

RESEARCH TRIANGLE INSTITUTE



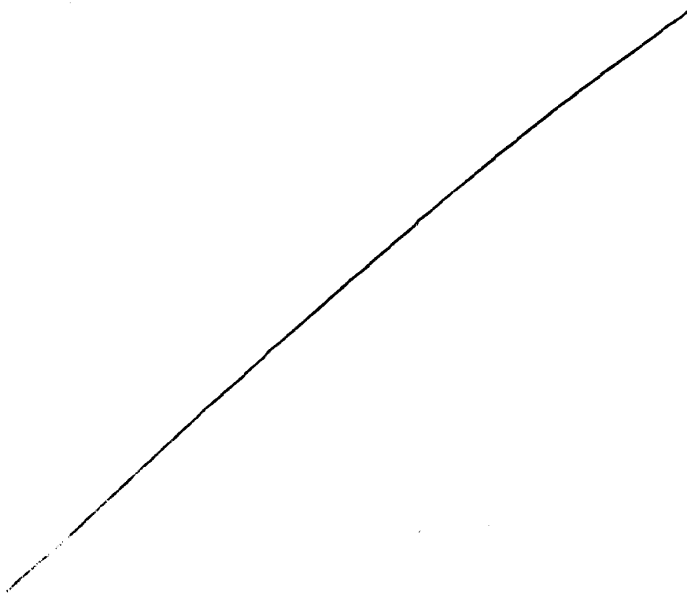
National Laboratory Certification Program

May 10, 1999

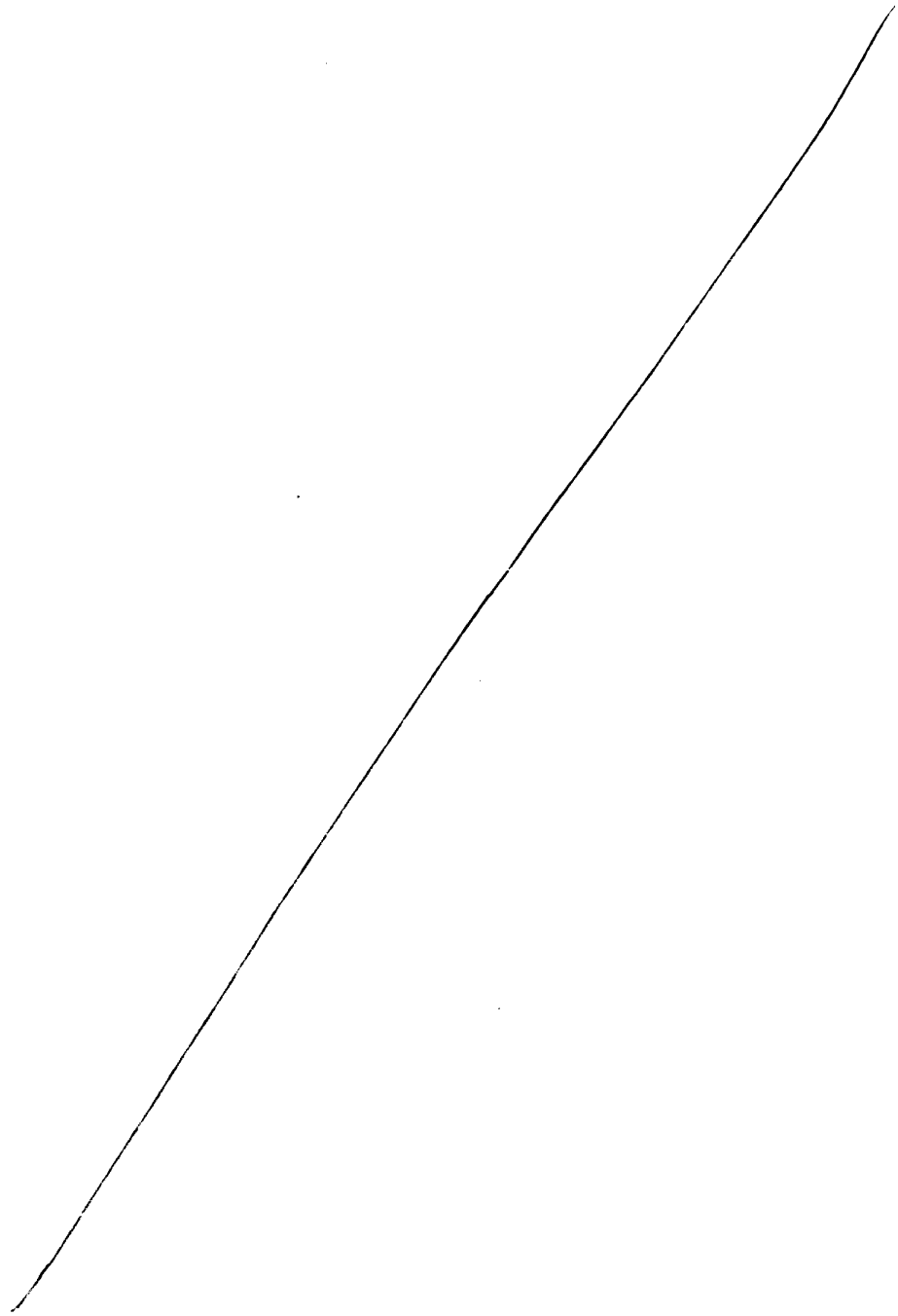
0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

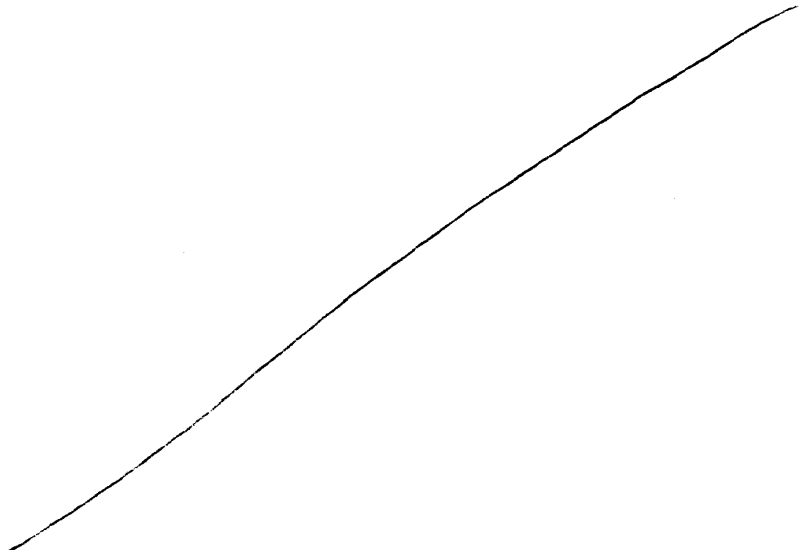
The enclosed critique was developed from the inspection reports of the two inspectors who conducted the initial inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the outcome of the laboratory's performance in this inspection is acceptable; however, the laboratory must clarify and/or correct the following issues before a recommendation for certification can be made:



Mr. Wahl
May 10, 1999
Page 2 of 3



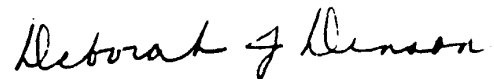
Mr. Wahl
May 10, 1999
Page 3 of 3



The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to clarify and/or correct the items cited above. Once the laboratory has successfully completed these actions, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory be certified under the NLCP. The laboratory must also review the enclosed critique and take all necessary corrective actions.

