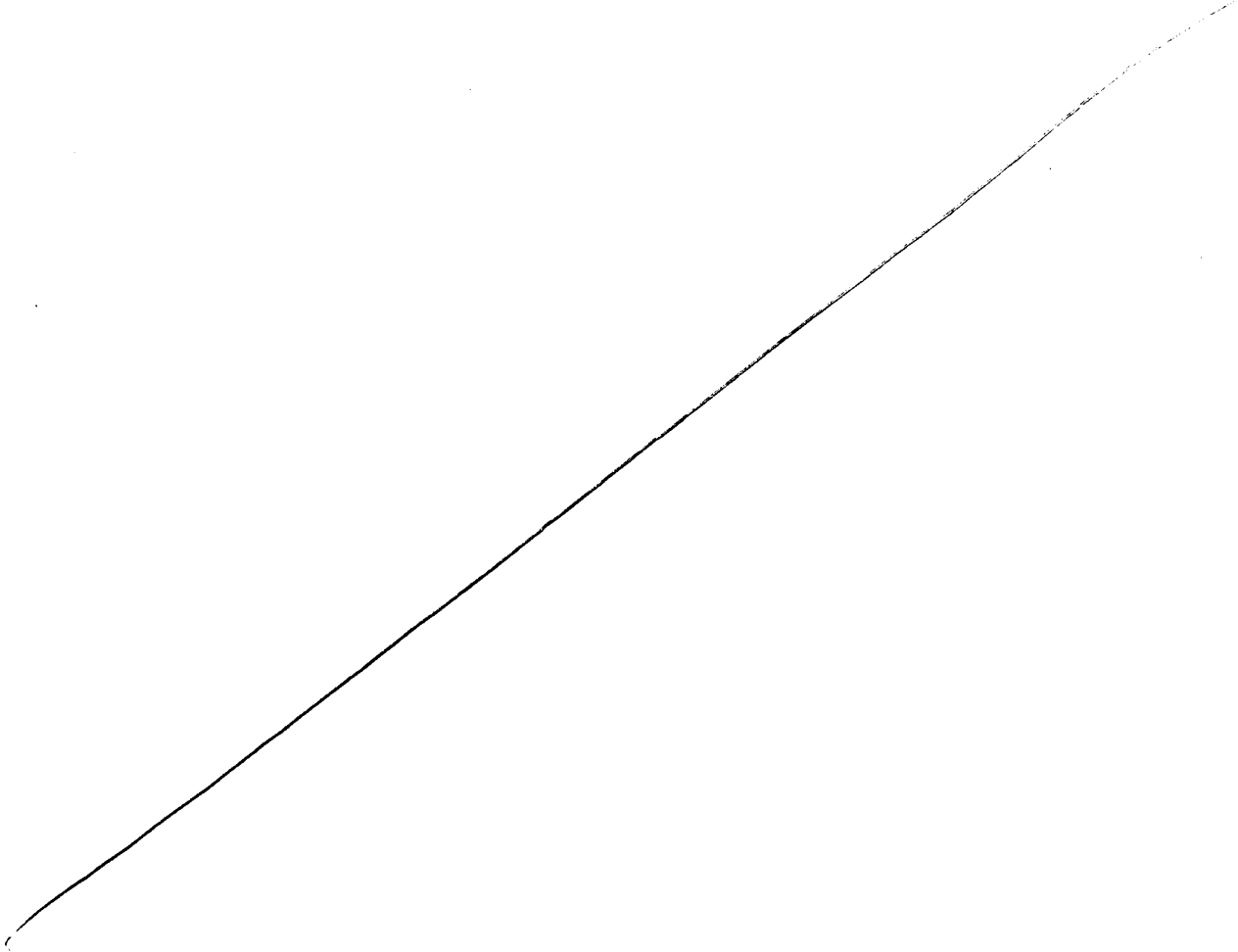
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

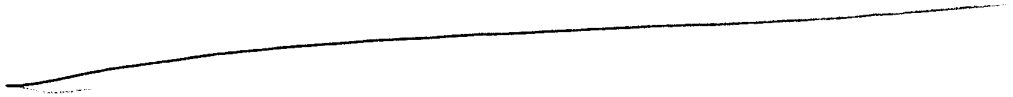
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

