

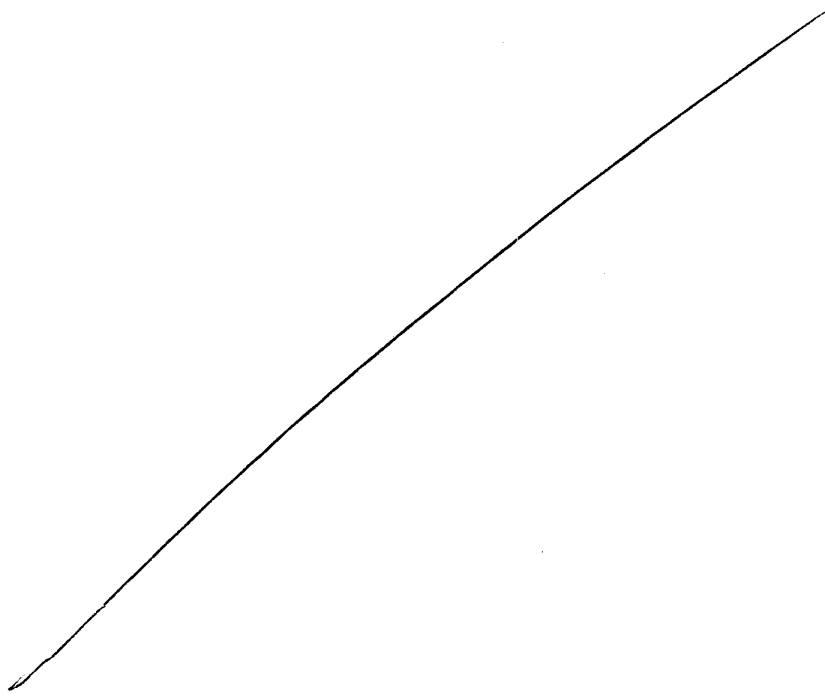


December 16, 1998

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

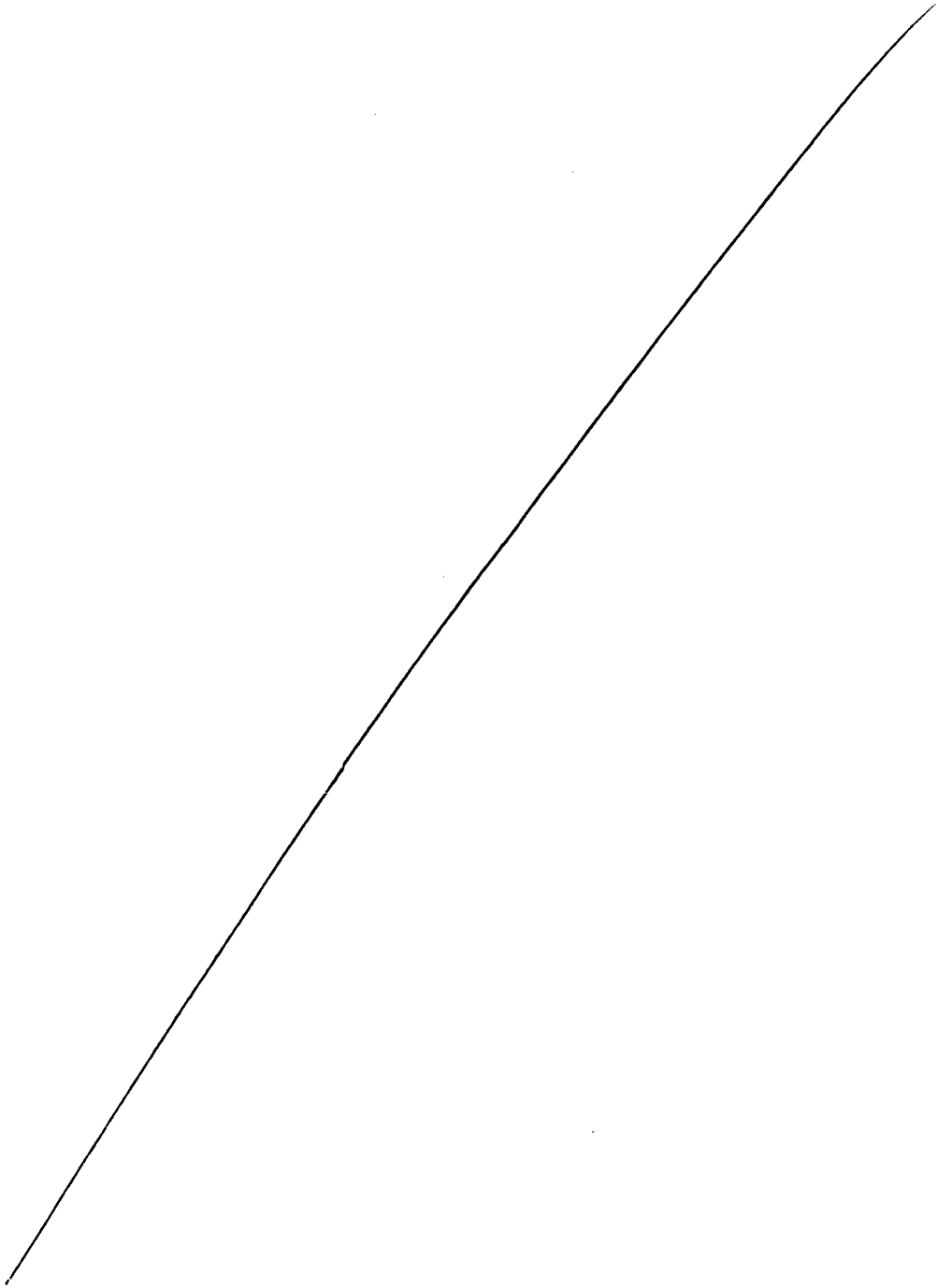
Dear Mr. Brady:

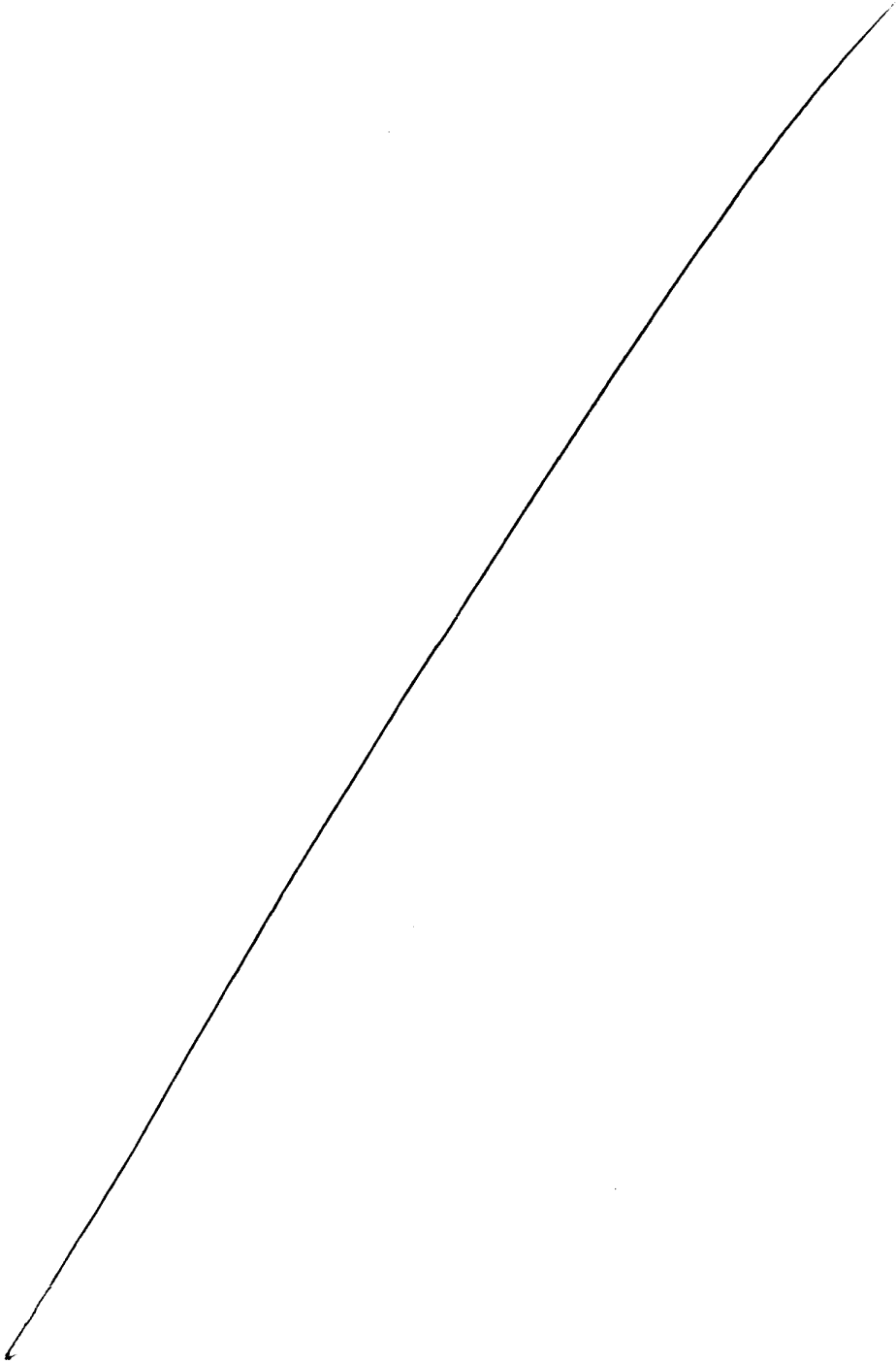
The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the outcome of the laboratory's performance in this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