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

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/1

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0220
Document No. Final

Laboratory: San Diego Reference Laboratory

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #1
 Other _____

Date: 8 April 1999

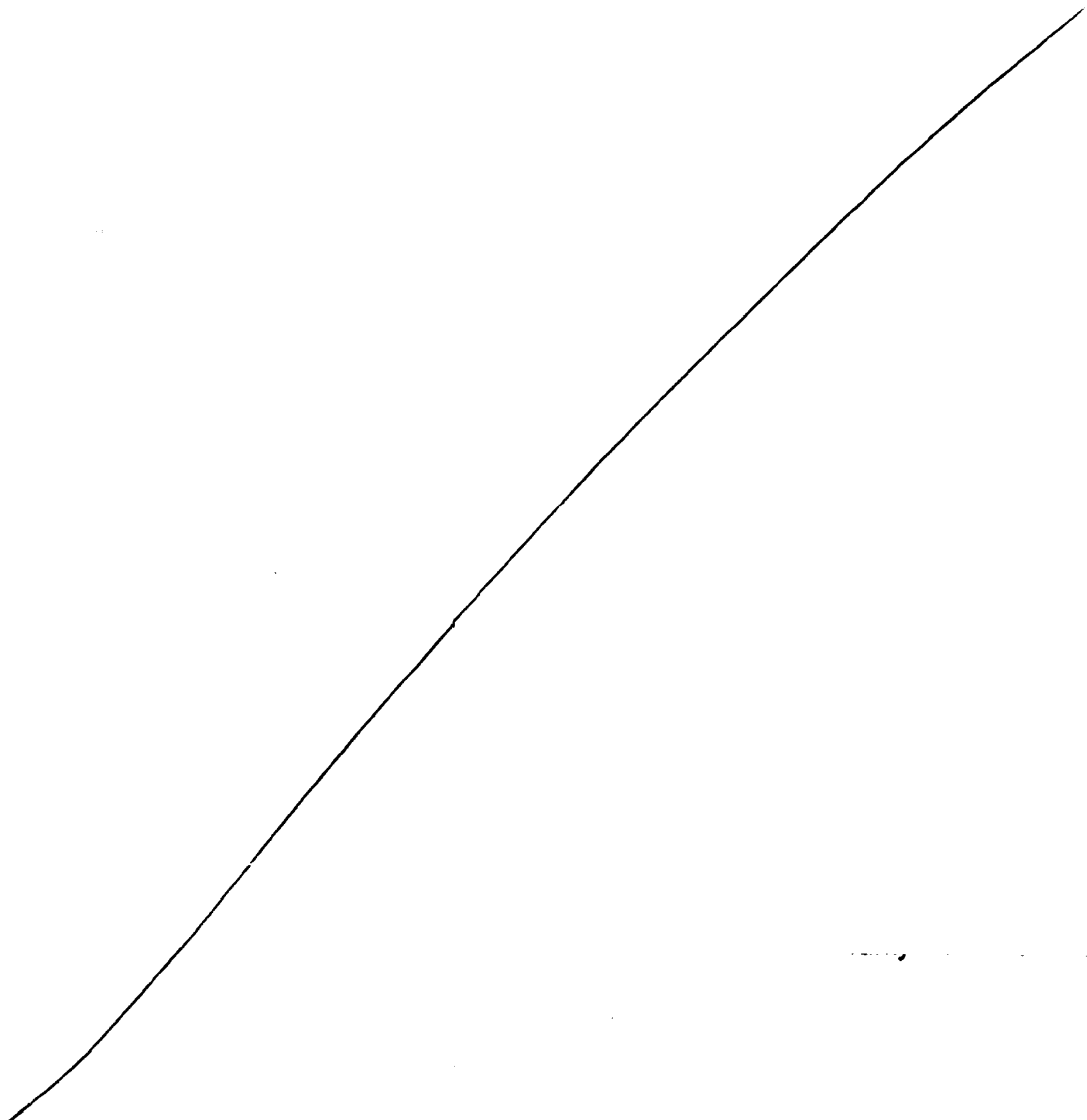
Status: Acceptable
 Failure

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.

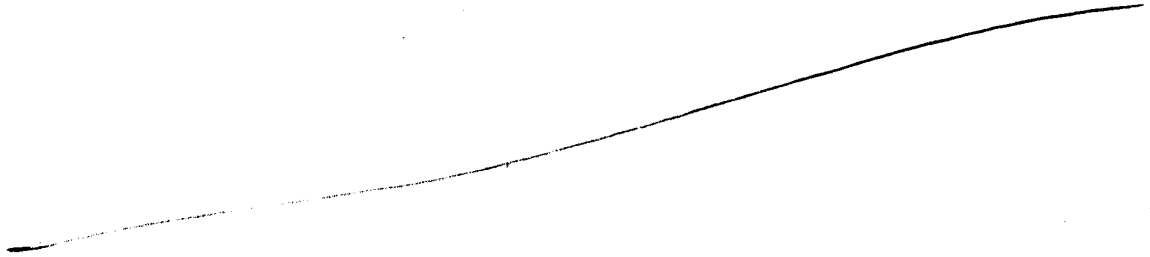
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

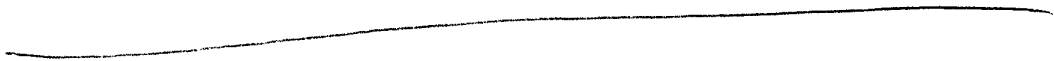


Section F. Chain-of-Custody, Accessioning, and Security

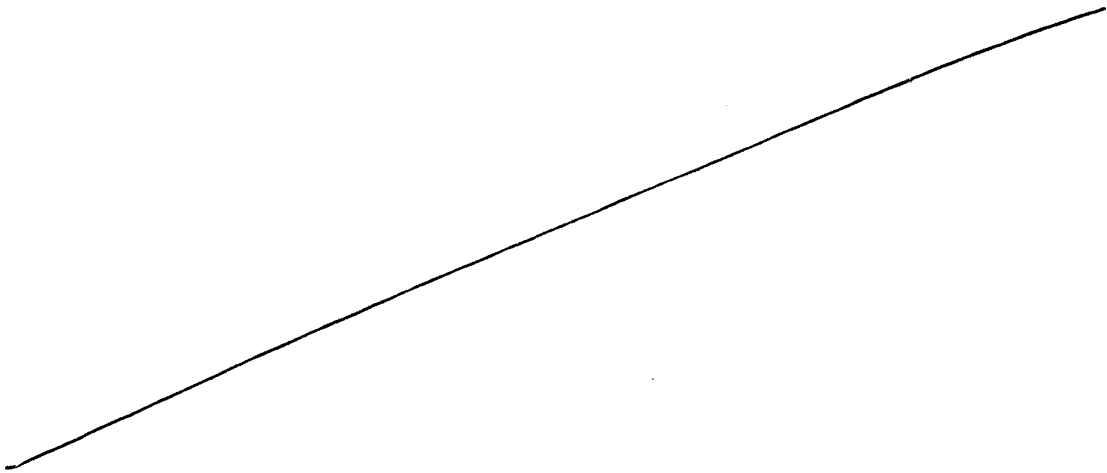
Section G. Quality Control



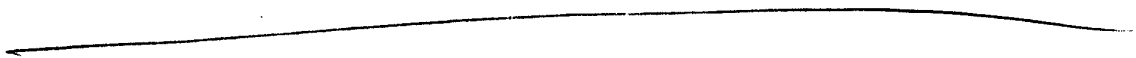
Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



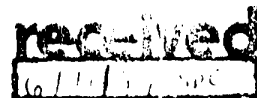
Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

San Diego Reference Laboratory
6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (619) 550-7344 fax: (619) 677-7998



June 10, 1999

Ms. Deborah Denson
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

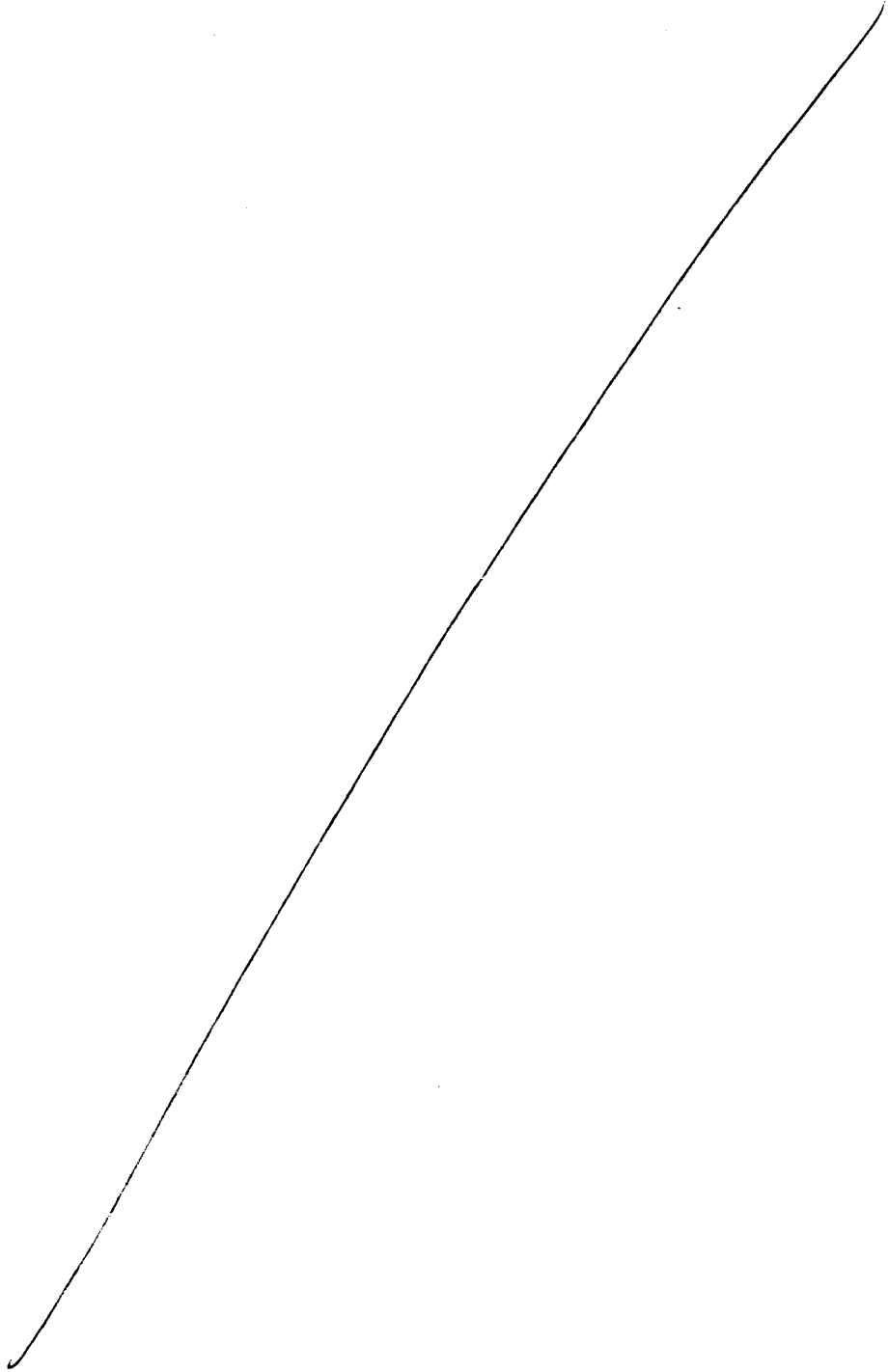
Re: Inspection Corrections

Dear Ms. Denson;

This letter is a response to your letter dated May 10, 1999 and received on May 14, 1999. We are very pleased to be eligible for certification under the NLCP program and have corrected the issues pointed out in your letter. The following are the actions in response to your letter.