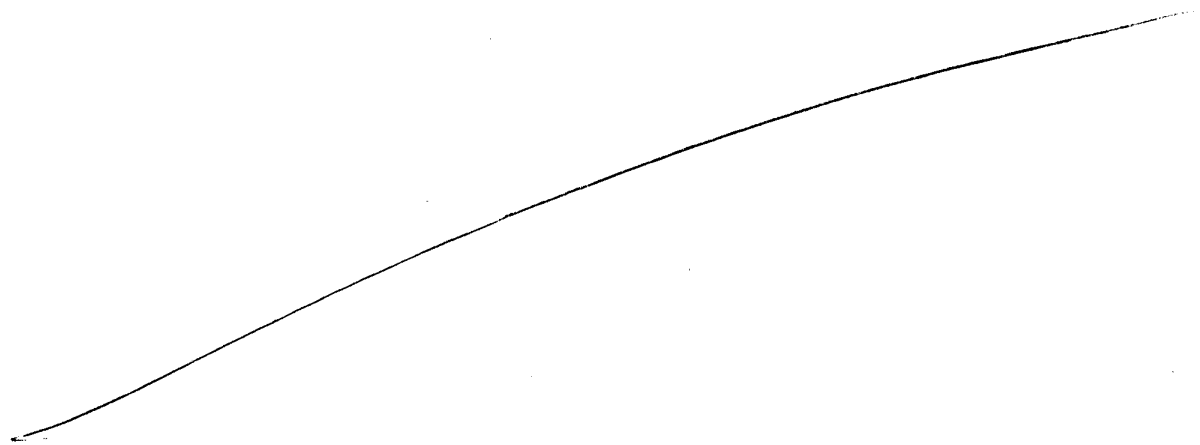
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

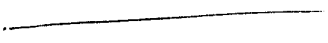




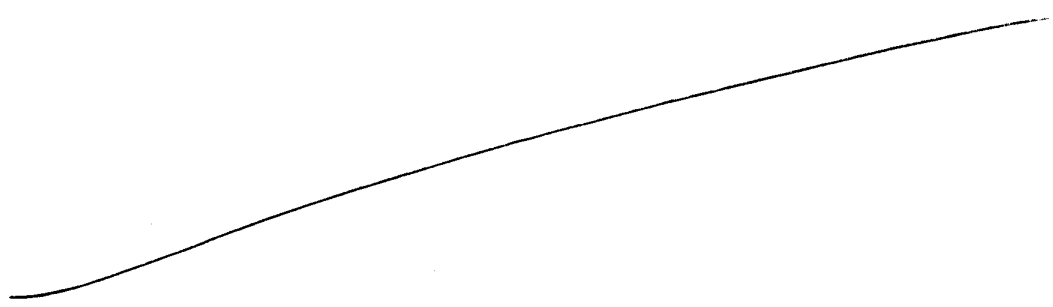
Section G. Quality Control



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

The University of Texas Medical Branch at Galveston

School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals and Clinics



Department of Pathology

Clinical Chemistry



4/01/99

Ms. Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

I have reviewed the critique and inspectors comments from the January 1999 inspection and proceeded with corrective action as follows:

SECTION E


SECTION F

SECTION I

SECTION K

Please let me know if additional or specific documentation is required.