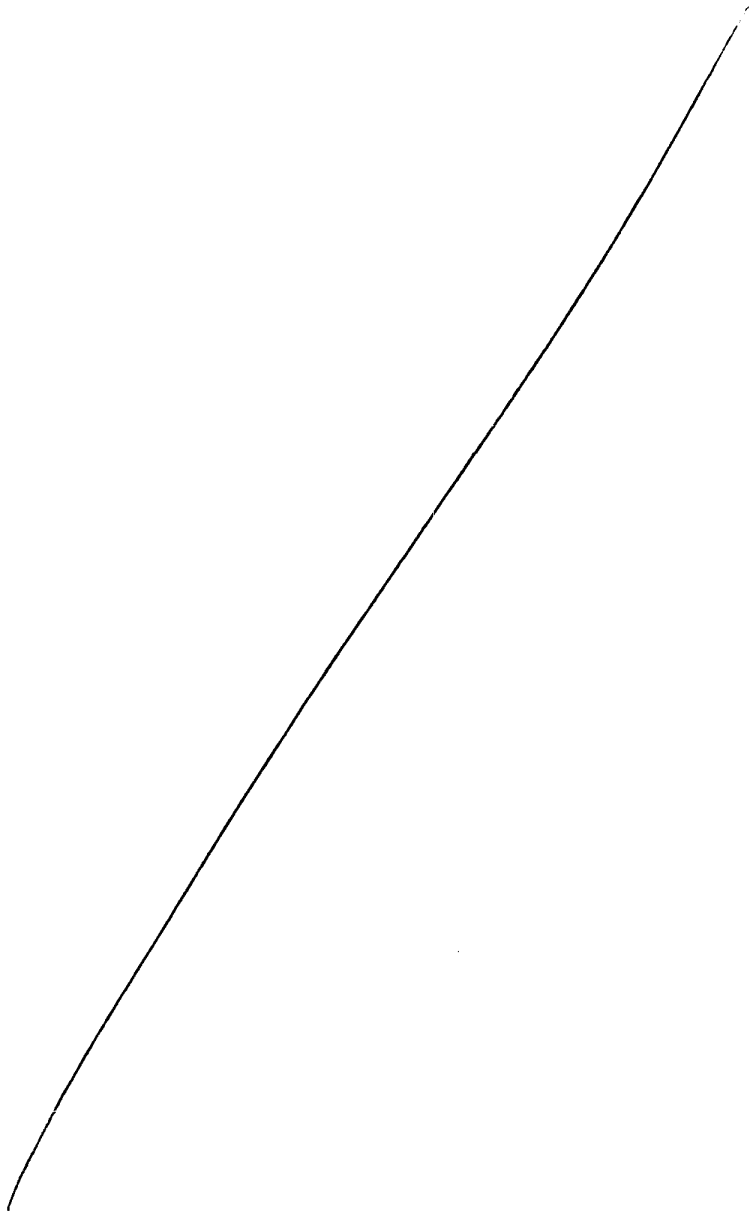
0296

Mr. Brady
Page 2 of 6
12/16/98

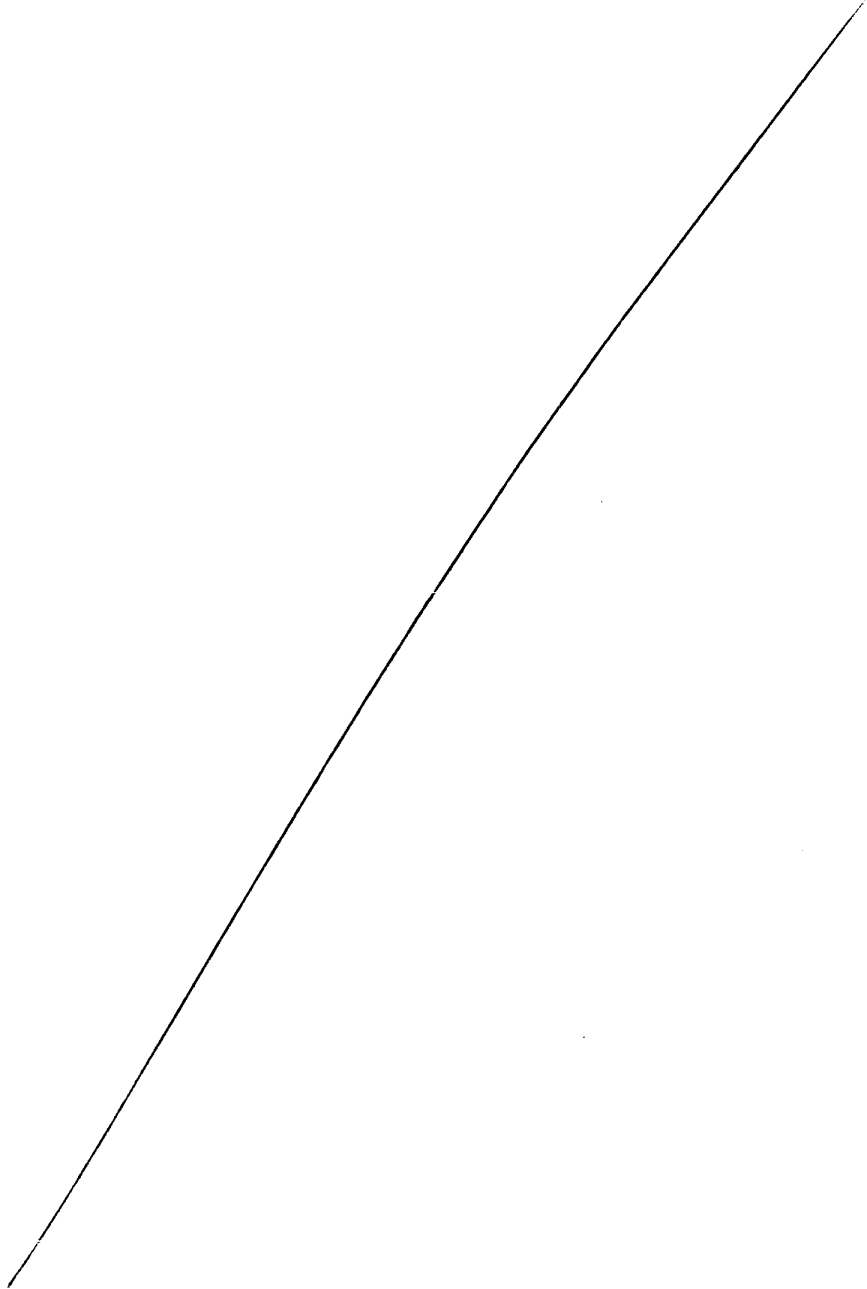




Mr. Brady
Page 4 of 6
12/16/98



Mr. Brady
Page 5 of 6
12/16/98



Mr. Brady
Page 6 of 6
12/16/98

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/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: Application Form
 Inspection Report #M15 Date: 29 October 1998
 Other _____

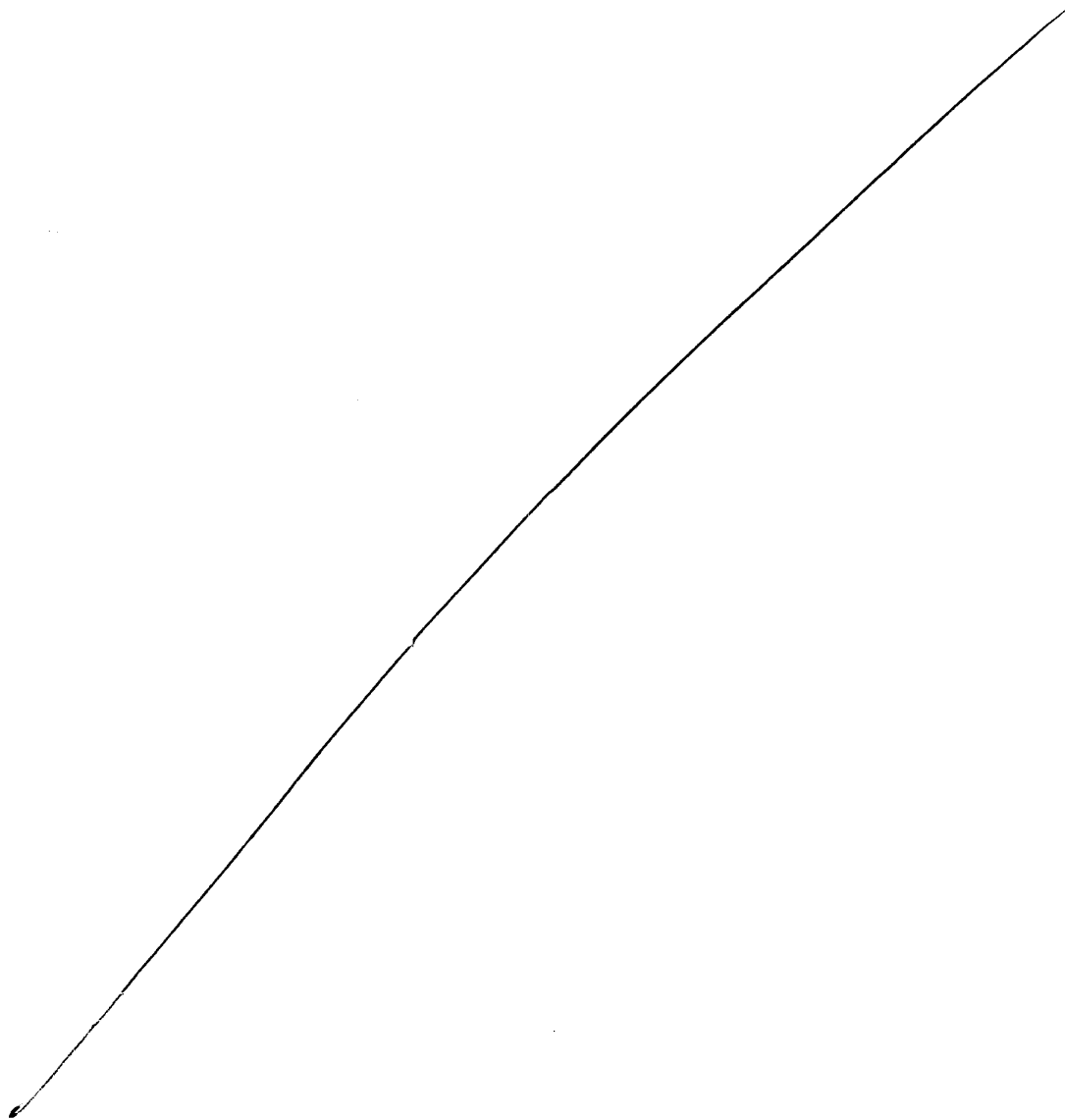
Status: Highly Acceptable Acceptable
 Unacceptable Failure

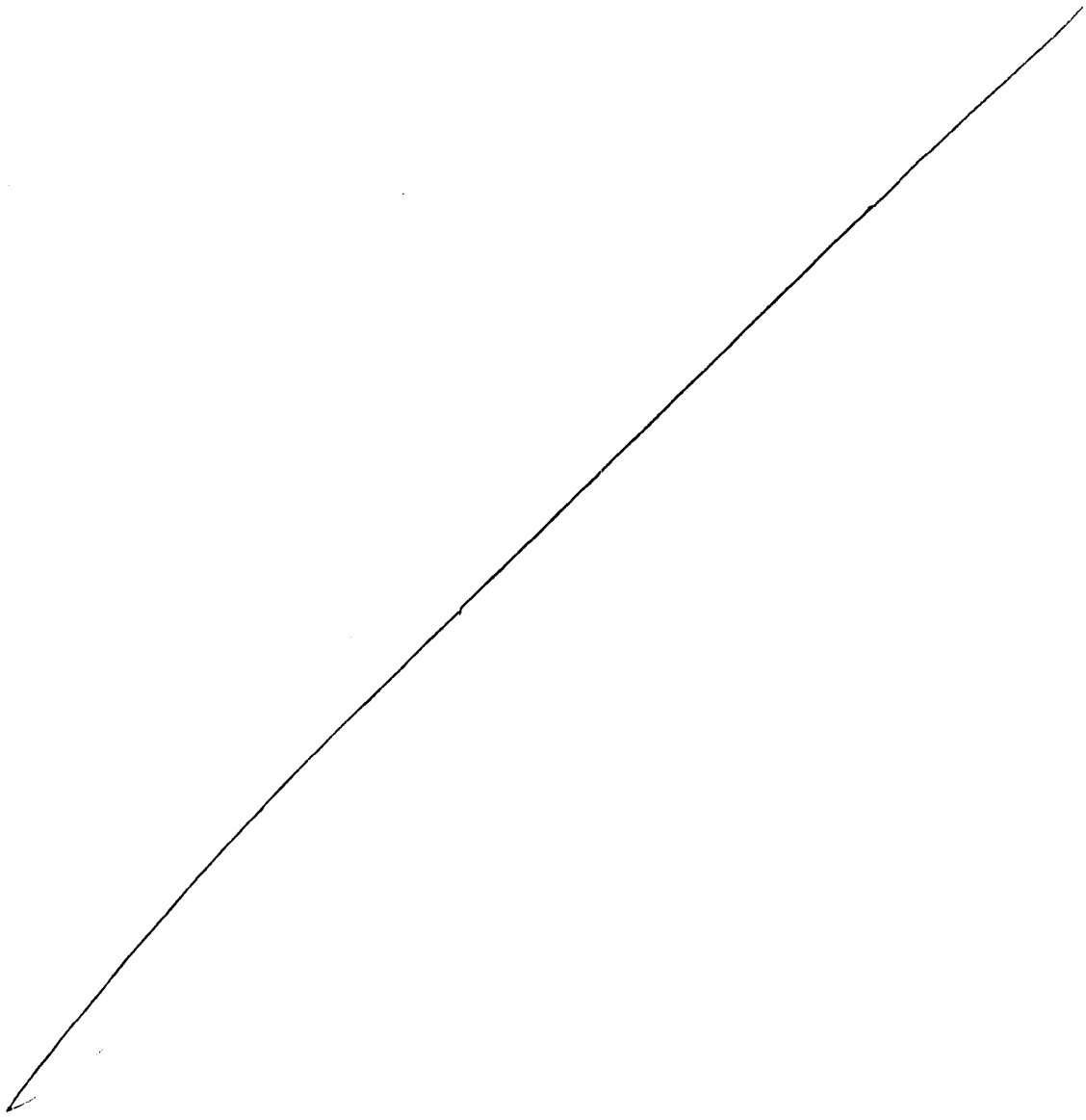
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required 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.

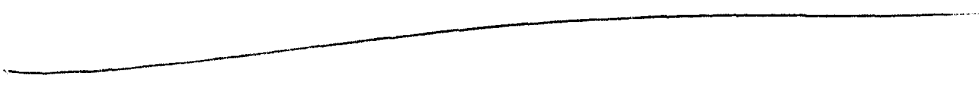
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





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



Section G. Records Audit

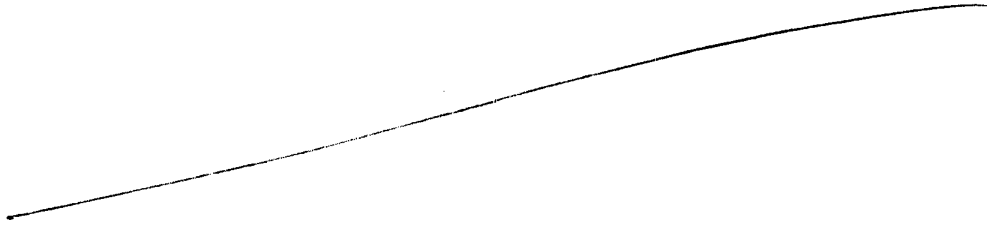
Section H. Personnel

Section I. Reagents

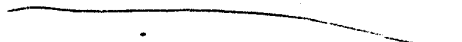
Section J. Quality Control and Standards

Section K. Reporting

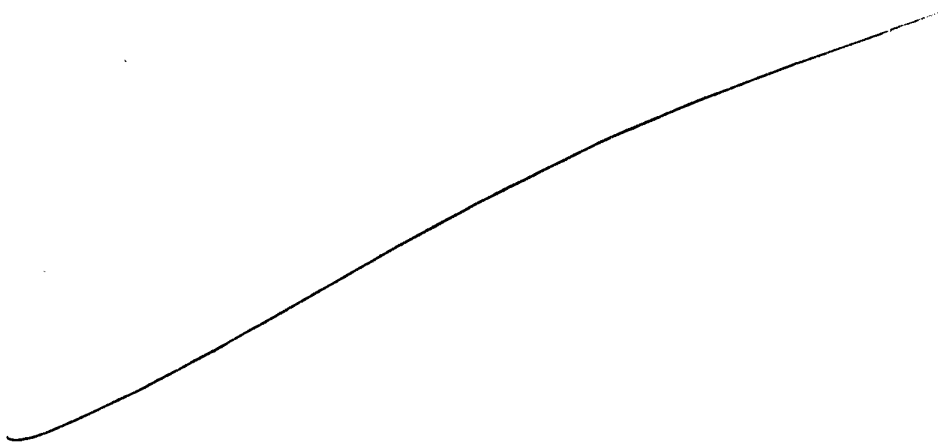
Section L. Equipment and Maintenance

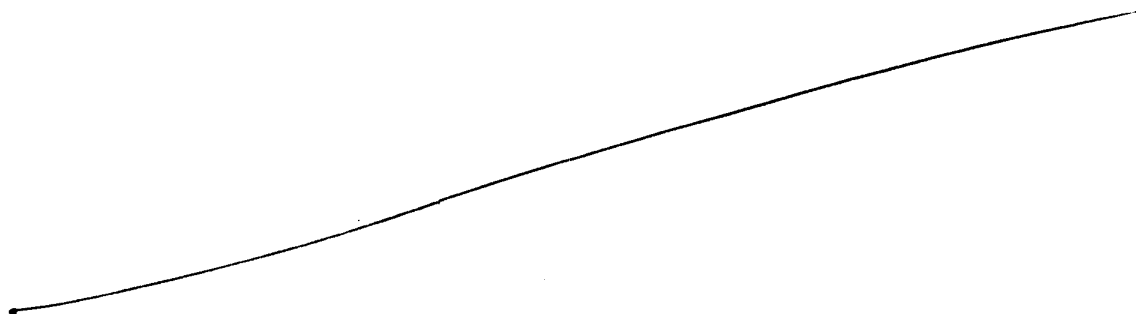


Section M. Immunoassay



Section N. Gas Chromatography/Mass Spectrometry





received
11/4/99 SDC



December 23, 1998

Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.