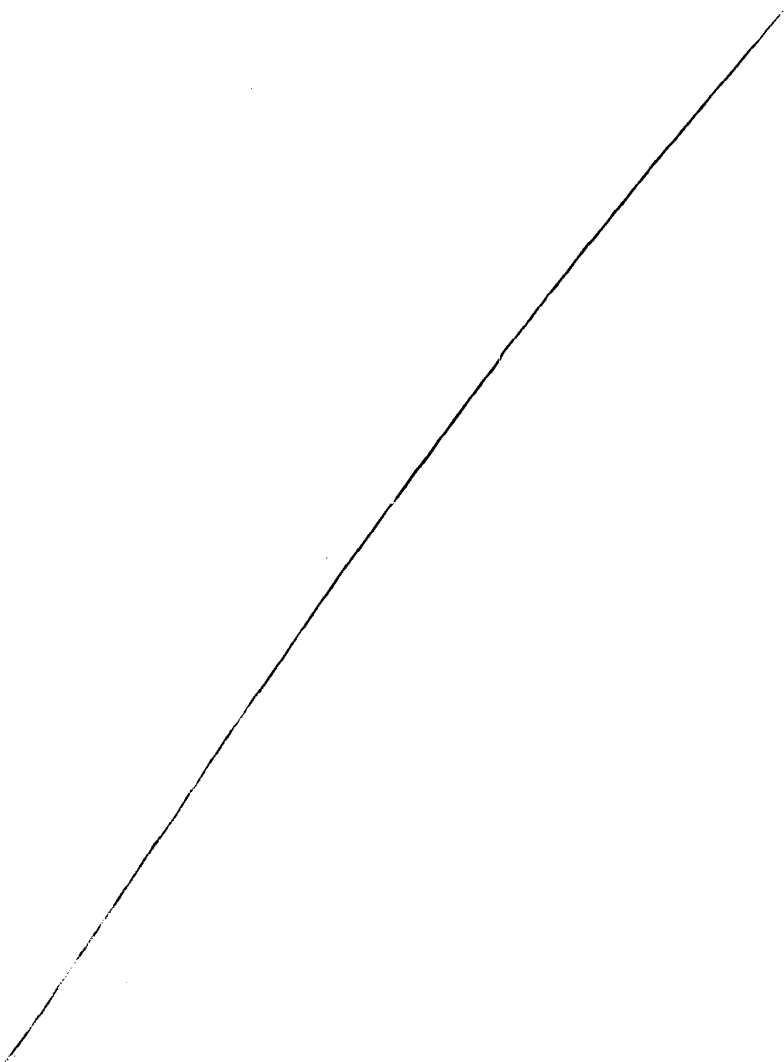
Ms. Deborah Denson
Research Triangle Institute

June 10, 1999
Page 2



Ms. Deborah Denson
Research Triangle Institute

June 10, 1999
Page 3



If you have any questions please do not hesitate to call me at (619) 677-7970, extension 117.

Sincerely,

Kenneth C. Wahl
Responsible Person



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 22, 1999

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

We have reviewed the material provided in your correspondence of June 10, 1999, provided in response to issues raised during the initial inspection of your laboratory as outlined in our correspondence of May 10, 1999. The laboratory appears to have addressed most issues raised. The following was noted during our review of the laboratory's submission:

Based upon our review of the submitted material, the laboratory has successfully completed the requirements for initial certification. RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory be certified under the National Laboratory Certification Program.

/

We look forward to continuing to work with your laboratory as a participant in the program. 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

Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/220

←

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 1, 1999

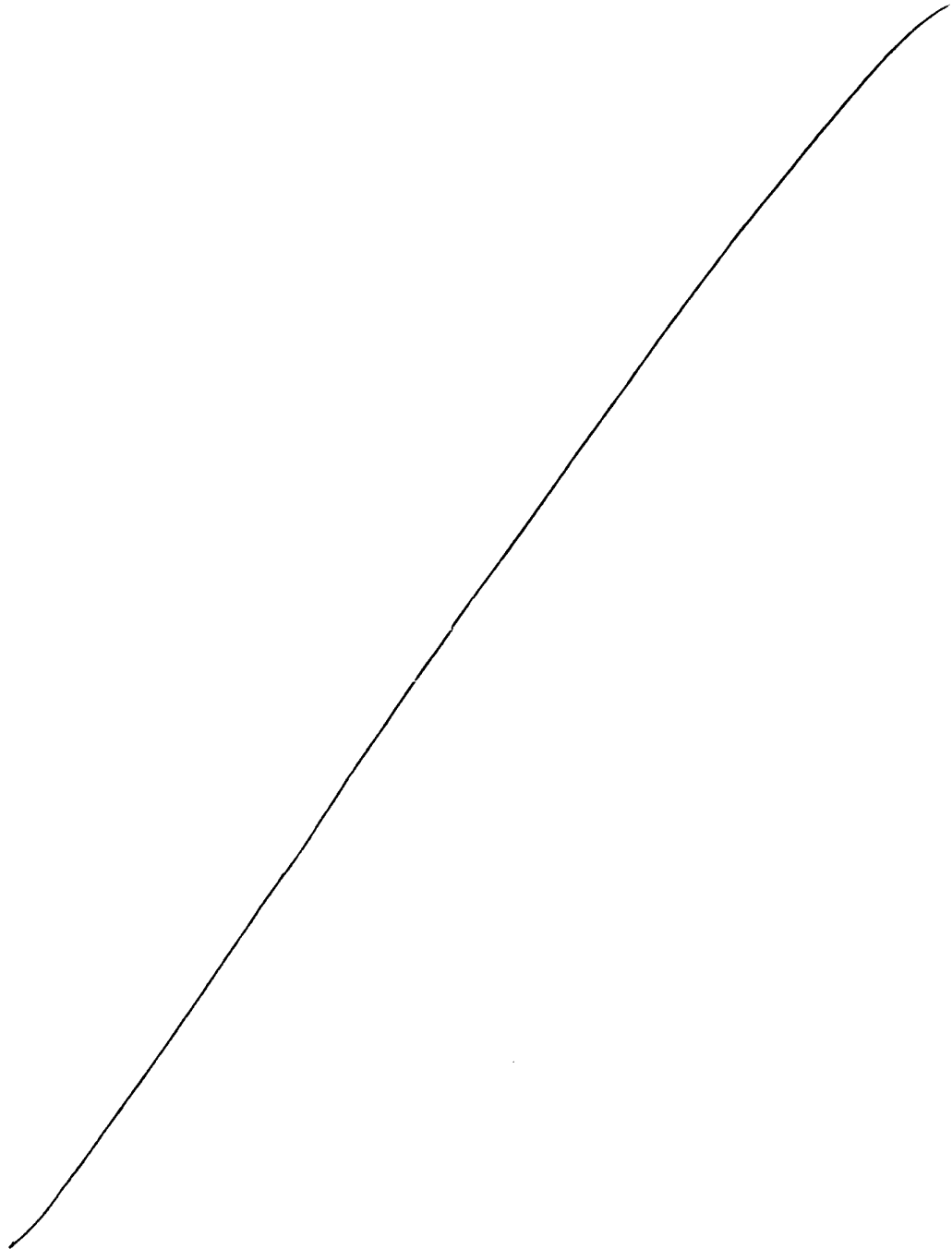
0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