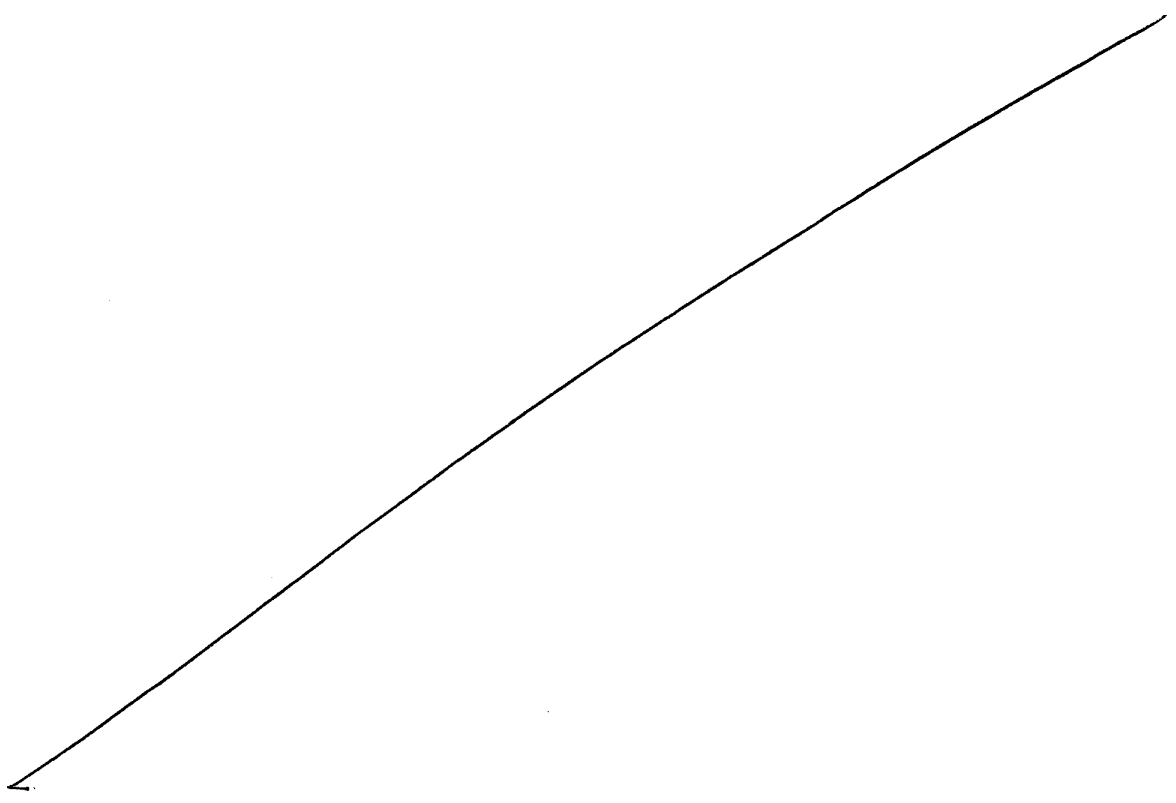
Sincerely,


Anthony O. Okorodudu, Ph.D.
Associate Professor & Director

0608
Dr. Anthony Okorodudu
University of Texas Medical Branch Toxicology Lab
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Okorodudu:

We have reviewed the material provided in your correspondence of April 1, 1999, submitted in response to issues raised during the fourth maintenance inspection of your laboratory as outlined in our correspondence of February 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 issues remain:



Dr. Okorodudu
Page 2 of 2
04/06/99

The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. Once these issues have been successfully addressed, RTI will recommend to HHS that the laboratory's certification be continued. If the laboratory fails to address these unresolved issues within the specified time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of 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 Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M4

The University of Texas Medical Branch at Galveston



*School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing*

*Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals and Clinics*

Department of Pathology

Clinical Chemistry



4/15/99

**Ms. Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194**

Dear Ms. Crumpton:

I have reviewed the critique per your letter dated 4/6/99 and proceeded with corrective action as follows:

SECTION E

SECTION I

Please let me know if additional or specific documentation is required.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony O. Okorodudu".

**Anthony O. Okorodudu, Ph.D.
Associate Professor & Director**

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

April 21, 1999

0608
Dr. Anthony Okorodudu
University of Texas Medical Branch Toxicology Lab
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Okorodudu:

We have reviewed the material provided in your correspondence of April 15, 1999, submitted in response to issues raised during the fourth maintenance inspection of your laboratory as outlined in our correspondence of April 6, 1999. The information submitted by the laboratory does not demonstrate that appropriate corrective actions have been completed to address all issues raised.

The laboratory must submit a report addressing these issues within 10 working days of receipt of this letter. We have discussed these deficiencies with the technical staff at the Department of Health and Human Services (HHS). If these issues are not successfully resolved through remedial correspondence, it may be necessary to schedule a special inspection of your laboratory to ensure that all deficiencies have been corrected. If it is determined that a special inspection is warranted, RTI staff will contact you to schedule the inspection and obtain payment of required fees.



received
5/14/99 SDC

The University of Texas Medical Branch at Galveston



School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals and Clinics

Department of Pathology
Clinical Chemistry

5/3/99

Dr. Michael R. Baylor
Senior Forensic Toxicologist
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Dear Dr. Baylor:

I have revised the standard operating procedures per your correspondence dated 4/21/99 and proceeded with corrective action as contained in the attachment:

SECTION E

Please let me know if additional or specific documentation is required.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony O. Okorodudu".

