# RESEARCH TRIANGLE INSTITUTE



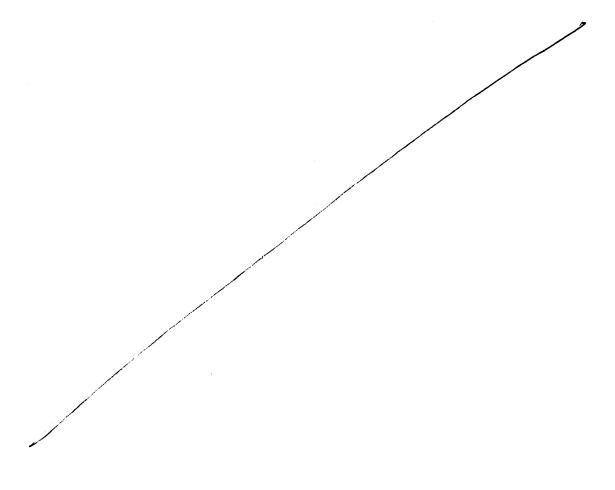
National Laboratory Certification Program

November 16, 1998

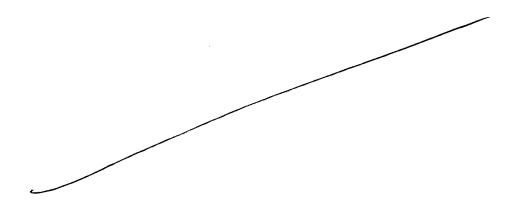
0154 Mr. Thomas Sneath Mr. Hasmukh Shah National Toxicology Laboratories, Inc. 1100 California Avenue Bakersfield, CA 93304

Dear Mr. Sneath and Mr. Shah:

The enclosed critique was developed from the inspection reports of the two 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:



Mr. Sneath and Mr. Shah Page 2 of 2 11/16/98



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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely.

Deborah J. Denson

**NLCP Inspection Analyst** 

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**Enclosure** 

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Project Files/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM		
	Document Review and	Critique
		Laboratory I.D. Number: <u>0154</u> Document No. Fina
Laboratory:	National Toxicology Laboratories, Inc.	
Location:	Bakersfield, CA	
Document Reviewed:	[ ] Application Form [XX] Inspection Report #M15 [ ] Other	Date: 15 October 1998
Status:	[XX] Highly Acceptable [	] Acceptable ] Failure

A review of the two independent 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.

Section E. Standard Operating Procedures - Procedures Manual



NLCP ◆ Research Triangle Institute Page 2

Ver. Final		Lab ID# 015-
		and way
Section G. Records Audit		
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Section H. Personnel		
Section I. Reagents		
Section J. Quality Control and Standards		
Section K. Reporting	· 	
ection L. Equipment and Maintenance		
	Manager to	
ection M. Immunoassay		
ection N. Gas Chromatography/Mass Spectrometry		
AND THE CAS OFFICINATOGRAPHY MASS Spectrometry		



National Laboratory Certification Program

May 25, 1999

0154 Mr. Thomas Sneath Mr. Hasmukh Shah National Toxicology Laboratories 1100 California Avenue Bakersfield, CA 93304

Dear Mr. Sneath and Mr. Shah:

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.

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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

**NLCP Inspection Analyst** 

**Enclosure** 

CC:

Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM		
	Document Review and Criti	que
		Laboratory I.D. Number: <u>0154</u> Document No. Final
Laboratory:	National Toxicology Laboratories, Inc.	
Location:	Bakersfield, CA	
Document Reviewed:		Date: 22 April 1999

] 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.

[ ] Other \_

[XX] Highly Acceptable

[ ] Unacceptable

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.

Status:

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

Ver. Final	· Lab ID# 0154
Section J. Records Audit	
Section K. Reporting	
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Section L. Computers, Software, and LIMS	
Section M. Equipment and Maintenance	
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Section N. Personnel	



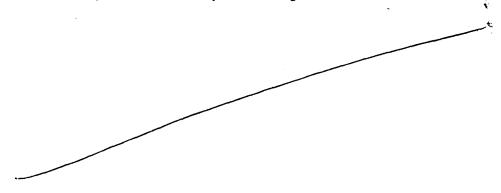
National Laboratory Certification Program

November 10, 1999

0154
Mr. Thomas Sneath
Mr. Hasmukh Shah
National Toxicology Laboratories, Inc.
1100 California Avenue
Bakersfield, CA 93304

Dear Mr. Sneath and Mr. Shah:

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



RTI is recommending to 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 issue 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.



Mr. Sneath Mr. Shah Page 2 of 2 11/10/99

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: 0154 Document No. Final National Toxicology Laboratories, Inc. Laboratory: Bakersfield, CA Location: [ ] Application Form **Document Reviewed:** [XX] Inspection Report #M17 Date: 21 October 1999 [ ] Other \_\_\_\_ Status: [XX] Highly Acceptable ] Acceptable [ ] Unacceptable ] Failure

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

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

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, a	and Security
Section G. Quality Control	
Section H. Initial Tests	
Section I. Confirmatory Tests	
Section J. Records Audit	

Ver. Final	Lab ID# 0154
Section K. Reporting	
Section L. Computers, Software, and LIMS	
Section M. Equipment and Maintenance	
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Section N. Personnel	



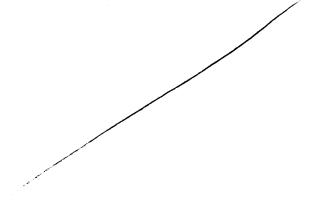
National Laboratory Certification Program

May 24, 2000

0154 Mr. Thomas Sneath Mr. Hasmukh Shah National Toxicology Laboratories, Inc. 1100 California Avenue Bakersfield, CA 93304

Dear Mr. Sneath and Mr. Shah:

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.



Mr. Sneath Mr. Shah Page 2 of 3 05/24/00

RTI is recommending to 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.

Mr. Sneath Mr. Shah Page 3 of 3 05/24/00

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/M18

#### NATIONAL LABORATORY CERTIFICATION PROGRAM

#### **Document Review and Critique** Laboratory I.D. Number: 0154 Document No. Final National Toxicology Laboratories, Inc. Laboratory: Bakersfield, CA Location: ] Application Form Document Reviewed: Date: 13 April 2000 [XX] Inspection Report #M18 ] Other \_ [XX] Highly Acceptable 1 Acceptable Status: ] 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.

Section E. Standard Operating Procedures - Procedures Manual

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

NLCP ◆ Research Triangle Institute

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

Ver. Final	Lab ID# 0154
Section M. Equipment and Maintenance	
Section N. Personnel	

### RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 21, 2000

0154 Mr. Thomas Sneath Mr. Hasmukh Shah National Toxicology Laboratories, Inc. 1100 California Avenue Bakersfield, CA 93304

Dear Mr. Sneath and Mr. Shah:

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 is highly acceptable. The inspection team had some areas of concern, which are detailed in the attached critique.

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

Detoral & Denson

Enclosure

cc: Project Files/M19



## NATIONAL LABORATORY CERTIFICATION PROGRAM **Document Review and Critique** Laboratory I.D. Number: 0154 Document No. Final National Toxicology Laboratories, Inc. Laboratory: Location: Bakersfield, CA Document Reviewed: [ ] Application Form [XX] Inspection Report # M19 Date: 19 October 2000 [ ] Other Status: [XX] Highly Acceptable ] 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.

[ ] Unacceptable

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.

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

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Section L. Computers, Software, and LIMS	
Section M. Equipment and Maintenance	
Section N. Personnel	