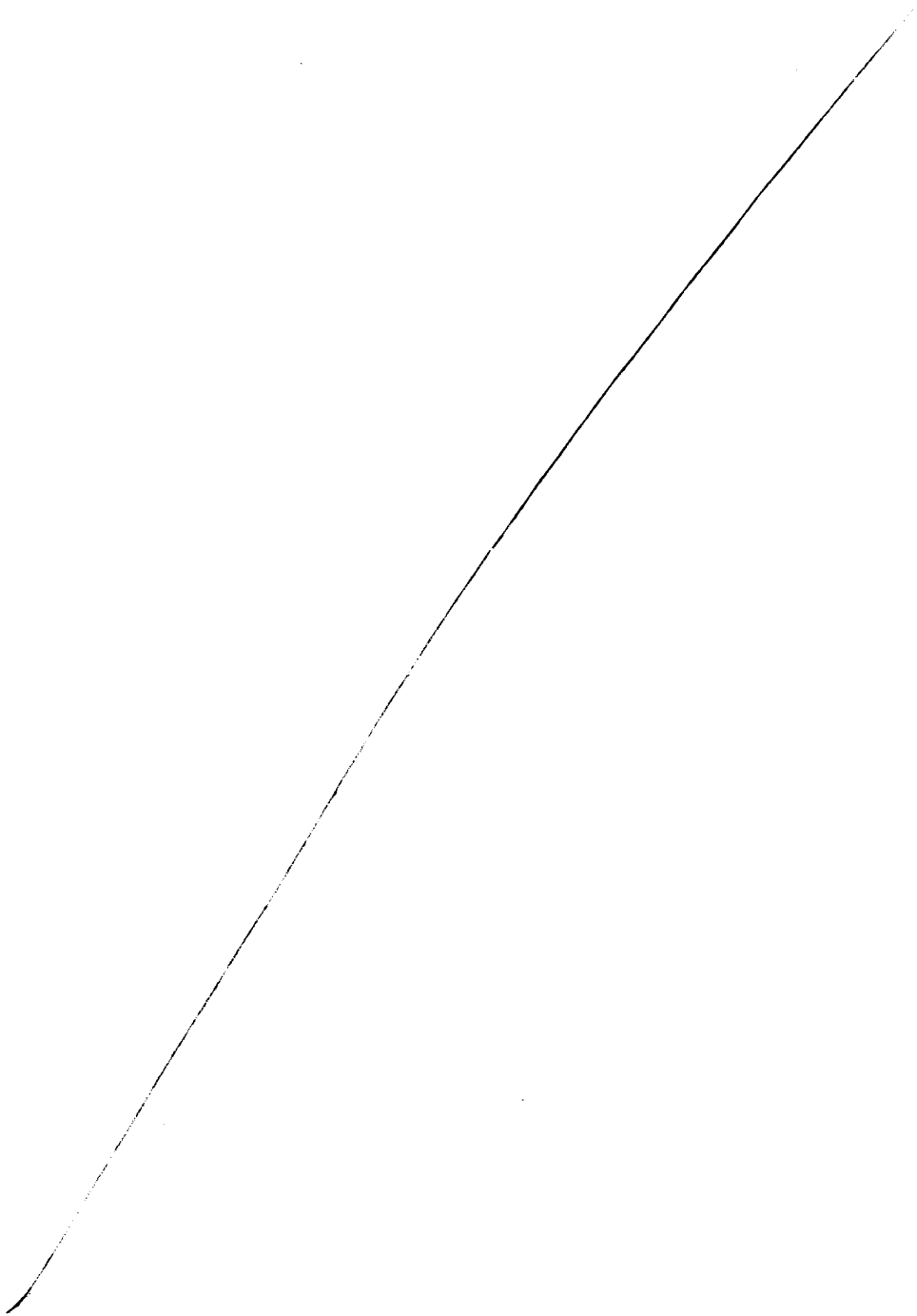
Dear Mr. Wahl:

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



Mr. Wahl
Page 2 of 4
12/01/99



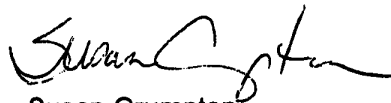


The laboratory must submit, within 5 calendar days of receipt of this letter, a plan to complete all remedial actions. Once this plan is approved, the laboratory will have a maximum of 30 calendar days to implement the plan and to complete all necessary remedial actions. If the laboratory fails to provide and execute an approved plan, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be suspended and/or revoked. The laboratory should also review the enclosed critique and take all necessary corrective actions.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to sustain acceptable performance in the inspection phase of this program may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the Mandatory Guidelines.

In responding to the issues raised, please organize the material in accordance with the item numbers listed in the text of this letter. If we can be of assistance or answer any questions, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/2
Dr. Robert Turk
Dr. David Roberts

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0220
Document No. Final

Laboratory: San Diego Reference Laboratory

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #12 Date: 7 October 1999
 Other _____

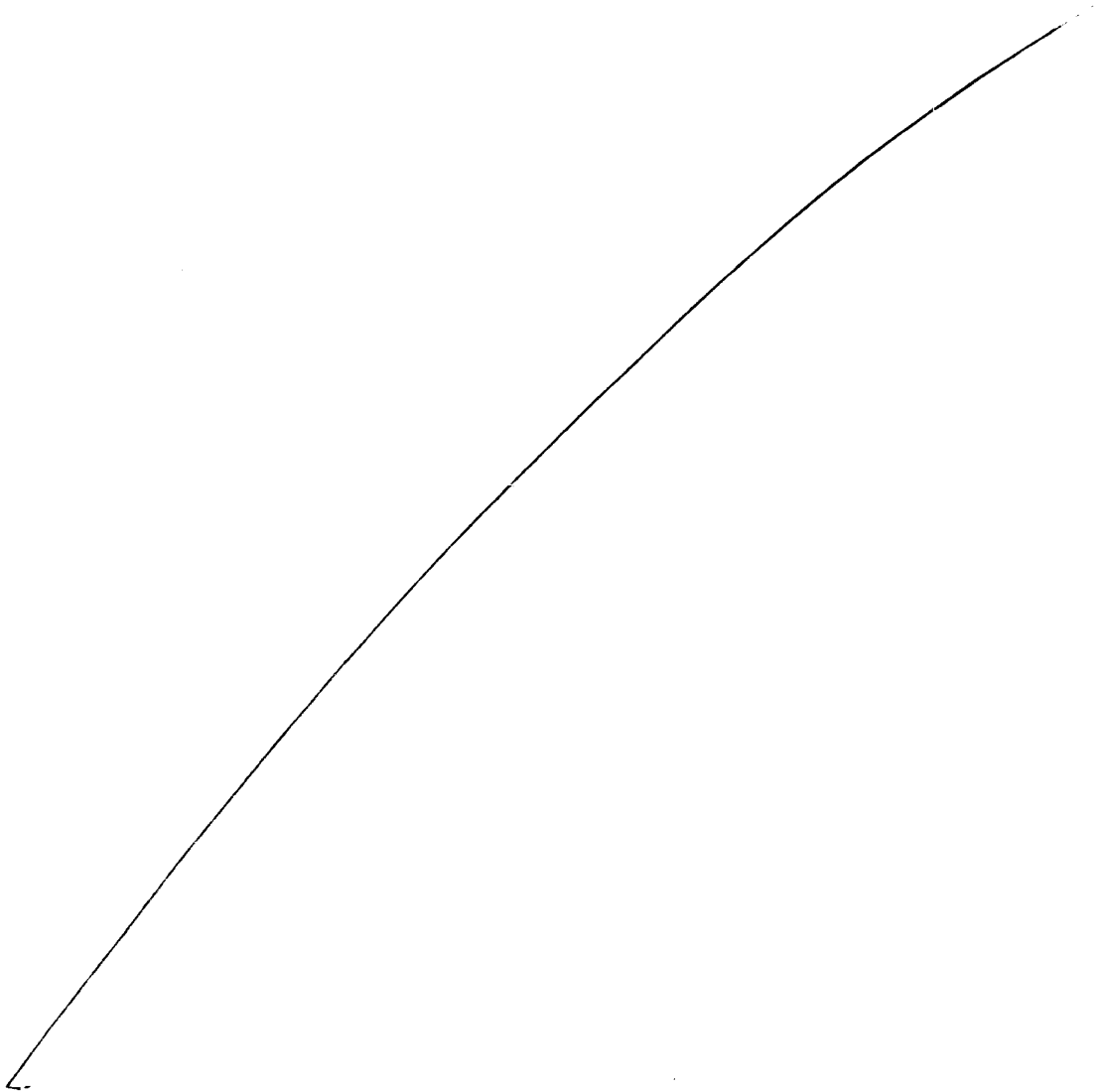
Status; Highly Acceptable Acceptable
 Unacceptable Failure

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 not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required for continued certification.

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

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

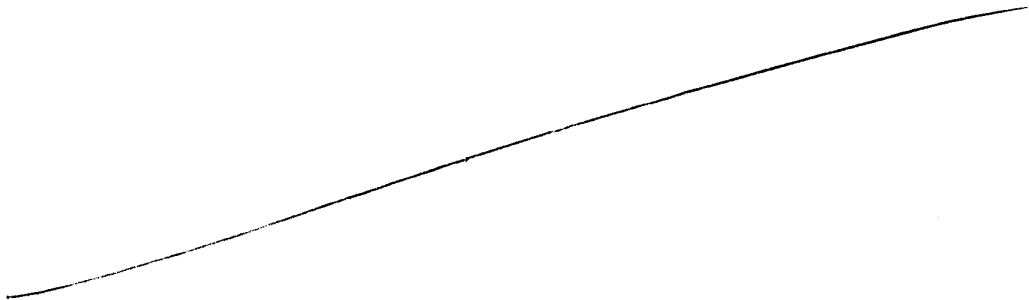
Section E. Standard Operating Procedures - Procedures Manual



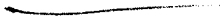
Section F. Chain-of-Custody, Accessioning, and Security