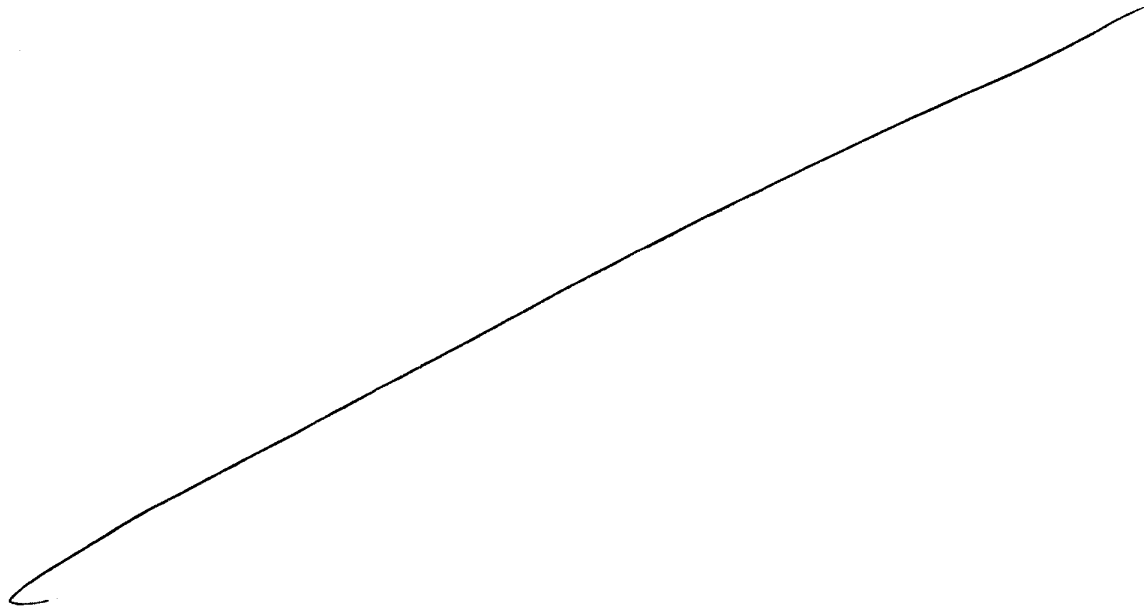
Anthony O. Okorodudu, Ph.D.
Associate Professor & Director

May 19, 1999

0608
Dr. Anthony Okorodudu
University of Texas Medical Branch Toxicology Lab
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Okorodudu:

We have reviewed the material provided in your correspondence of May 3, 1999, submitted in response to two issues remaining from the fourth maintenance inspection of your laboratory as outlined in our correspondence of April 21, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to marginally address the issues. However, the following concerns were raised during our review of the submitted material:



Dr. Okorodudu
Page 2 of 2
05/19/99

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. ***The laboratory must further revise its procedures to address the concerns outlined above.*** 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/M4

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

September 30, 1999

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Zaun:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete all corrective actions described in this critique and cover letter:



Dr. Zaun
September 30, 1999
Page 2 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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Dr. Zaun
September 30, 1999
Page 3 of 3

Enclosure

cc: Project Files/M5

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0608
Document No. Final

Laboratory: One Source Toxicology Laboratory, Inc.

Location: Galveston, TX

Document Reviewed: Application Form
 Inspection Report #M5 Date: 19 August 1999
 Other _____