S.E.D. Medical Laboratories

5601 Office Blvd., NE

Albuquerque, New Mexico 87109-5811

505-727-6300

800-999-LABS

Fax 505-727-6315

P.O. Box 12194

Research Triangle Park, North Carolina 27709-2194

The enclosed is in response to your critique of our laboratory as a result of our fifteenth maintenance inspection under the National Laboratory Certificate Program (NLCP), which we received on December 18, 1998.

James E. Farius
President and CEO

Jonny L. Salyer, MD
Medical Director

Thomas A. Kettb, MD

I. David Mones, MD

Scott Otteson, MD

Ellen J. Giampoli, MD

Emeritus:

S. Victor Savino, MD

David W. Dain, MD

Alan G. Engberg, MD

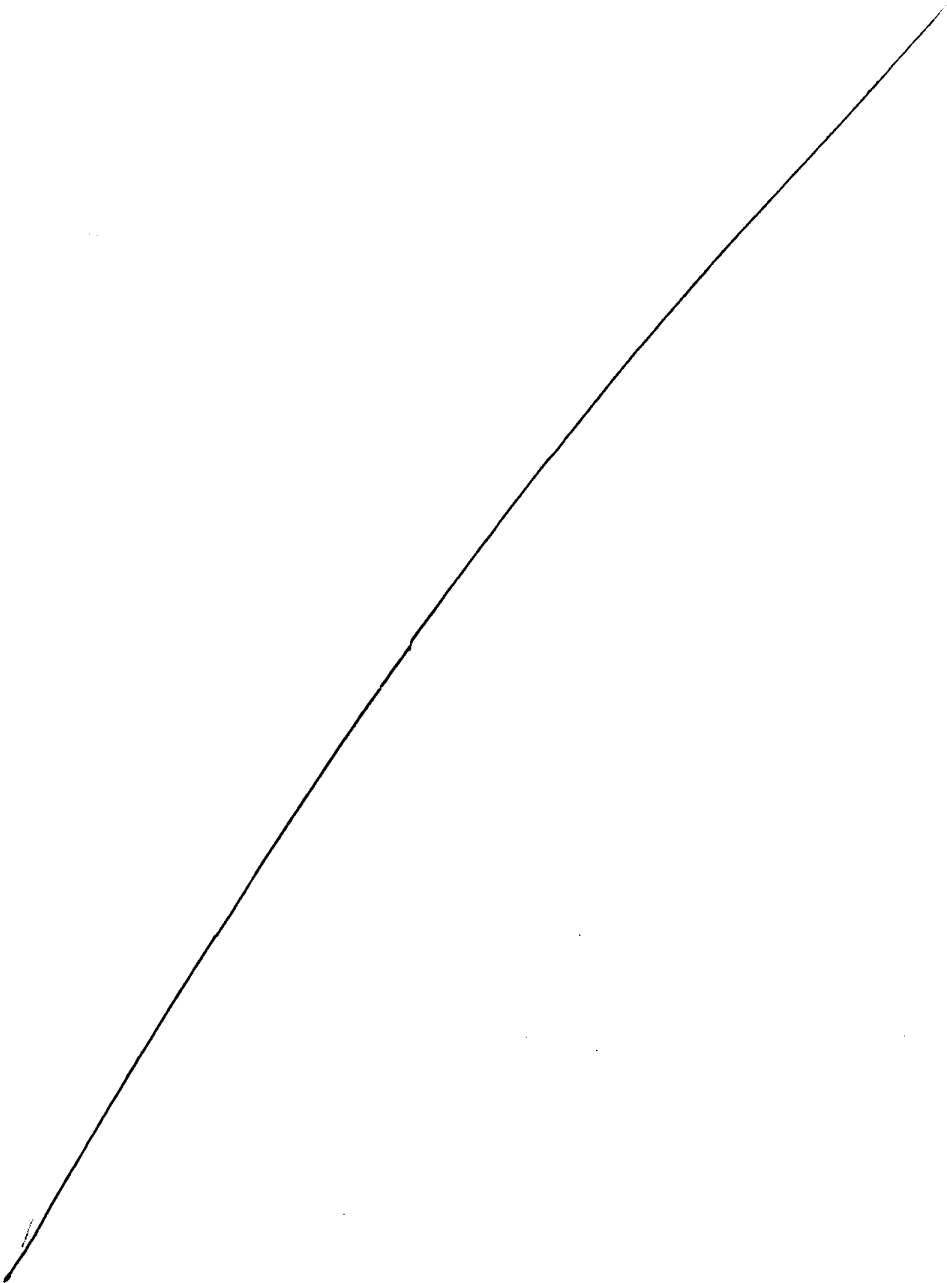
Robert M. List, MD

Nanci M. George
Vice President, Marketing

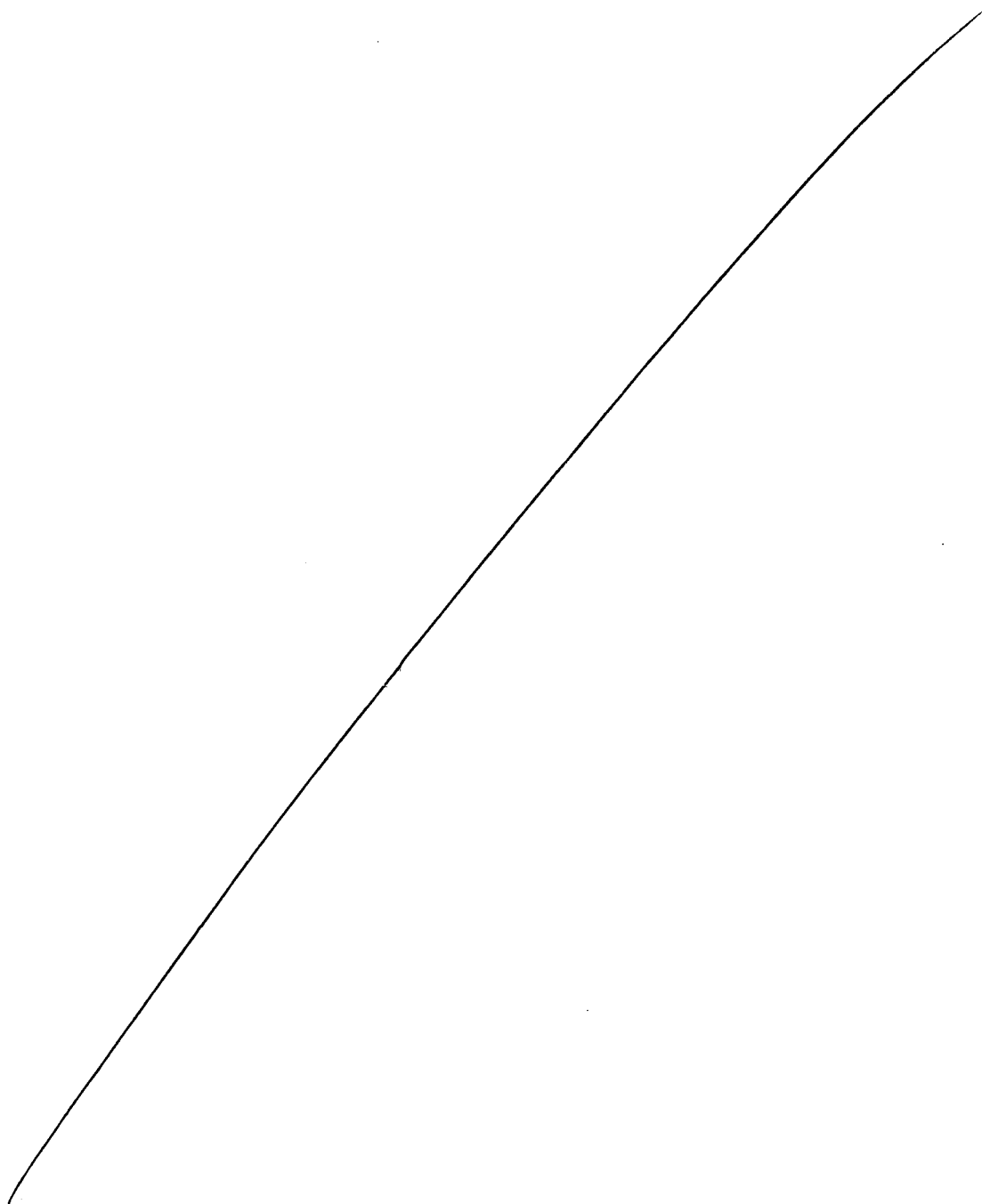
Hector Sanchez, MS, MT(ASCP)
Vice President, Operations

Kari A. Young, CPA
Vice President, Finance

Ms. Susan Crumpton
Page 2 of 6
12/23/98



Ms. Susan Crumpton
Page 3 of 6
12/23/98



G.1. Records Audit.

G.7. Records Audit.

G.8. Records Audit.

G.9. Records Audit.

G.12. Records Audit.

G.17. Records Audit.

H.5g. Personnel section.

H.12. Personnel section.



J.4. Quality Control and Standards.



J.26. Quality Control and Standards.



J.27. Quality Control and Standards.



L.5. Equipment and Maintenance.



L.10. Equipment and Maintenance.



L.12. Equipment and Maintenance.



Ms. Susan Crumpton
Page 6 of 6
12/23/98

N.1b. Gas Chromatography/Mass Spectrometry.



N.3a. Gas Chromatography/Mass Spectrometry.




N.8d. Gas Chromatography/Mass Spectrometry.



N.14a. Gas Chromatography/Mass Spectrometry.



Sincerely,



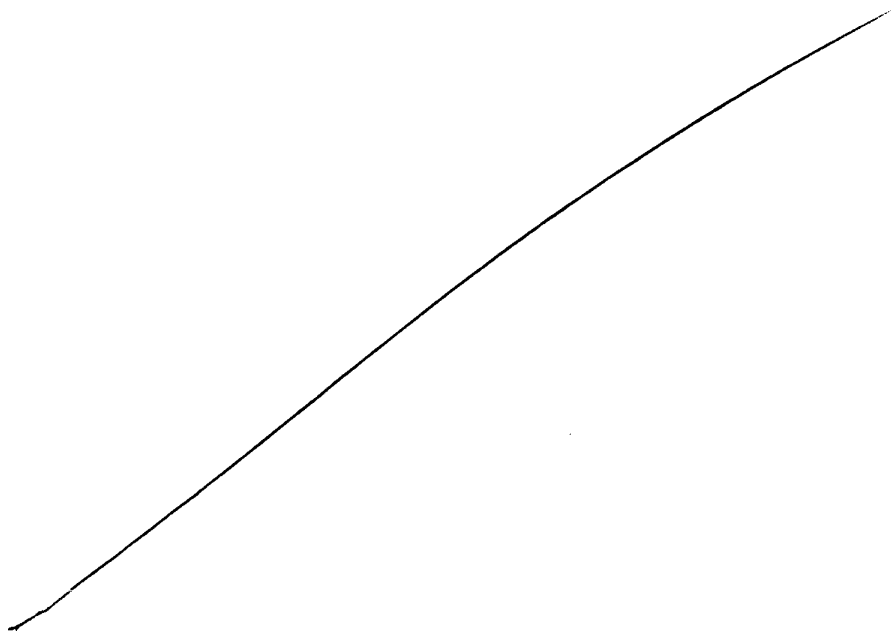
Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories

January 5, 1999

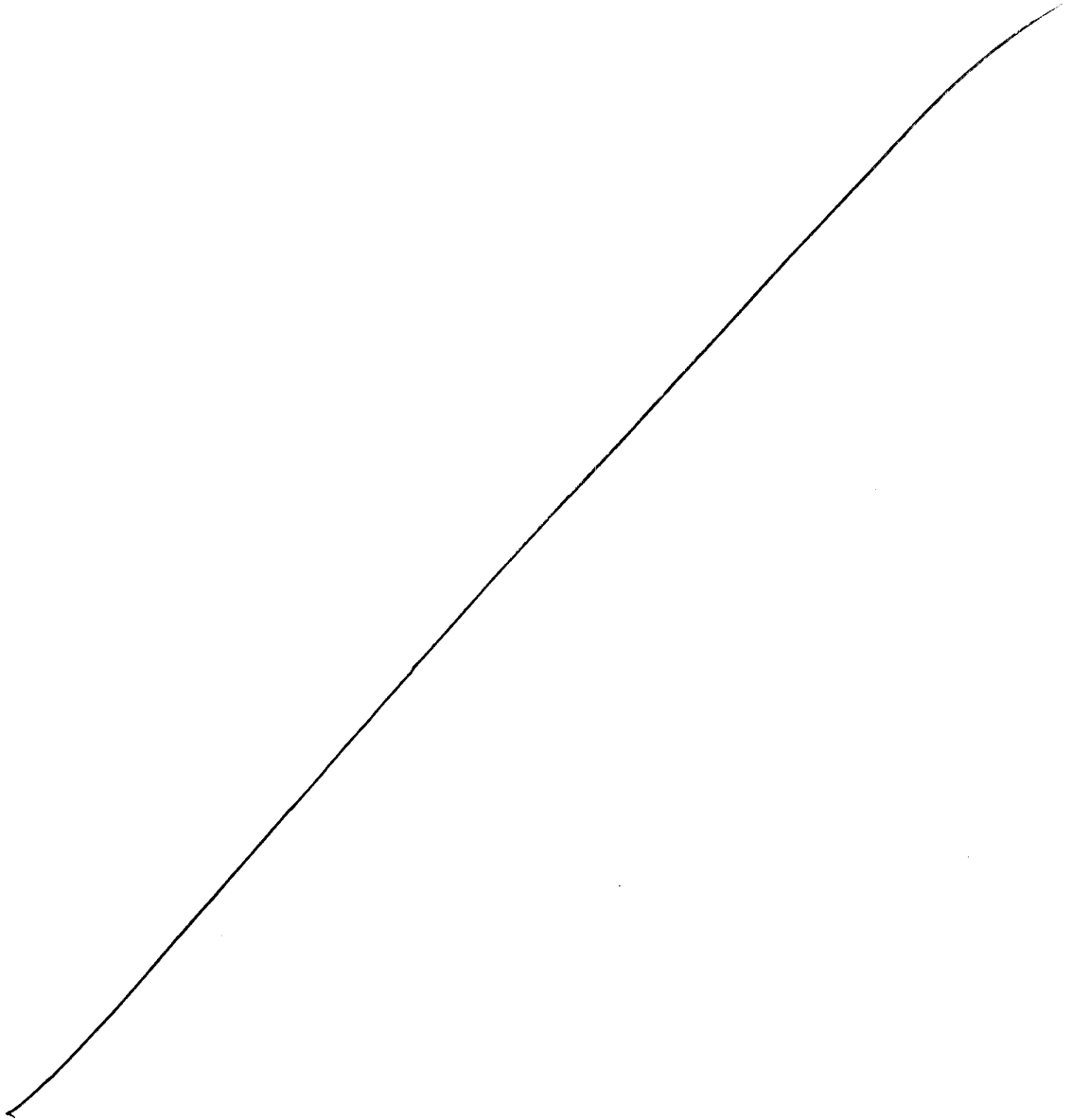
0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of December 23, 1998. This plan addressed the deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of December 16, 1998. The plan to clarify and/or correct the deficiencies noted was found acceptable. However, the following issues were raised during our review:



Mr. Brady
Page 2 of 3
01/05/99



Mr. Brady
Page 3 of 3
01/05/99

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 D. Crumpton
NLCP Inspection Analyst

cc: Project Files/M15

received
SDC 2/5/99



February 4, 1999

Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
Research Triangle Park, North Carolina 27709-2194

S.E.D. Medical Laboratories

5001 Office Blvd., NE
Albuquerque, New Mexico 87109-5816
505-727-6300 800-999-LABS
Fax 505-727-6315

The enclosed is in response to your critique of our laboratory as a result of our fifteenth maintenance inspection under the National Laboratory Certificate Program (NLCP), which we received on January 7, 1999.

James E. Fantus
President and CEO

Jonny L. Sulzer, MD
Medical Director

Thomas A. Keith, MD

I. David Mones, MD

Scott Otteson, MD

Ellen J. Giampoli, MD

Emeritus:

S. Victor Savino, MD

David W. Dain, MD

Alan G. Engberg, MD

Robert M. List, MD

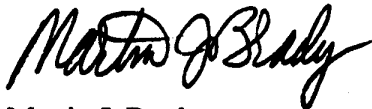
Nanci M. George
Vice President, Marketing

Hector Sanchez, MS, MT(ASCP)
Vice President, Operations

Karl A. Young, CPA
Vice President, Finance

Ms. Susan Crumpton
Page 2 of 2
2/4/99

Sincerely,

A handwritten signature in cursive script that reads "Martin J. Brady".

Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories

February 12, 1999

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5801 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

We have reviewed the material provided in your correspondence of February 4, 1999, submitted in response to deficiencies cited during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of January 5, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most deficiencies cited. However, the following issues remain:

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 (NLCP). The laboratory must take steps to correct the issues cited above. All corrective actions must be



Mr. Brady
Page 2 of 2
02/12/99

implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

cc: Project Files/M15

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 27, 1999

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

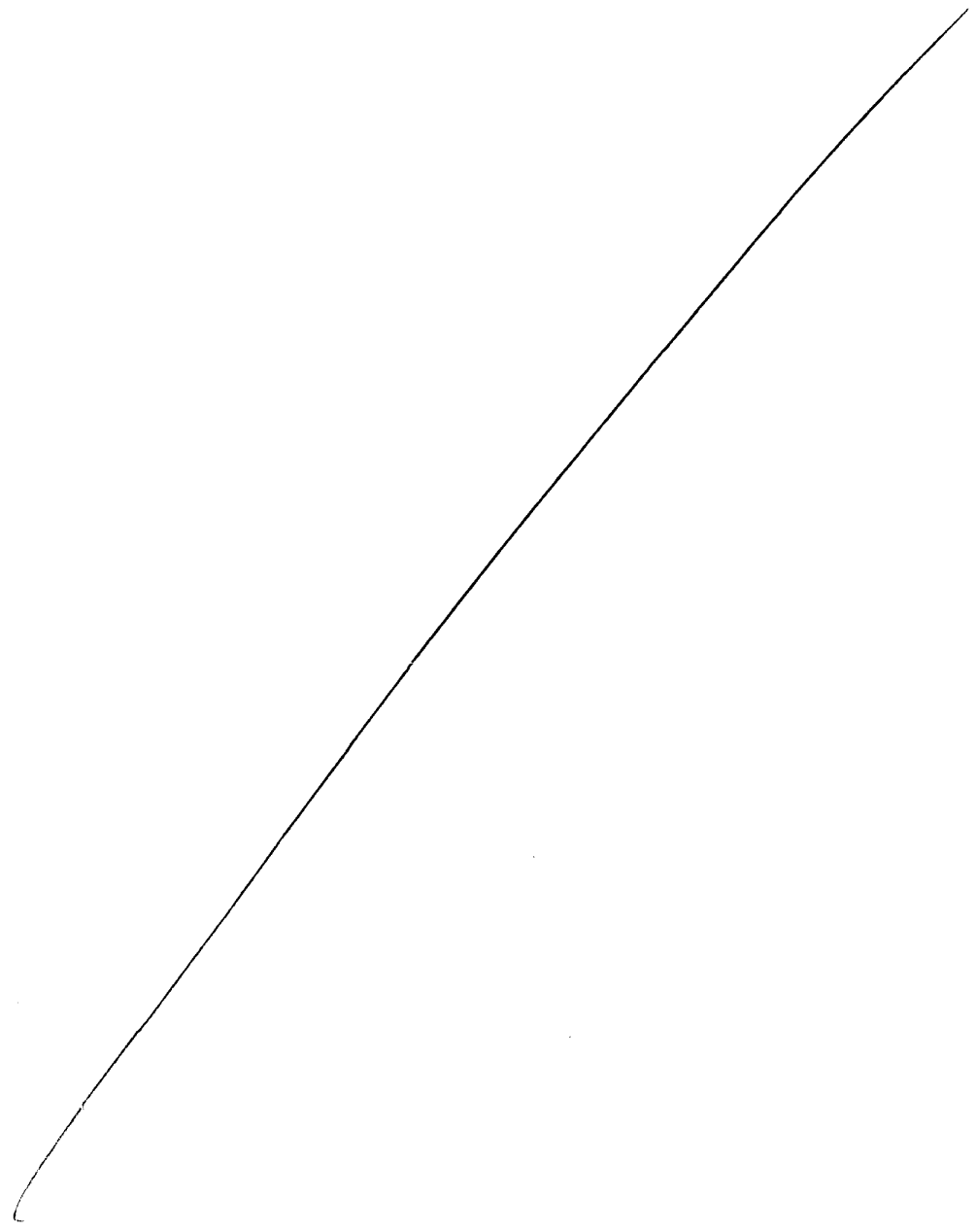
Dear Mr. Brady:

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

MAR-19-01 MON 01:55 PM SED TOX CLIENT SERVICES

FAX NO. 00000000

Mr. Brady
May 27, 1999
Page 2 of 3



Mr. Brady
May 27, 1999
Page 3 of 3

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/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: Application Form
 Inspection Report #M16 Date: 15 April 1999
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

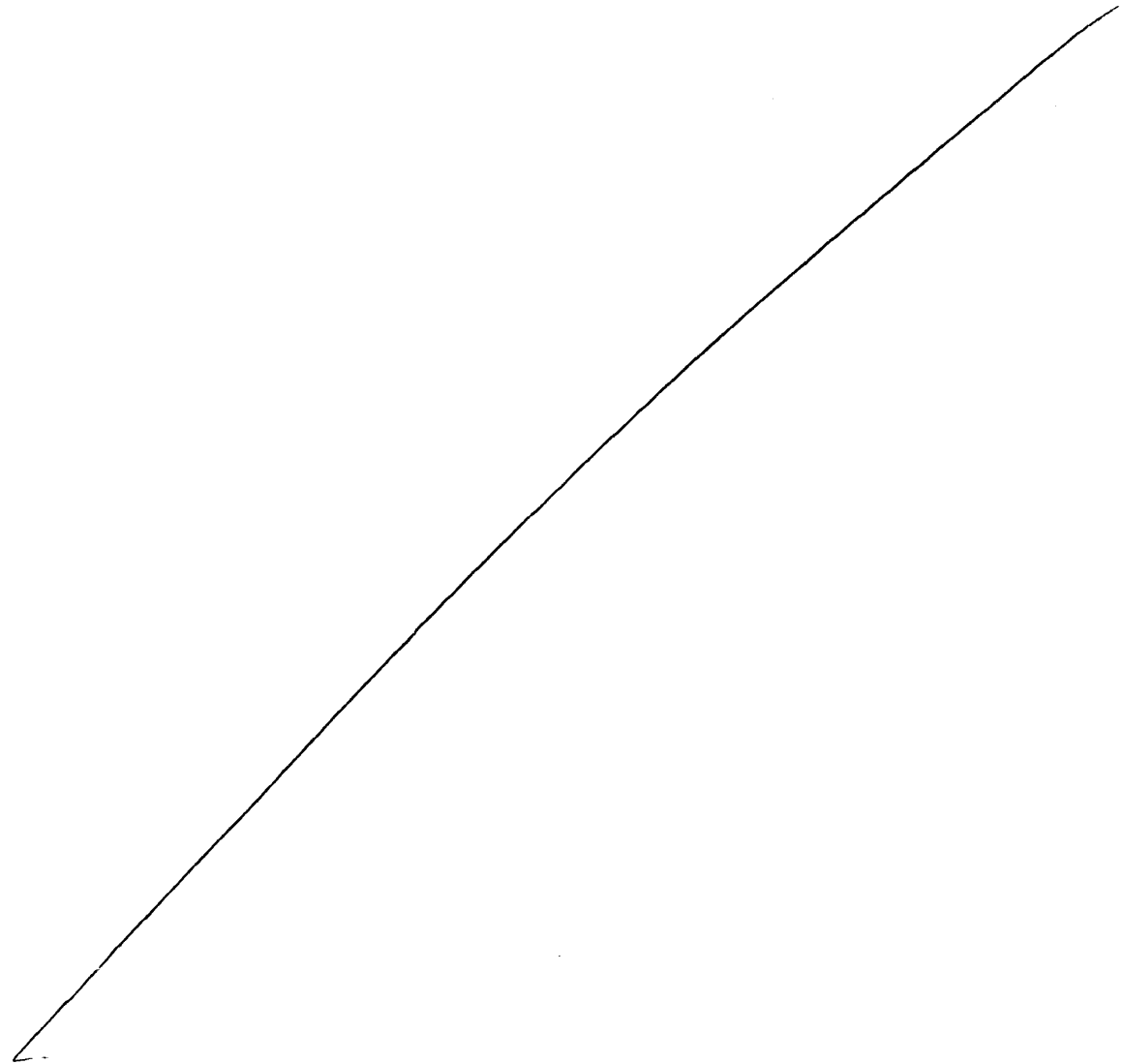
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