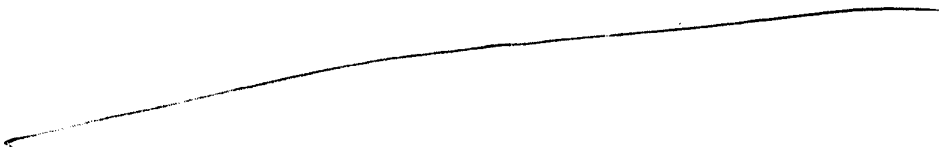
Section G. Quality Control

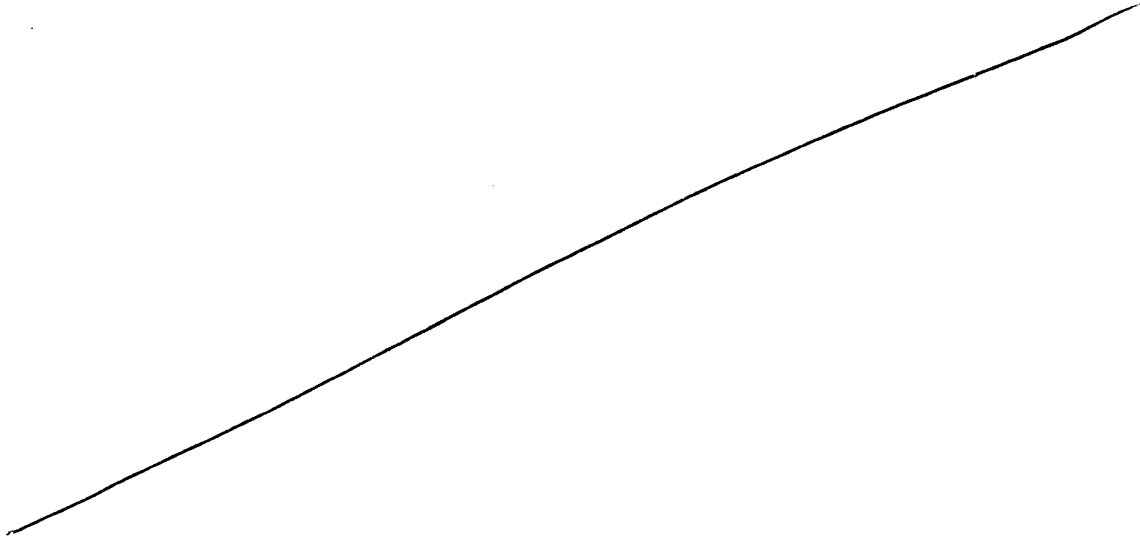


Section H. Initial Tests

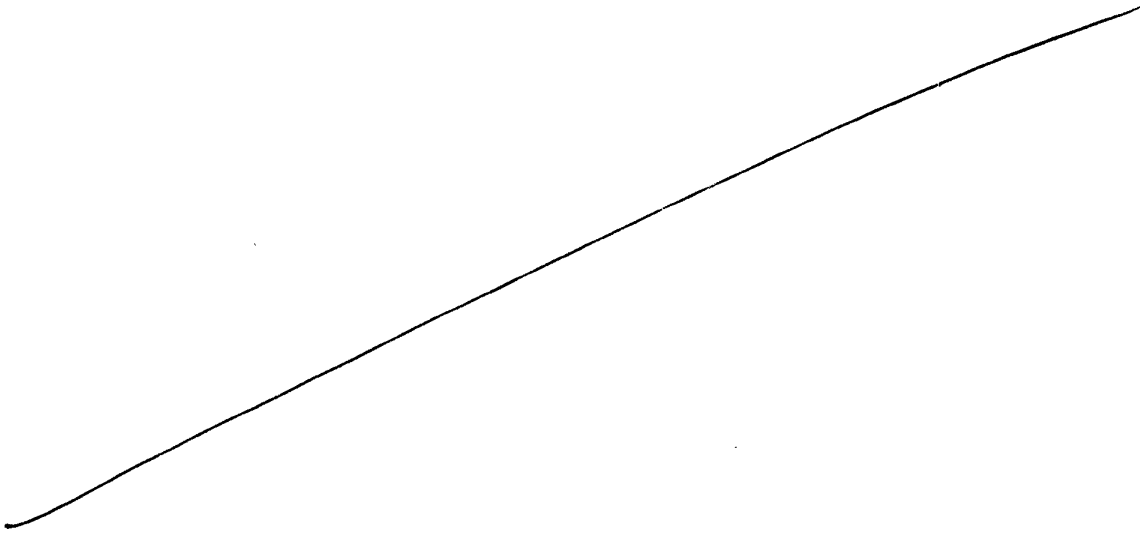


Section I. Confirmatory Tests





Section J. Records Audit



Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

San Diego Reference Laboratory
6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (858) 550-7344 fax: (858) 677-7998

received
12/7/99 SDC

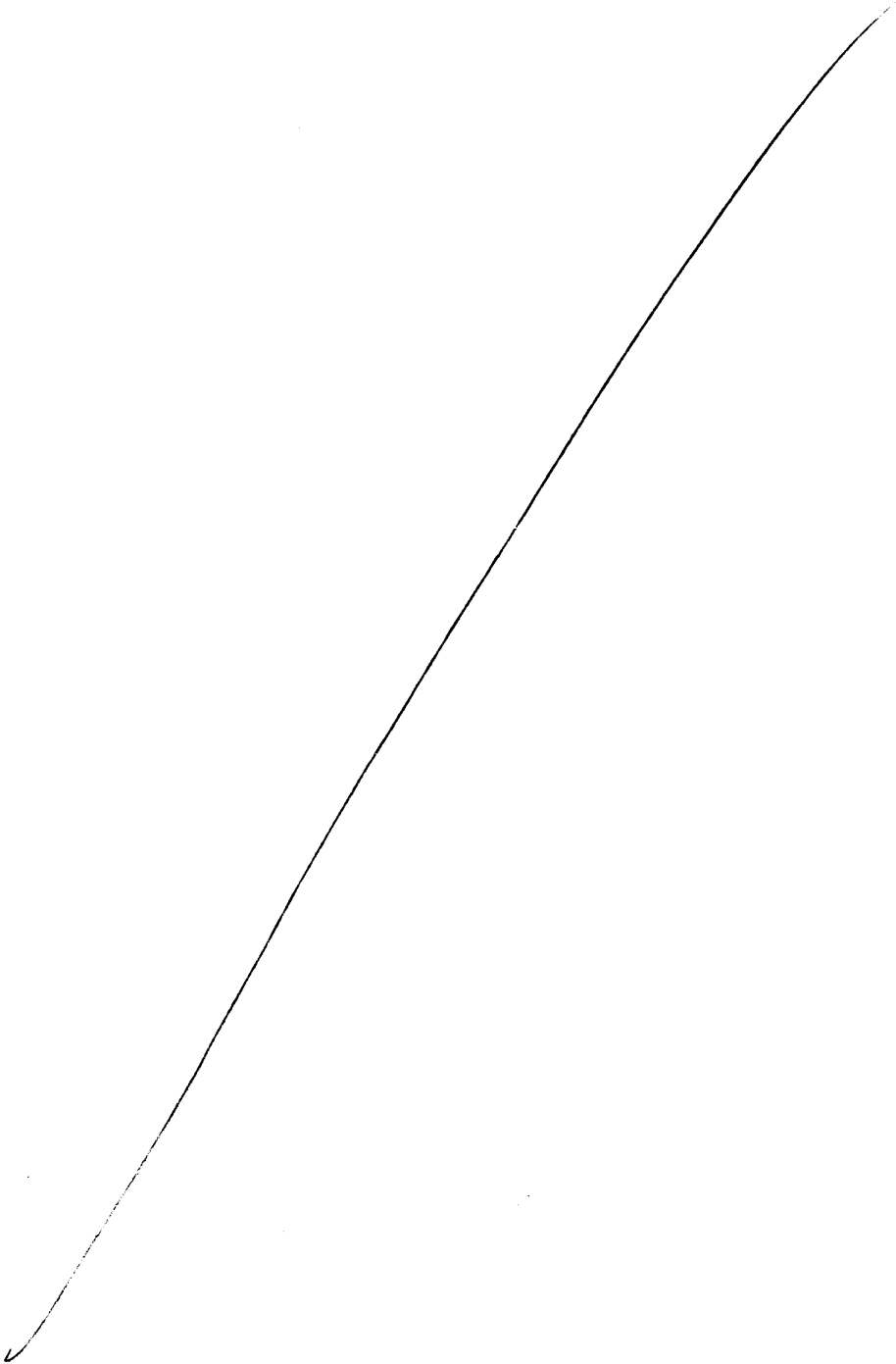
December 6, 1999

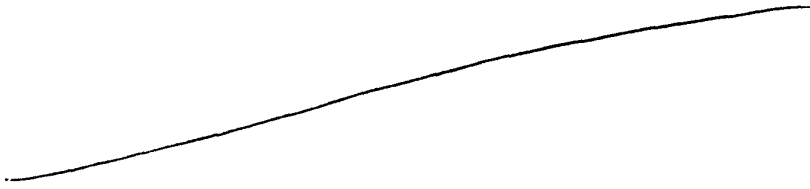
Ms. Susan Crumpton
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

Re: Inspection Corrections

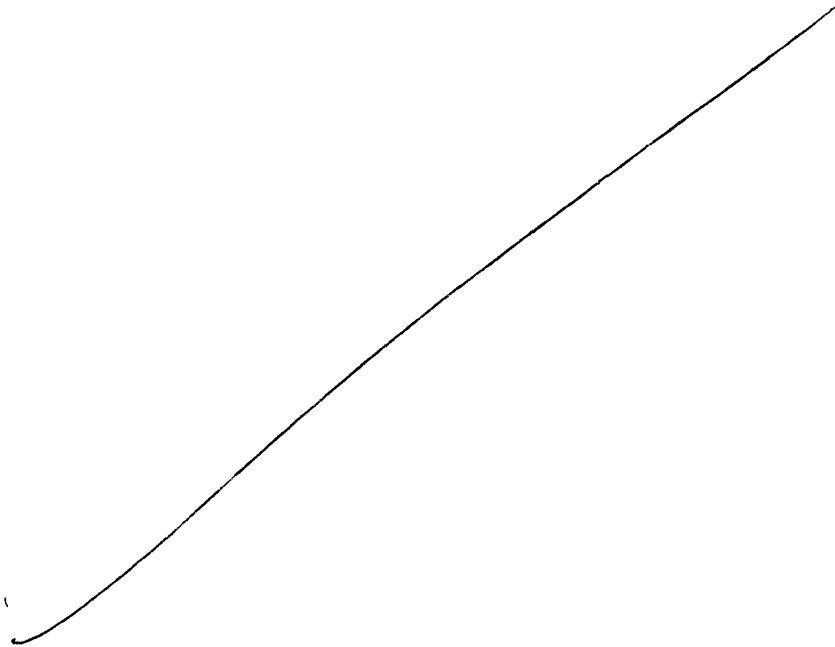
Dear Ms. Crumpton;

This letter is a response to your letter dated December 1 and received on December 2, 1999. The following is the general action plan in response to your letter. Unless otherwise listed in any action item below all activities will be completed by January 6th, 2000. All required documentation will be forwarded to you on or before then.