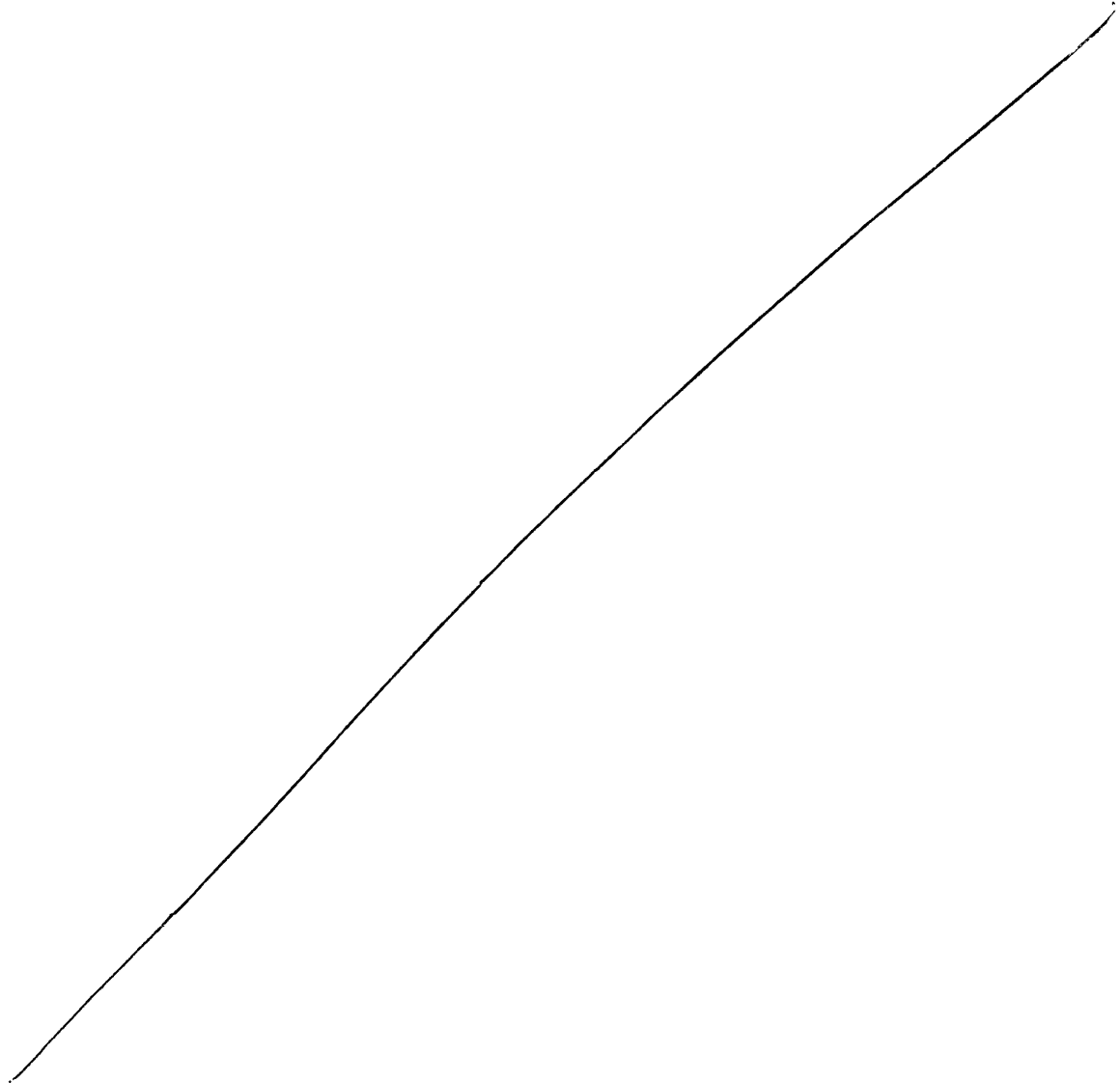
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

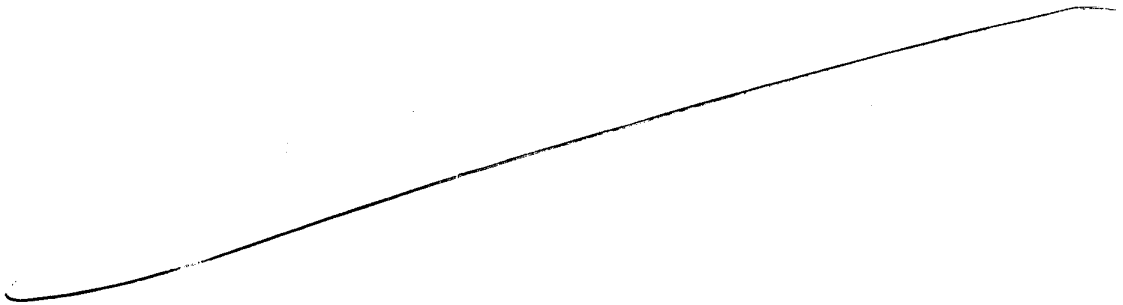
Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received
111 99 DD

One Source Toxicology Laboratory, Inc
301 University Blvd.
Rm. 5.160 McCullough Bldg.
Galveston, TX 77555

One Source Toxicology

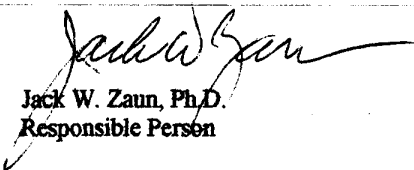
October 28, 1999

Deborah Denson
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
Research Triangle Park, NC 27709-2194

Dear Ms Denson:

This letter is the response to the August 1999 inspection by the NLCP.