Ver. Final

Lab ID# 0296

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# 0296

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

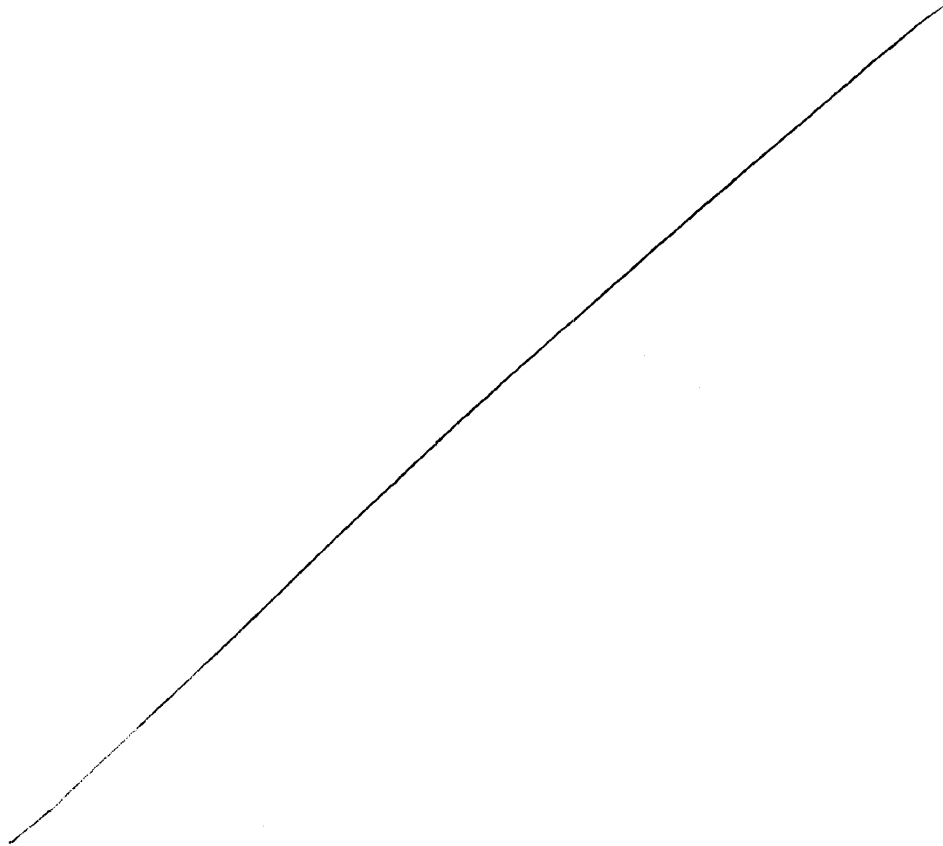
Section G. Quality Control

Triangle Institute

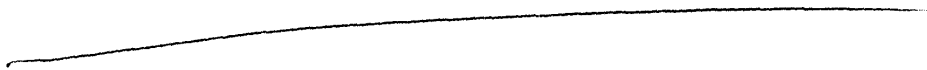
Ver. Final

Lab ID# 0296

Section H. Initial Tests



Section I. Confirmatory Tests



Ver. Final

Lab ID# 0296

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 3, 1999

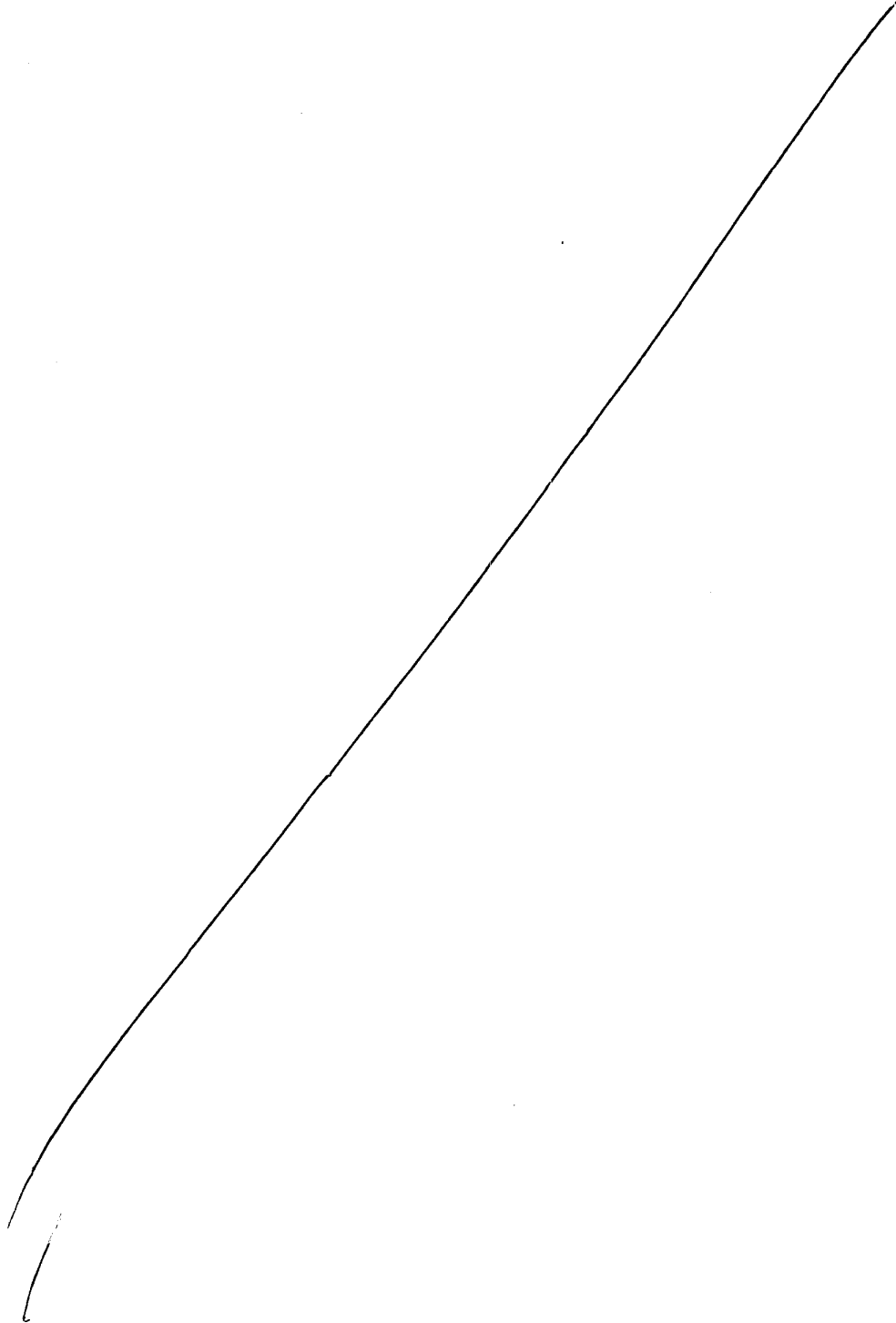
0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

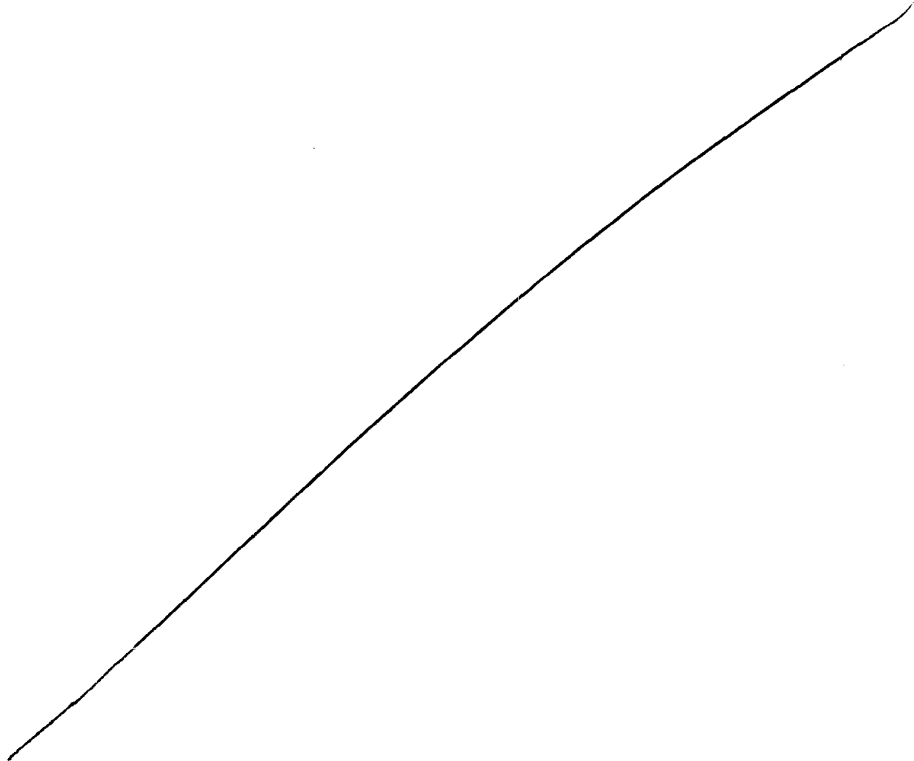
The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection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



Mr. Brady
December 3, 1999
Page 2 of 4



Mr. Brady
December 3, 1999
Page 3 of 4



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

Mr. Brady
December 3, 1999
Page 4 of 4

Enclosure
cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: Application Form
 Inspection Report #M17 Date: 21 October 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.

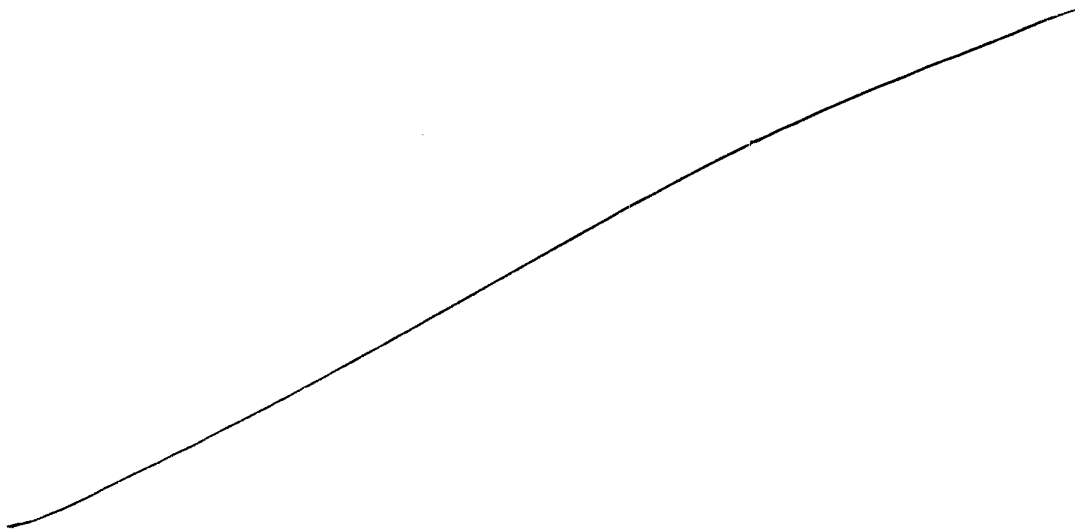
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

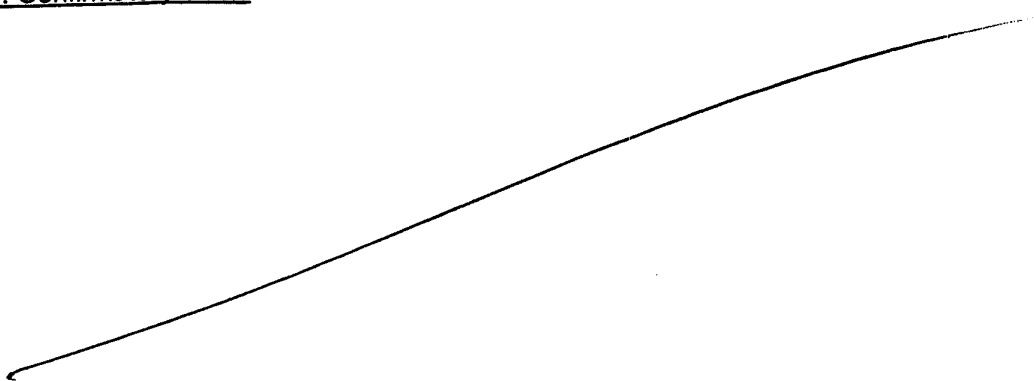
Section G. Quality Control



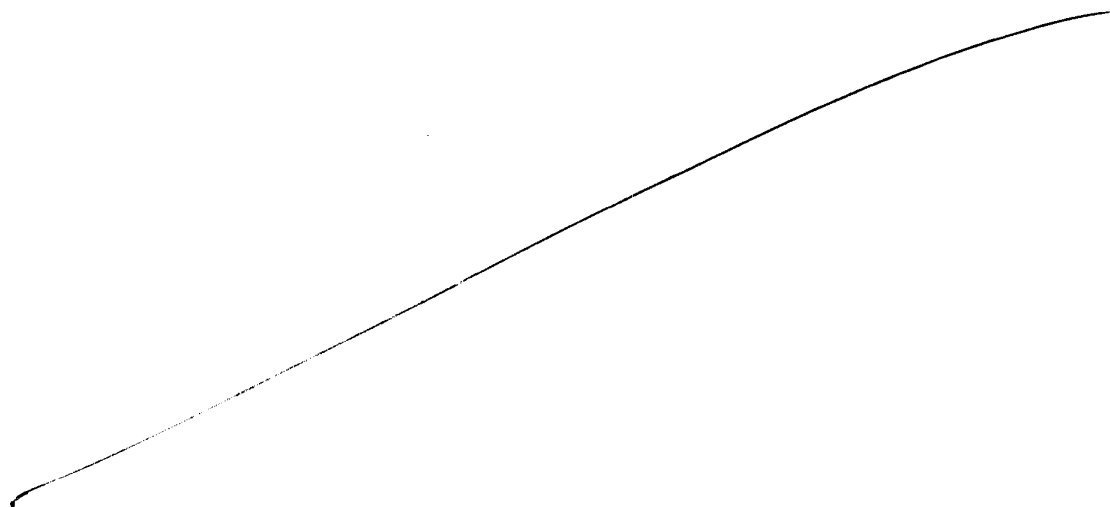
Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



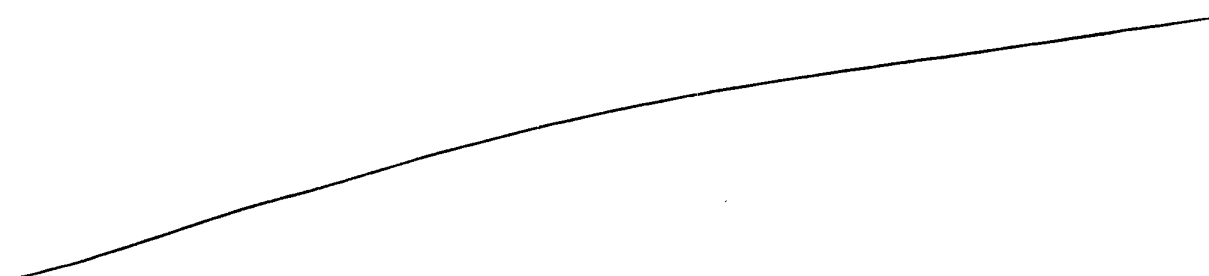
Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



received
01/05/2000 SD



January 4, 2000

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
Research Triangle Park, North Carolina 27709-2194

Medical Laboratories
5601 Office Blvd., NE
Albuquerque, New Mexico 87109-5816
505-727-6300 800-999-LABS
Fax 505-727-6205

The enclosed is in response to your critique of our laboratory as a result of our seventeenth maintenance inspection under the National Laboratory Certification Program (NLCP), which we received on December 6, 1999.