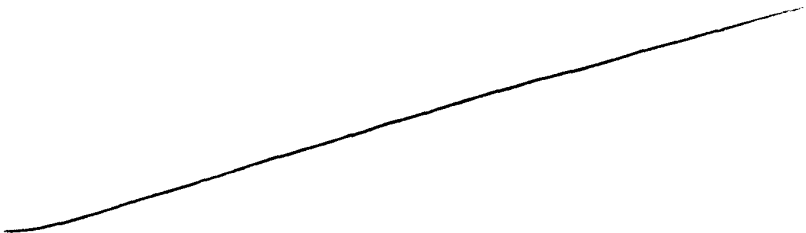




H. Confirmatory Tests



J. Records Audit



M. Equipment and Maintenance

If you have any questions please do not hesitate to call me at (858) 677-7970, extension 117.

Sincerely,



Kenneth C. Wahl
Responsible Person



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 9, 1999

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of December 6, 1999, provided in response to the deficiencies cited during the second inspection of your laboratory as outlined in our correspondence of December 1, 1999. The plan to clarify and/or correct the deficiencies noted was found acceptable. However, the following item was noted during our review of submitted material:

The laboratory must submit the final report within 30 calendar days of receipt of this letter. This report must include documentation to demonstrate completion of remedial actions outlined in your correspondence. If you have any questions or want to further clarify any of these issues, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/220



San Diego Reference Laboratory
6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (858) 550-7344 fax: (858) 677-7998

received
01/05/00

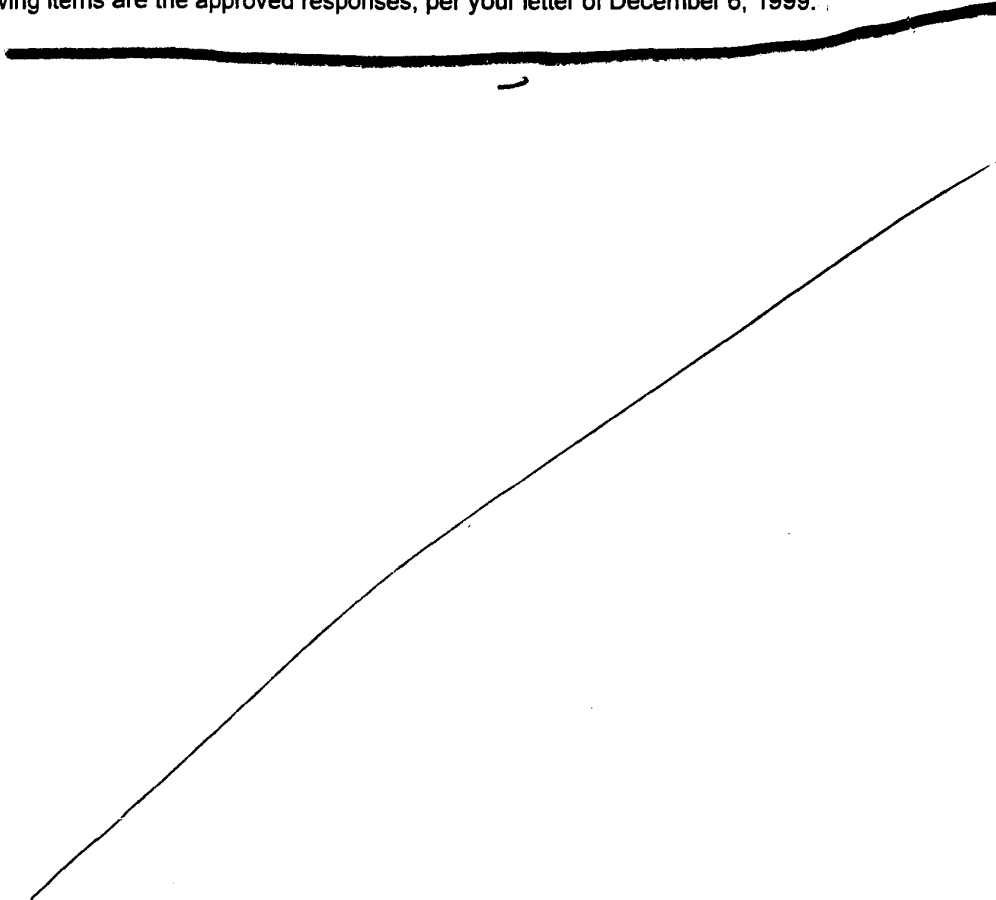
January 4, 2000

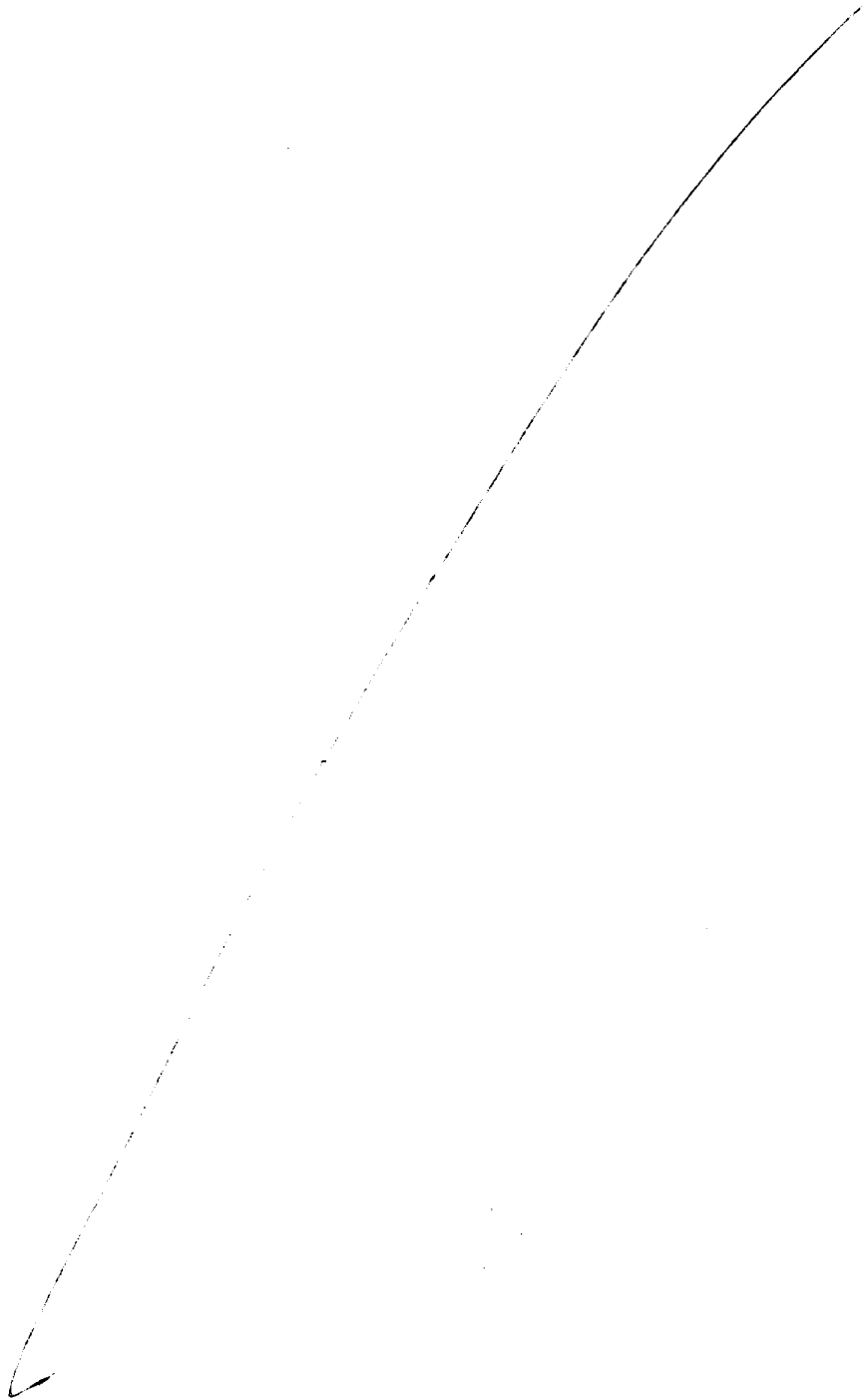
Ms. Susan Crumpton
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