Sincerely,


Jack W. Zaun, Ph.D.
Responsible Person



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 3, 1999

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
301 University Boulevard
Room 5160 McCullough Building
Galveston, TX 77555

Dear Dr. Zaun:

We have reviewed the material provided in your correspondence of October 28, 1999 submitted in response to issues raised during the fifth maintenance inspection of your laboratory as outlined in our correspondence of September 30, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,


Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M5





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 30, 2000

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
1705 Center Street
P. O. Box 260
Deer Park, TX 77536

Dear Dr. Zaun:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixth 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. Zaun
March 30, 2000
Page 2 of 2

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

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

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M6

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0608
Document No. Final

Laboratory: One Source Toxicology Laboratory, Inc.

Location: Deer Park, TX

Document Reviewed: Application Form
 Inspection Report #M6 Date: 17 February 2000
 Other _____

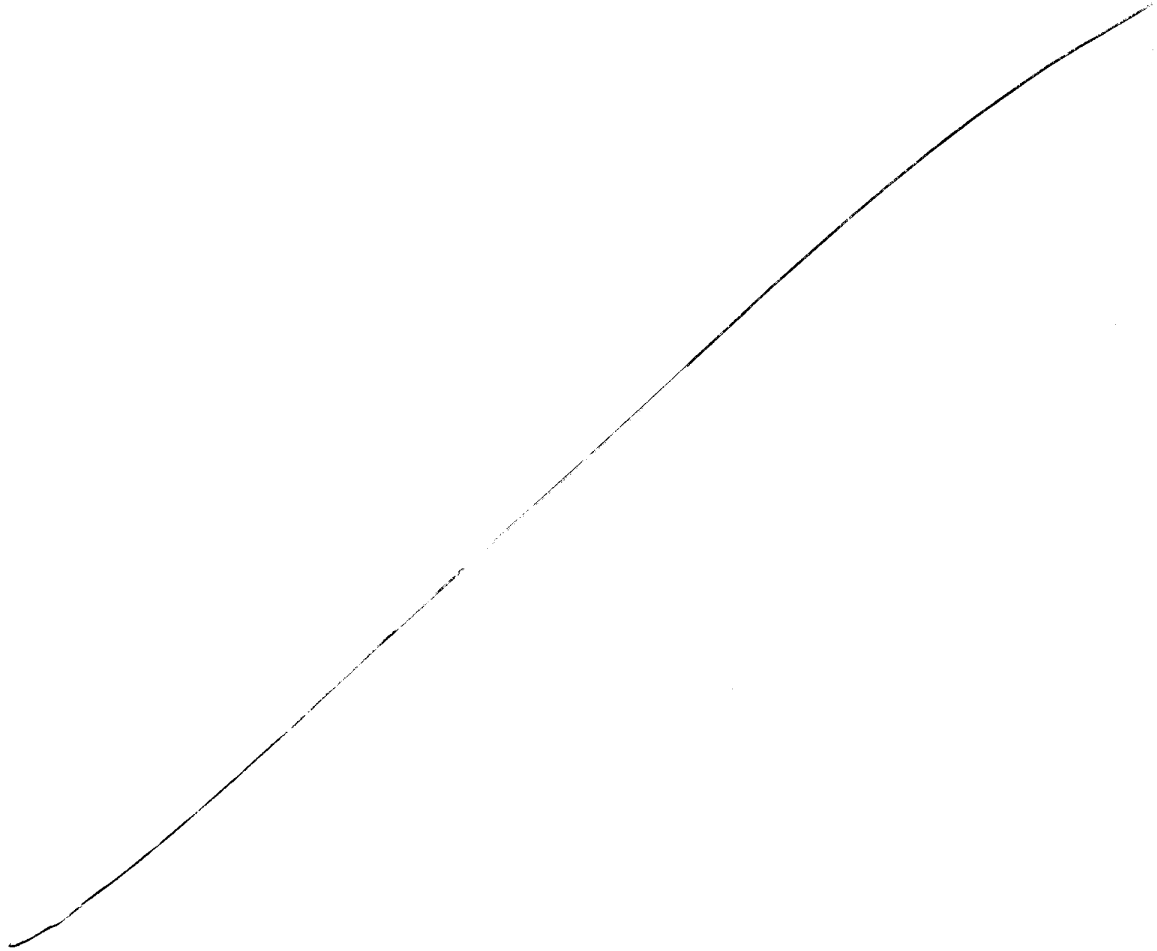
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

October 11, 2000

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
1705 Center Street
P. O. Box 260
Deer Park, TX 77536


Dear Dr. Zaun:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventh 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 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/M7



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0608
Document No. Final

Laboratory: One Source Toxicology Laboratory, Inc.

Location: Deer Park, TX

Document Reviewed: Application Form
 Inspection Report #M7 Date: 24 August 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