James E. Fantus
President and CEO

Jonny L. Salver, MD
Medical Director

Thomas A. Keith, MD

I. David Mones, MD

Scott Otteson, MD

Ellen J. Giampoli, MD

Lami Stoddart, MD

Emeritus:
S. Victor Savino, MD
David W. Dain, MD
Alan G. Engberg, MD
Robert M. List, MD

Nanci M. George
Vice President, Marketing

Kari Young, CPA
Vice President, Finance

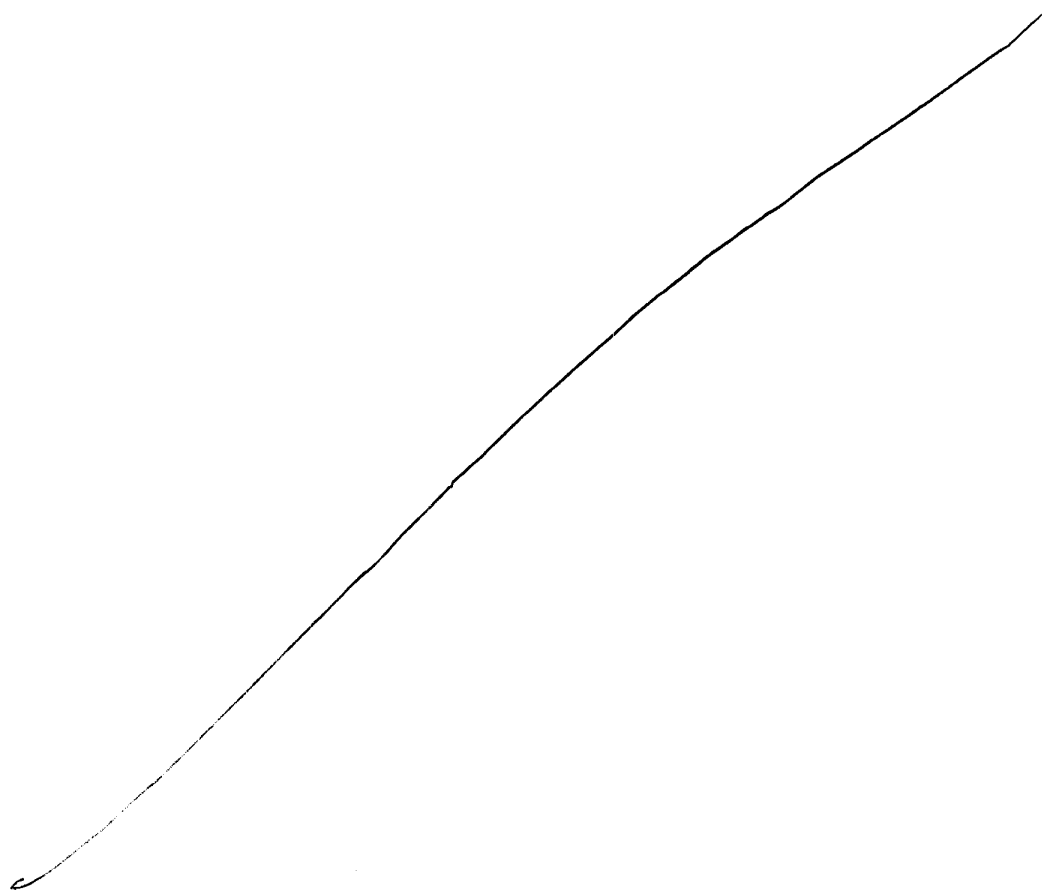
Charley Newcomb
Chief of Information Systems

Denise Ballou MS, MT (ASCP)
Director, Technical Operations

Liz Pratt, MT (ASCP)
Director, Service Operations

Rebecca Falance, SPHR
Director, Human Resources

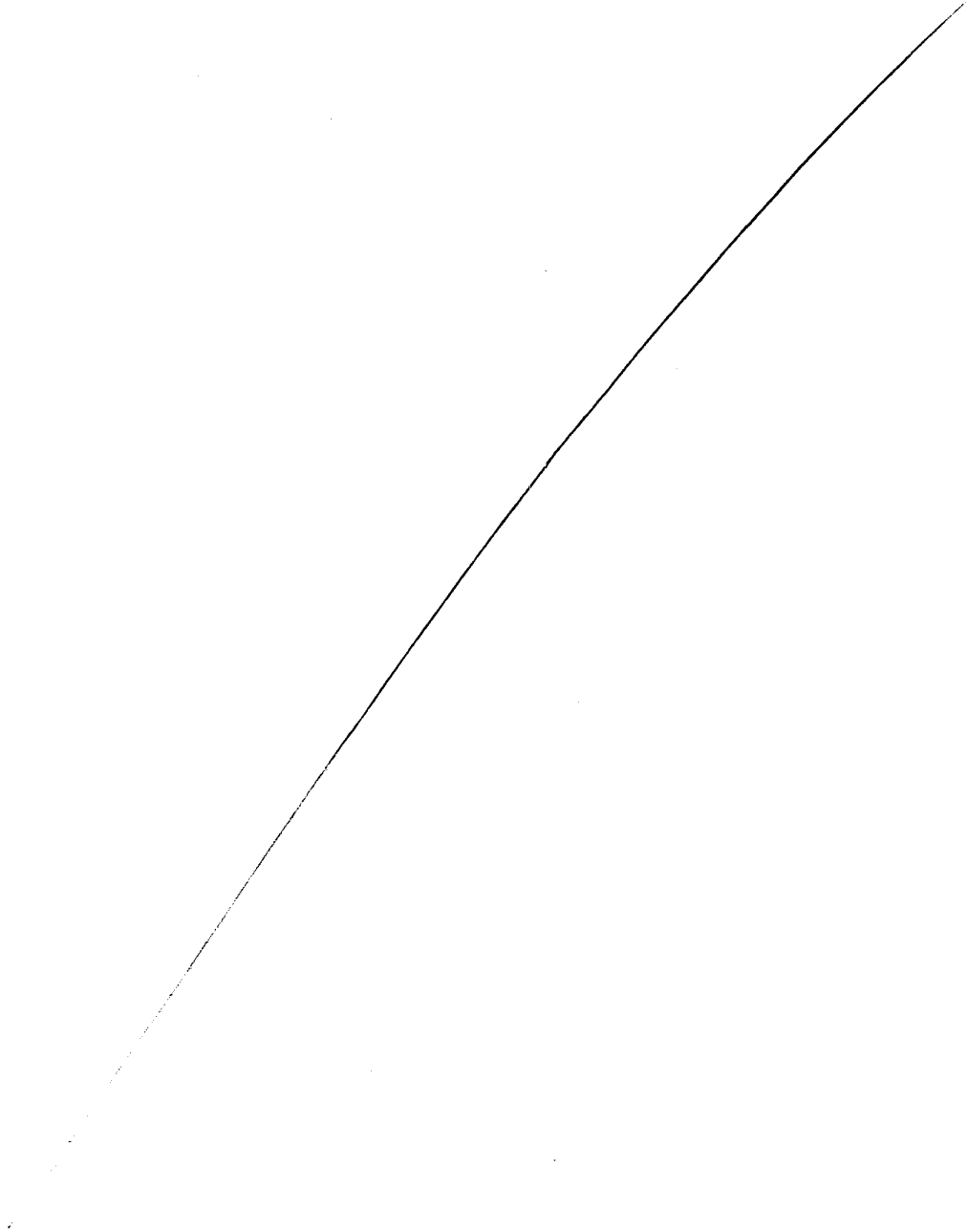
Ms. Deborah J. Denson
Page 2 of 6
1/4/00