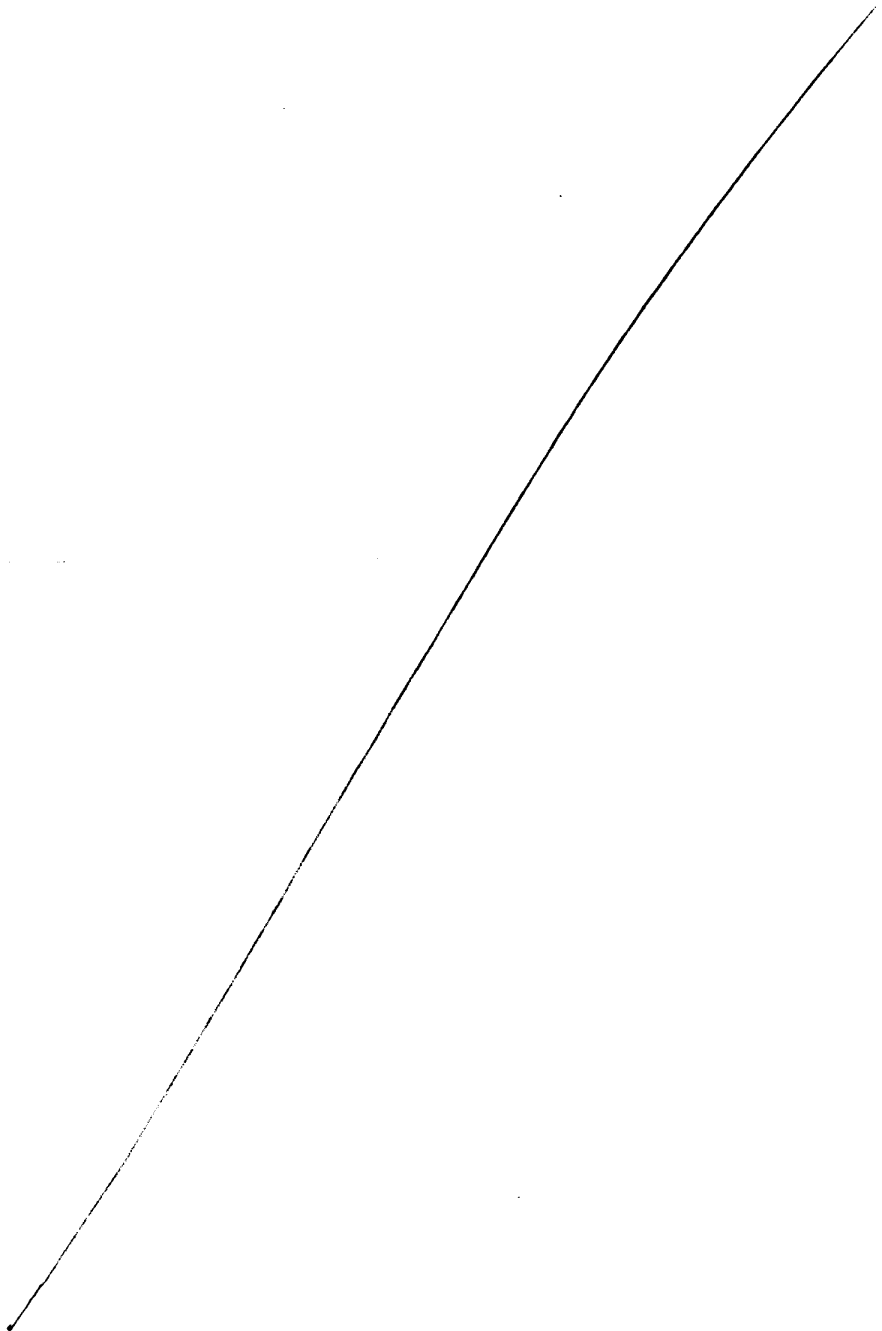
Re: Inspection Corrections

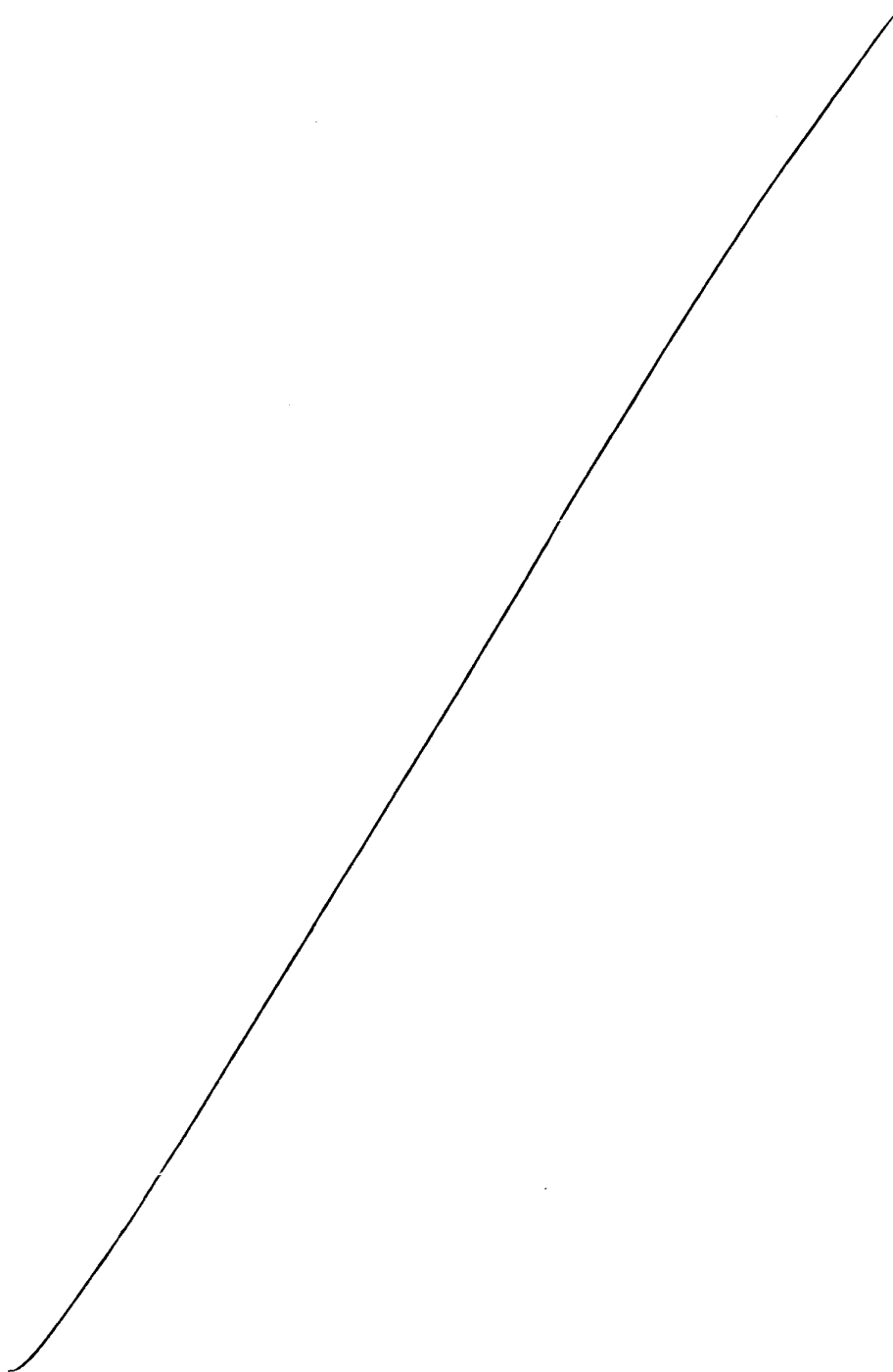
Dear Ms. Crumpton;

This letter is a response to your letter dated December 1 and received on December 2, 1999. The following items are the approved responses, per your letter of December 6, 1999.









If you have any questions please do not hesitate to call me at (858) 677-7970, extension 117.

Sincerely,



Kenneth C. Wahl
Responsible Person

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 10, 2000

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

We have reviewed the material provided in your correspondence of January 4, 2000, submitted in response to deficiencies cited during the second inspection of your laboratory as outlined in our correspondence of December 1, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the cited deficiencies.

The following items were noted during our review of submitted documentation:

[A large, faint, diagonal line is drawn across the page, likely a placeholder for a signature or a redaction.]

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



Mr. Wahl
Page 2 of 2
01/10/00

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,

A handwritten signature in cursive script, appearing to read "Susan Crumpton".

Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/2



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 23, 2000

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the first 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.

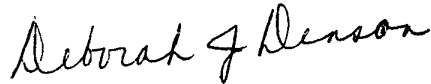
RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the 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.