Ms. Deborah J. Denson

Page 3 of 6

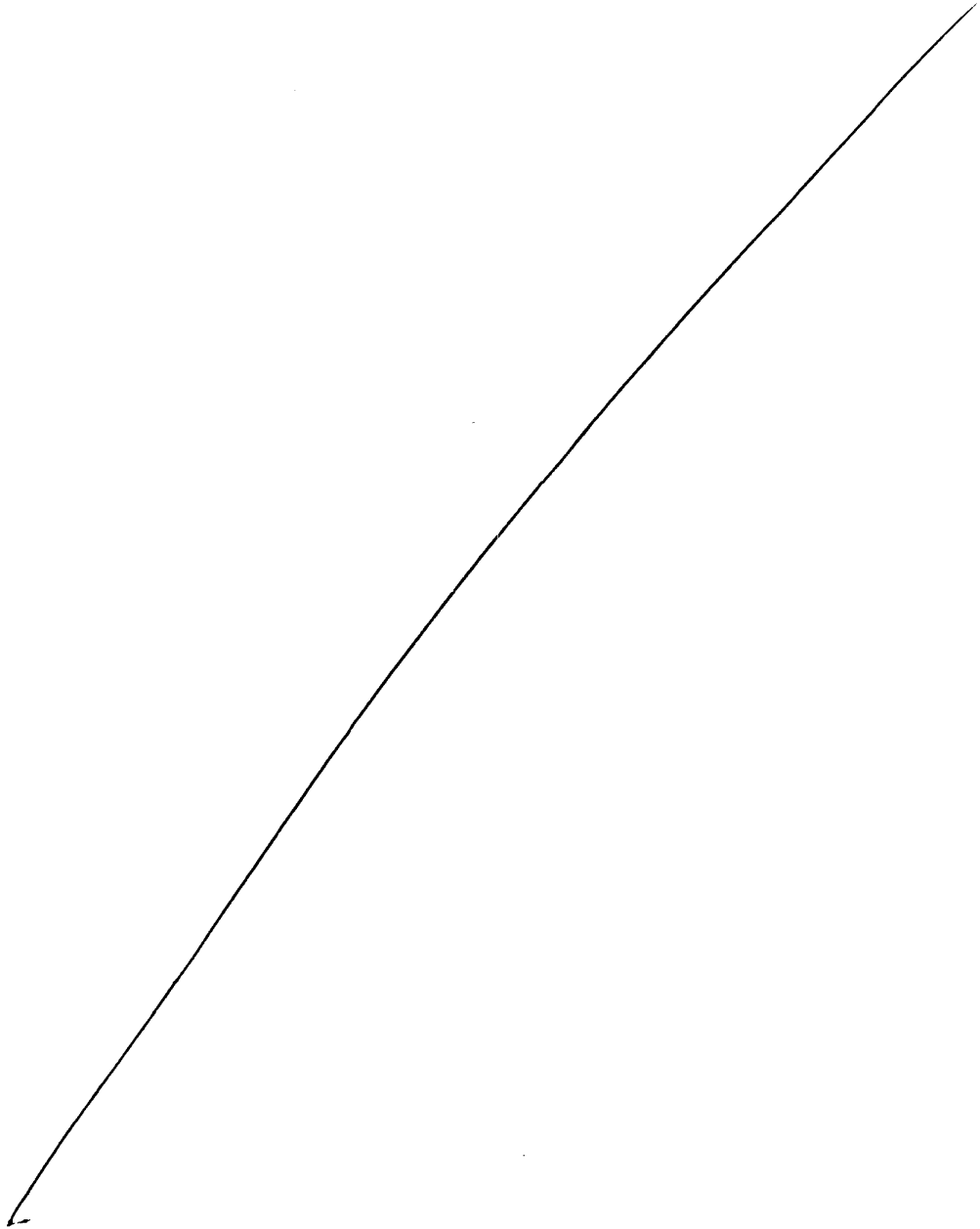
1/4/00



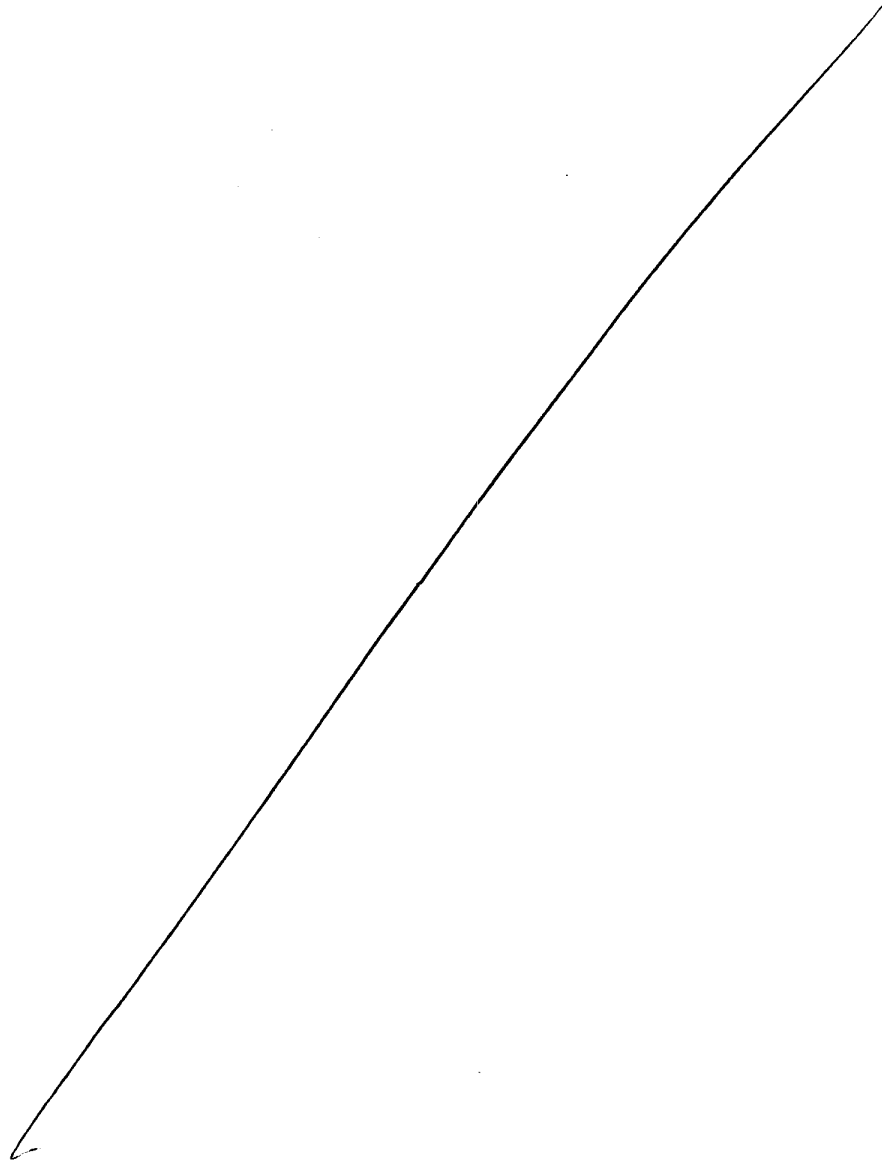
Ms. Deborah J. Denson

Page 4 of 6

1/4/00



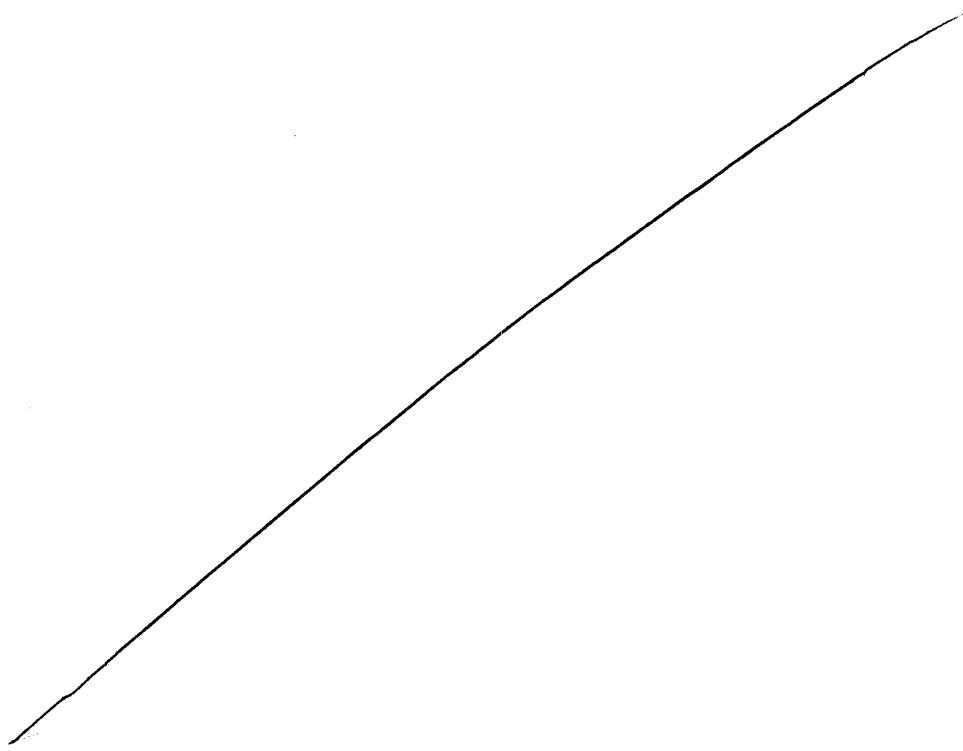
Ms. Deborah J. Denson
Page 5 of 6
1/4/00



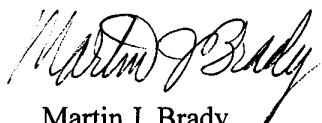
Ms. Deborah J. Denson

Page 6 of 6

1/4/00



Sincerely,



Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 7, 2000

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:


We have reviewed the material provided in your correspondence of January 04, 2000, submitted in response to issues raised during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of December 03, 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. Two issues remain unclear and additional clarification and correction is required:



Mr. Brady
January 13, 2000
Page 2 of 2

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/M17

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 5, 2000

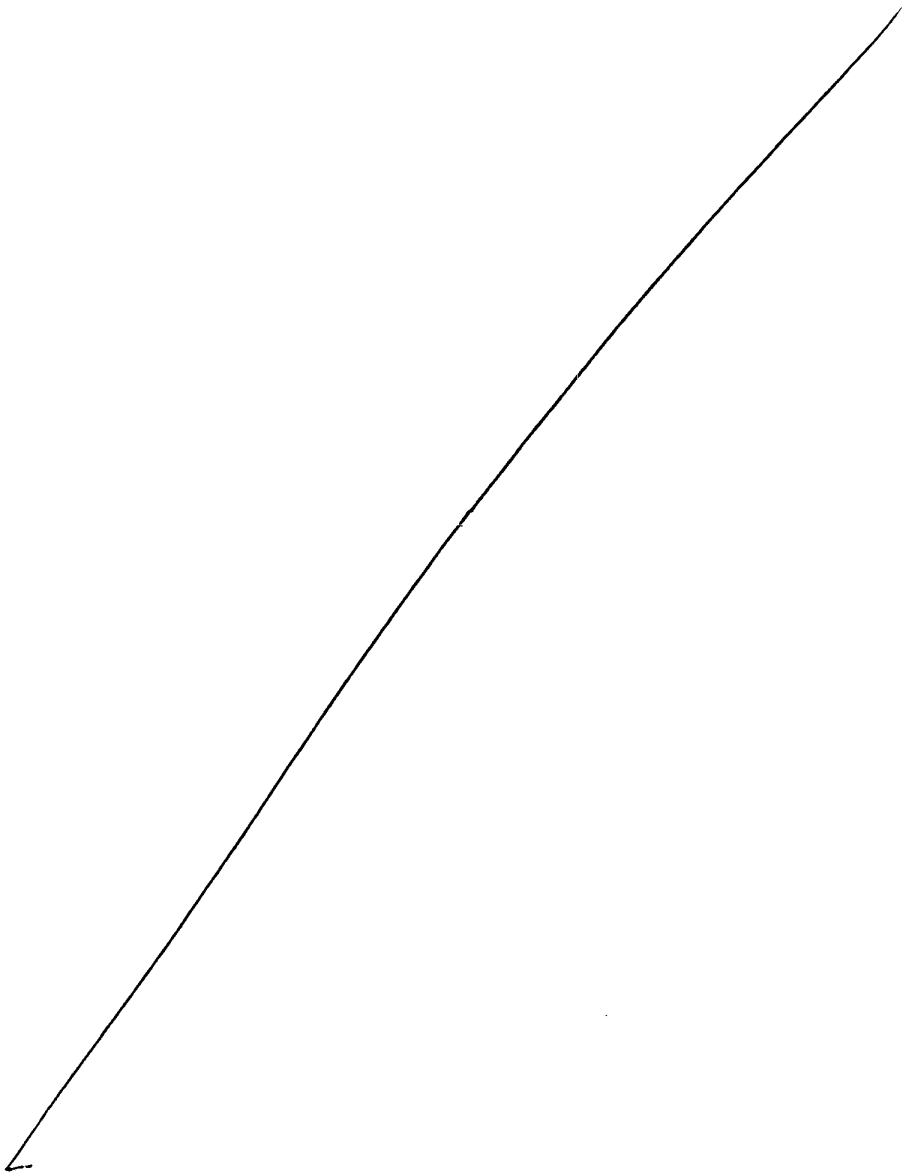
0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

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. Brady
Page 2 of 3
06/05/00

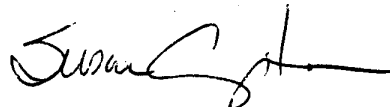


Mr. Brady
Page 3 of 3
06/05/00

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

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: Application Form
 Inspection Report #M18 Date: 13 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.

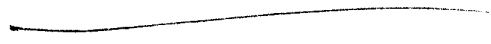
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

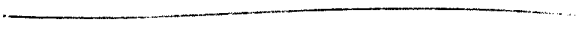
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control

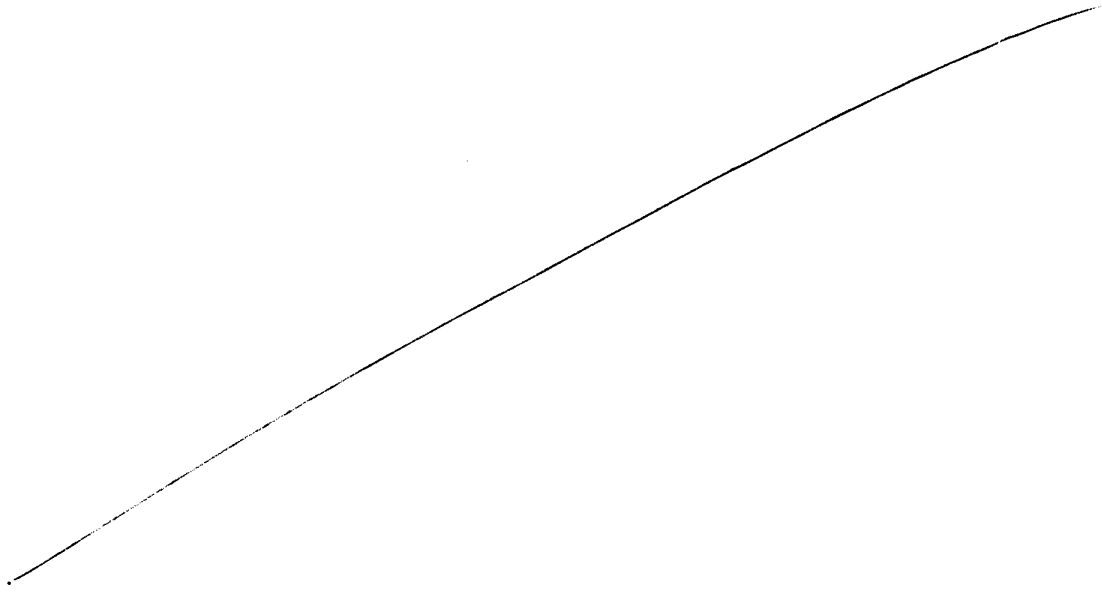


Section H. Initial Tests

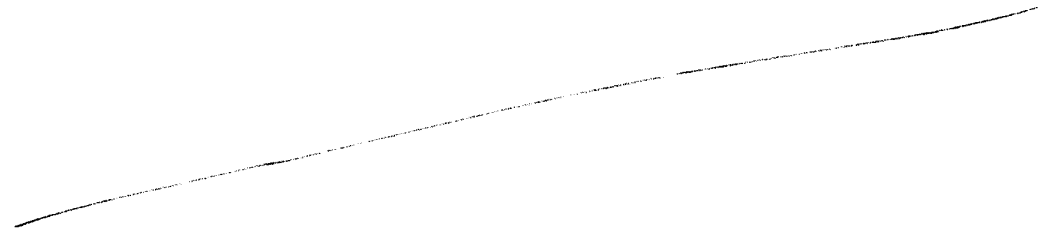


Section I. Confirmatory Tests

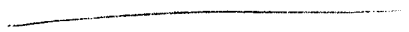




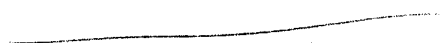
Section J. Records Audit



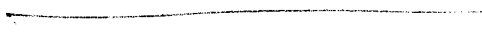
Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel

received
SIDC 7/24/00



July 21, 2000

Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
Research Triangle Park, North Carolina 27709-2194

S.E.D. Medical Laboratories

5601 Office Blvd., NE
Albuquerque, New Mexico 87109-5816
505-727-6300 800-999-LABS
Fax 505-727-6205

James E. Fantus
President and CEO

Lanu Stoddart, MD
Medical Director

Thomas A. Keith, MD

I. David Mones, MD

Scott Otteson, MD

Ellen J. Giampoli, MD

Emeritus:

S. Victor Savino, MD

David W. Dain, MD

Alan G. Engberg, MD

Robert M. List, MD

Nanci M. George
Vice President, Marketing

Kari Young, CPA
Vice President, Finance

Charley Neucomb, MS
Chief Information Officer

Denise Ballou, MS, MT (ASCP)
Director, Technical Operations

Liz Pratt, MT (ASCP)
Director, Service Operations

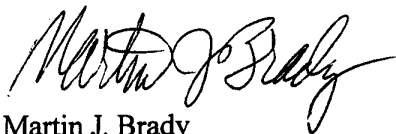
Rebecca Falance, SPHR
Director, Human Resources

July 21, 2000
Susan Crumpton
page 2

/

>

Sincerely,



Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 14, 2000

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

We have reviewed the material provided in your correspondence of July 21, 2000, submitted in response to an issue raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 5, 2000.

As noted in our previous correspondence, RTI has recommended to HHS that your laboratory continue to be certified under the NLCP. Any additional 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



Mr. Brady
Page 2 of 2
08/14/00

reviewed during the next inspection. If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M18

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 27, 2000

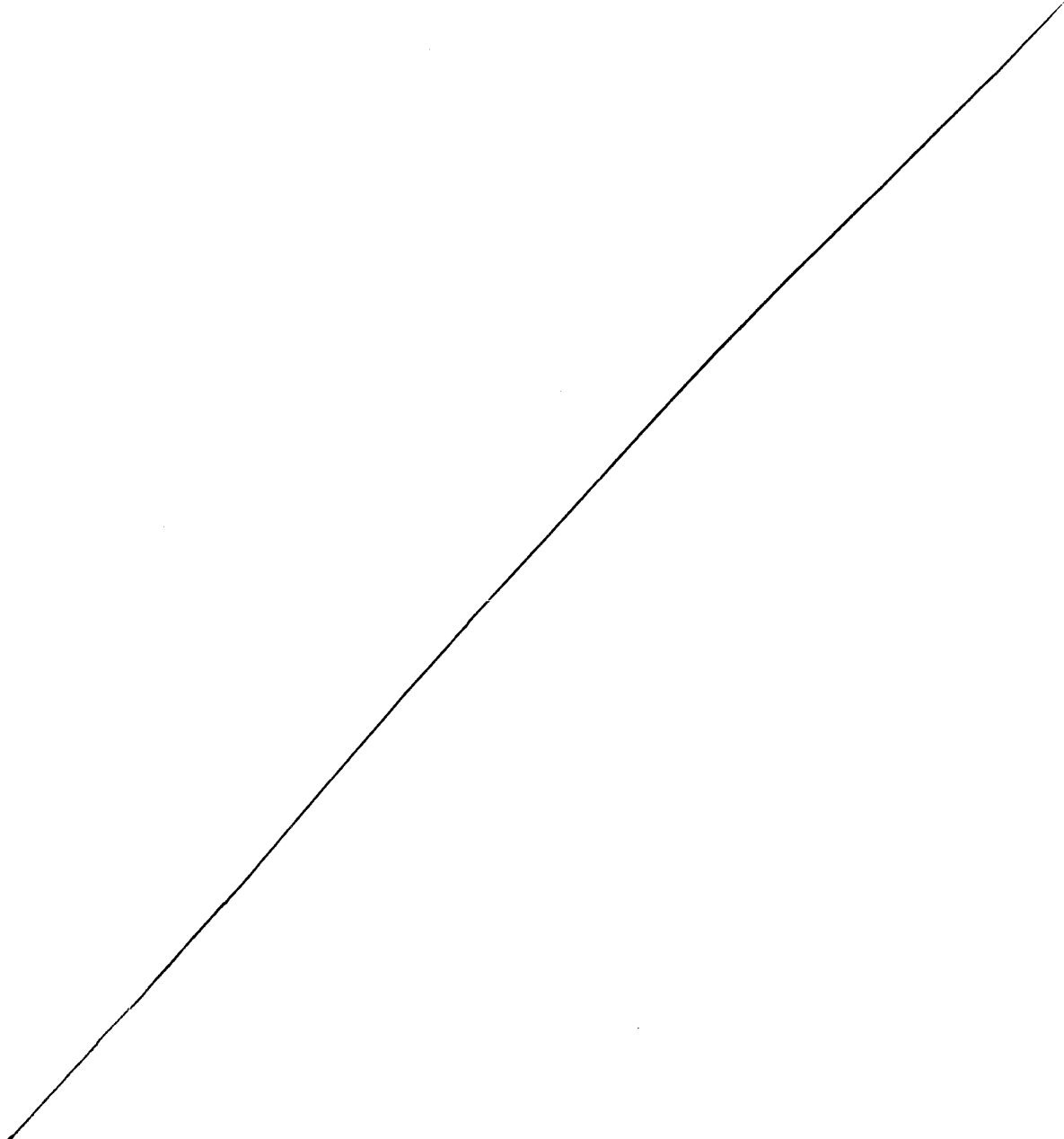
0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