Mr. Wahl
May 23, 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 Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M1



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0220
Document No. Final

Laboratory: San Diego Reference Laboratory

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M1 Date: 6 April 2000
 Other _____

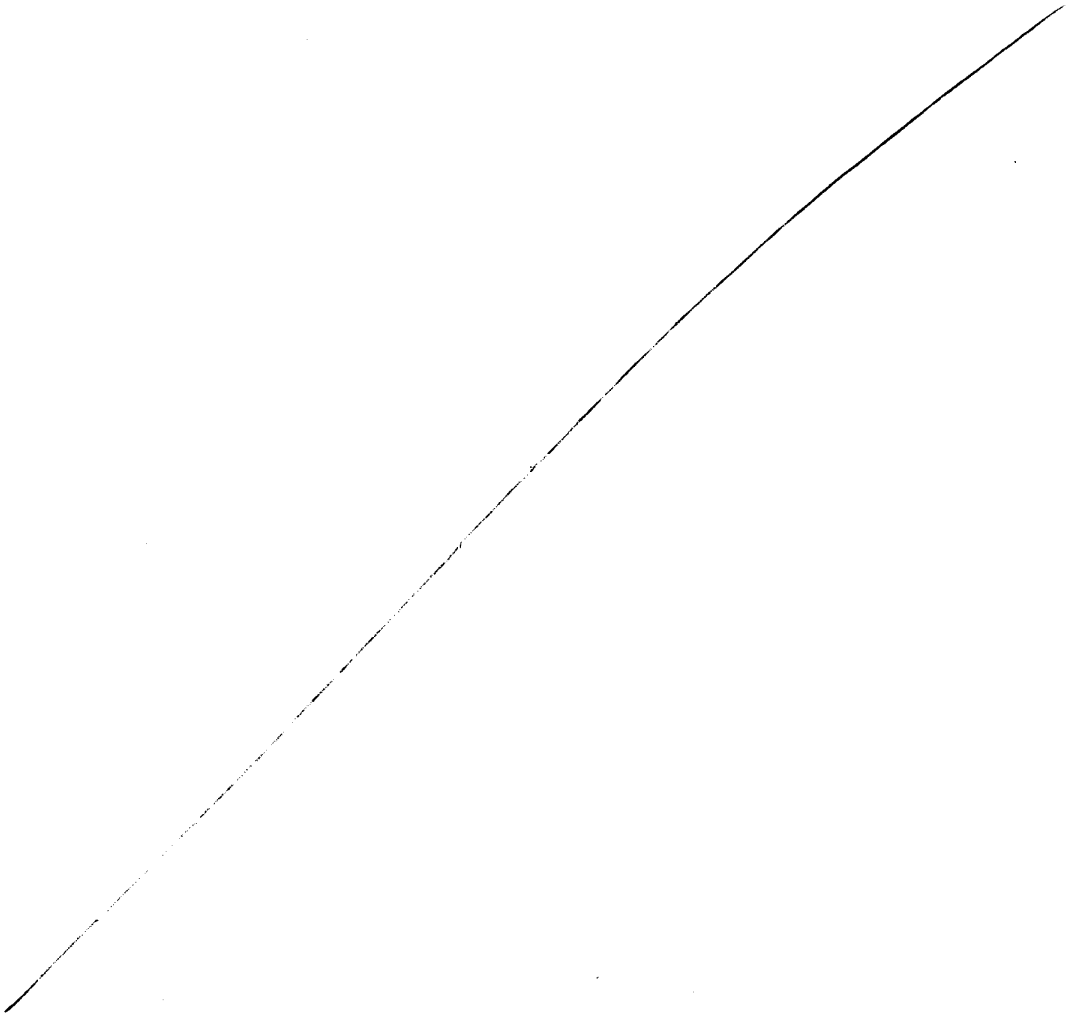
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

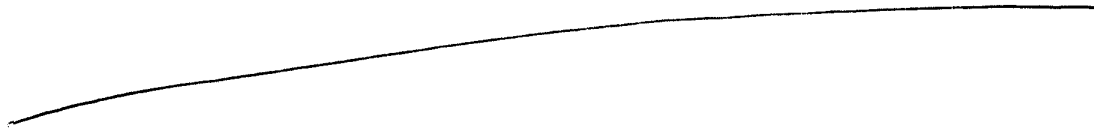
Section H. Initial Tests

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

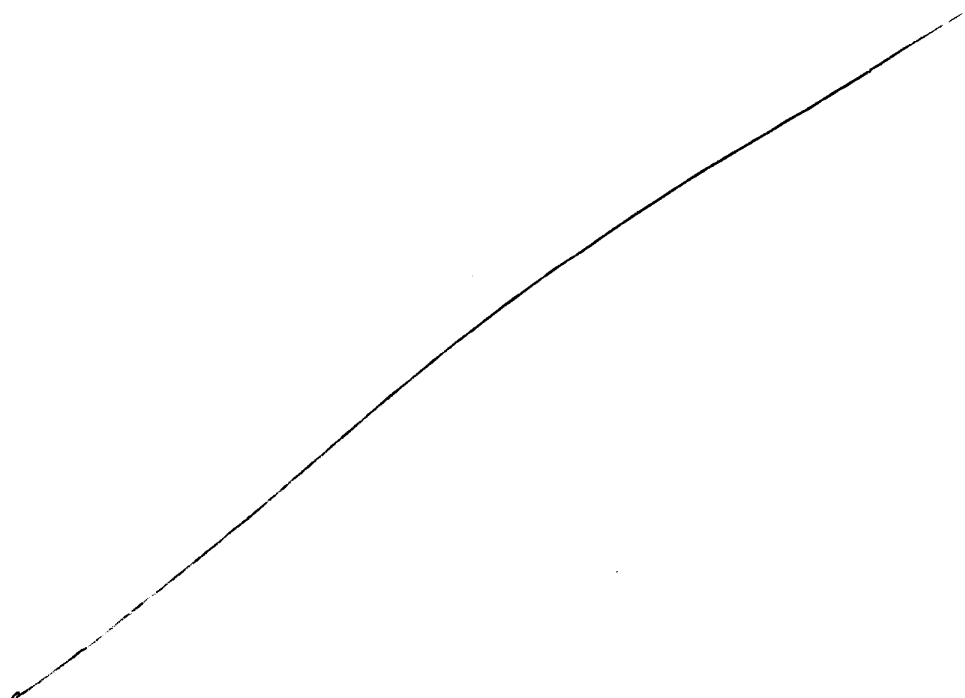
National Laboratory Certification Program

November 13, 2000

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the second 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. Wahl
November 13, 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 R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M2

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0220
Document No. Final

Laboratory: San Diego Reference Laboratory

Location: San Diego, CA

Document Reviewed: [] Application Form
 [XX] Inspection Report #M2 Date: 12 October 2000
 [] Other _____

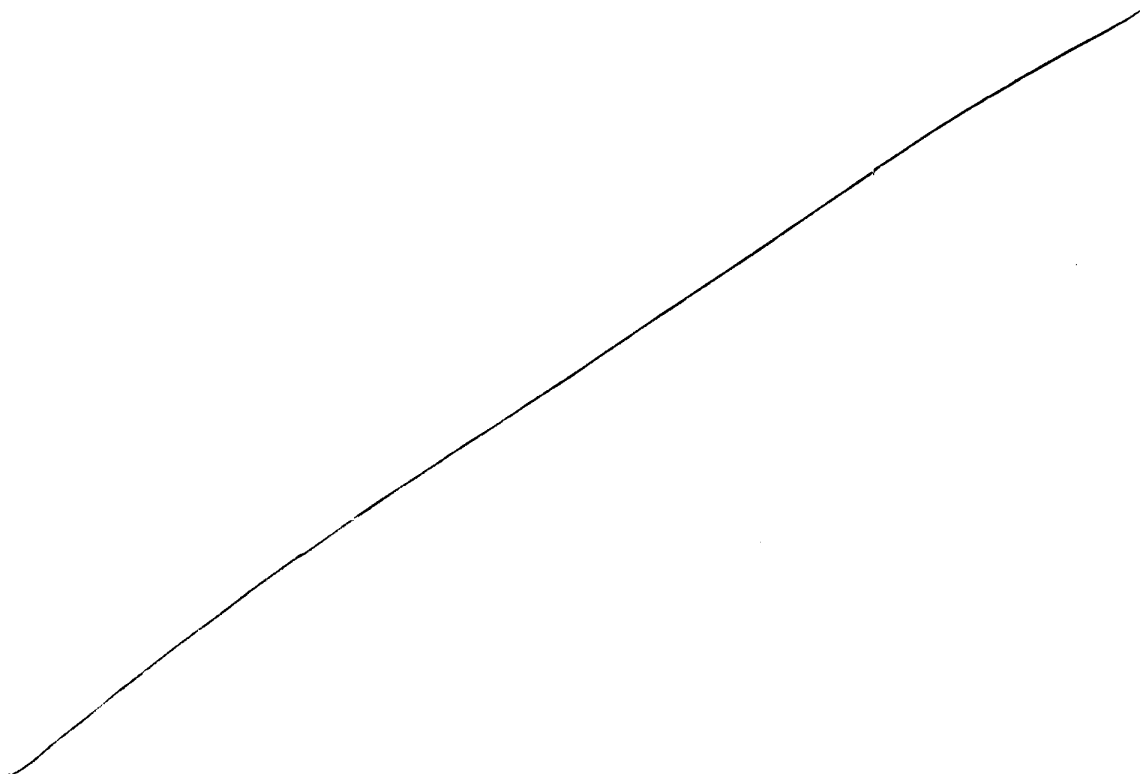
Status: [XX] Highly Acceptable [] Acceptable
 [] Unacceptable [] Failure

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.

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