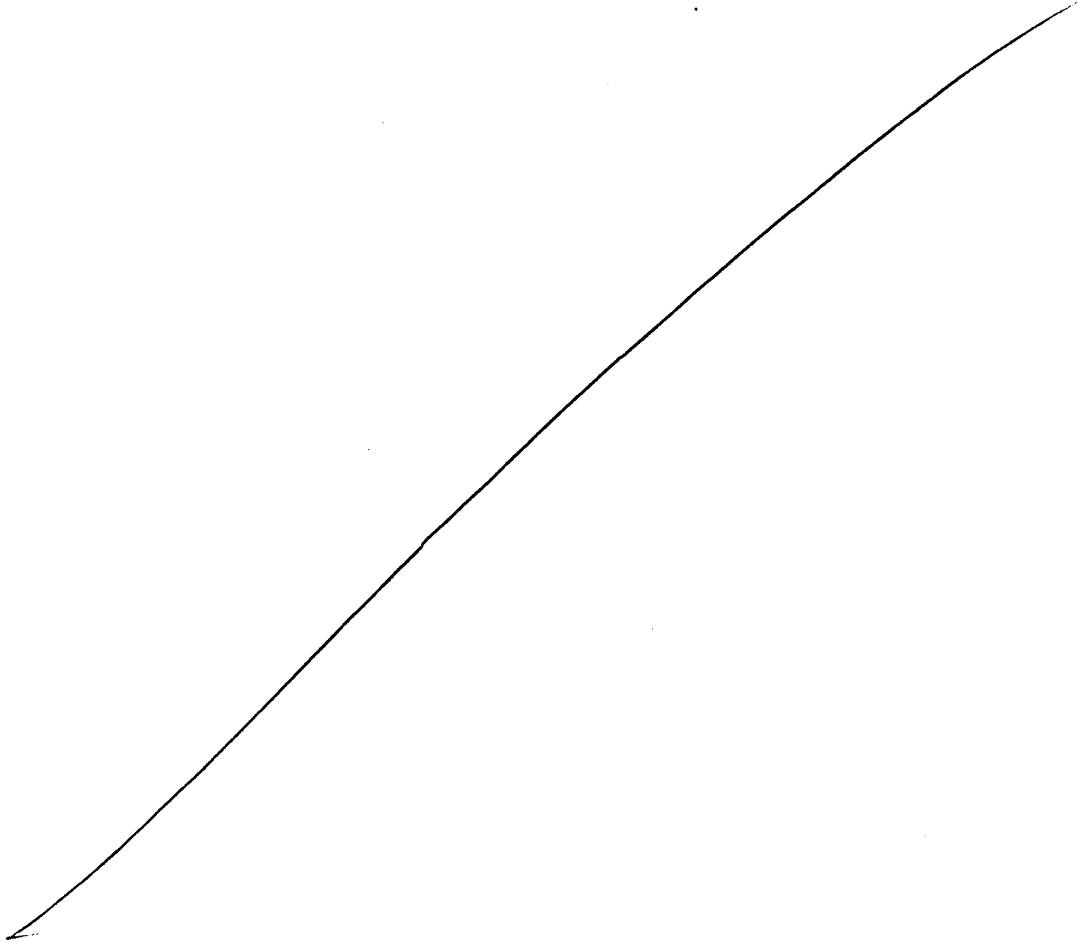
The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Mr. Brady
December 27, 2000
Page 2 of 4



Mr. Brady
December 27, 2000
Page 3 of 4

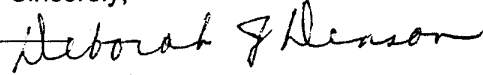


The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item 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.

Mr. Brady
December 27, 2000
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 R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: Application Form
 Inspection Report #M19 Date: 19 October 2000
 Other _____

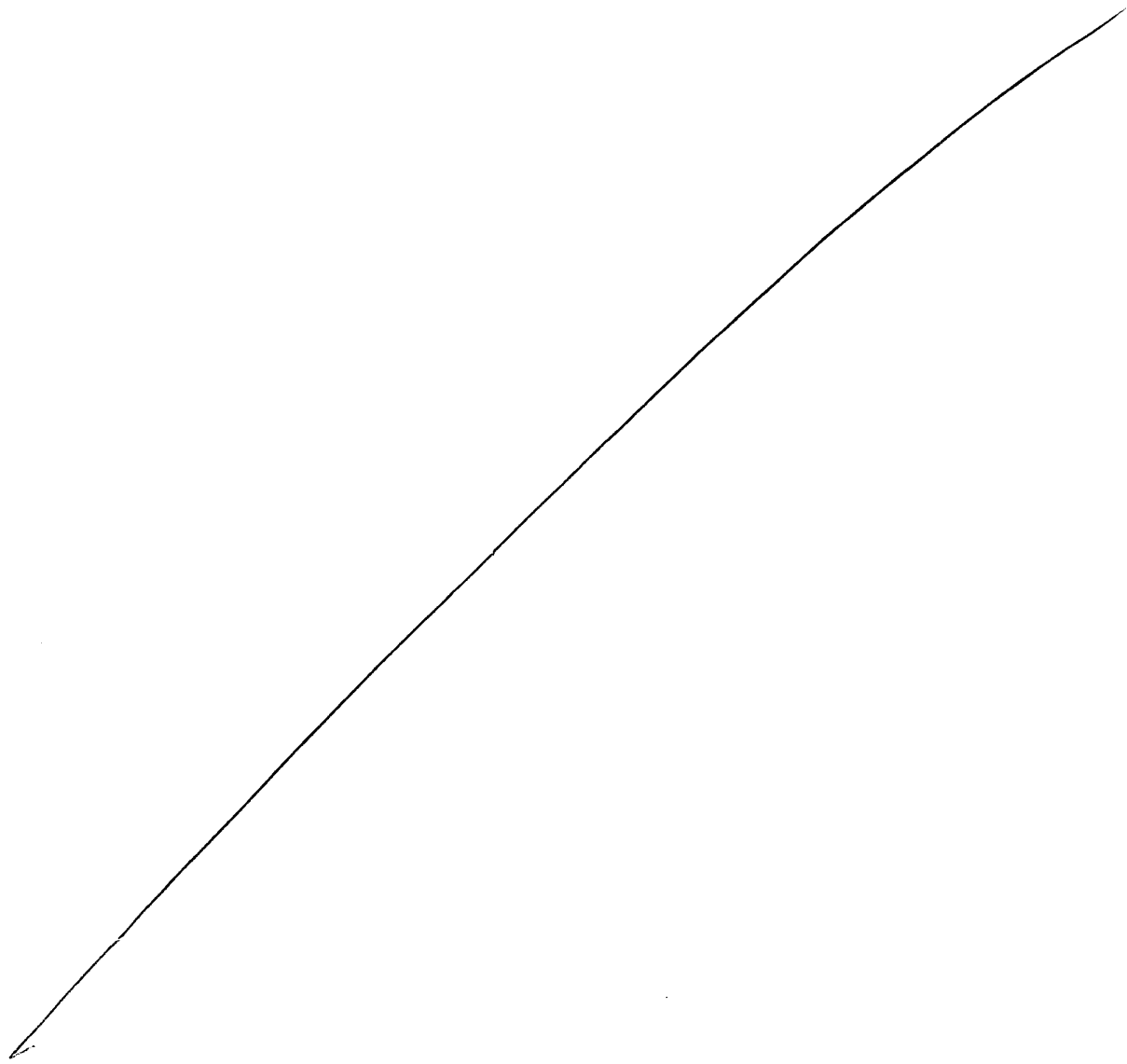
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

2

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
2/02/01 DD



February 1, 2001

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
Research Triangle Park, North Carolina 27709-2194

S.E.D. Medical Laboratories

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Fax 505-727-6205

James E. Fantus
President and CEO

Lanu Stoddart, MD
Medical Director

Thomas A. Keith, MD

I. David Mones, MD

Scott Otteson, MD

Ellen J. Giampoli, MD

The enclosed is in response to your critique of our laboratory as a result of our nineteenth maintenance inspection under the National Laboratory Certificate Program (NLCP), which we received on January 2, 2001.

Emeritus:

S. Victor Savino, MD
David W. Dain, MD
Alan G. Engberg, MD
Robert M. List, MD

Nanci M. George
Vice President, Marketing

Kari Young, CPA
Vice President, Finance

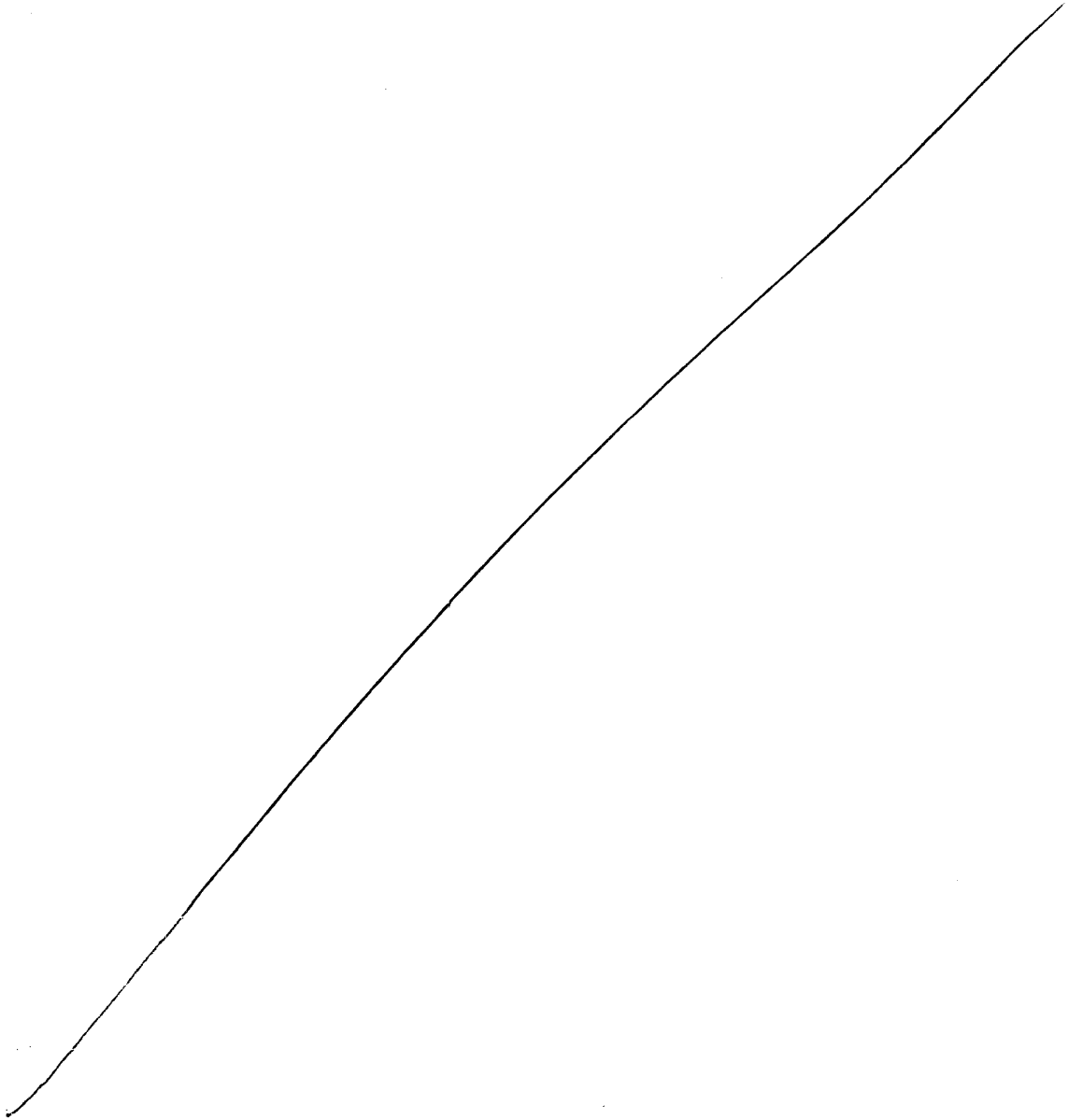
Charley Newcomb, MS
Chief Information Officer

Denise Ballou, MS, MT (ASCP)
Director, Technical Operations

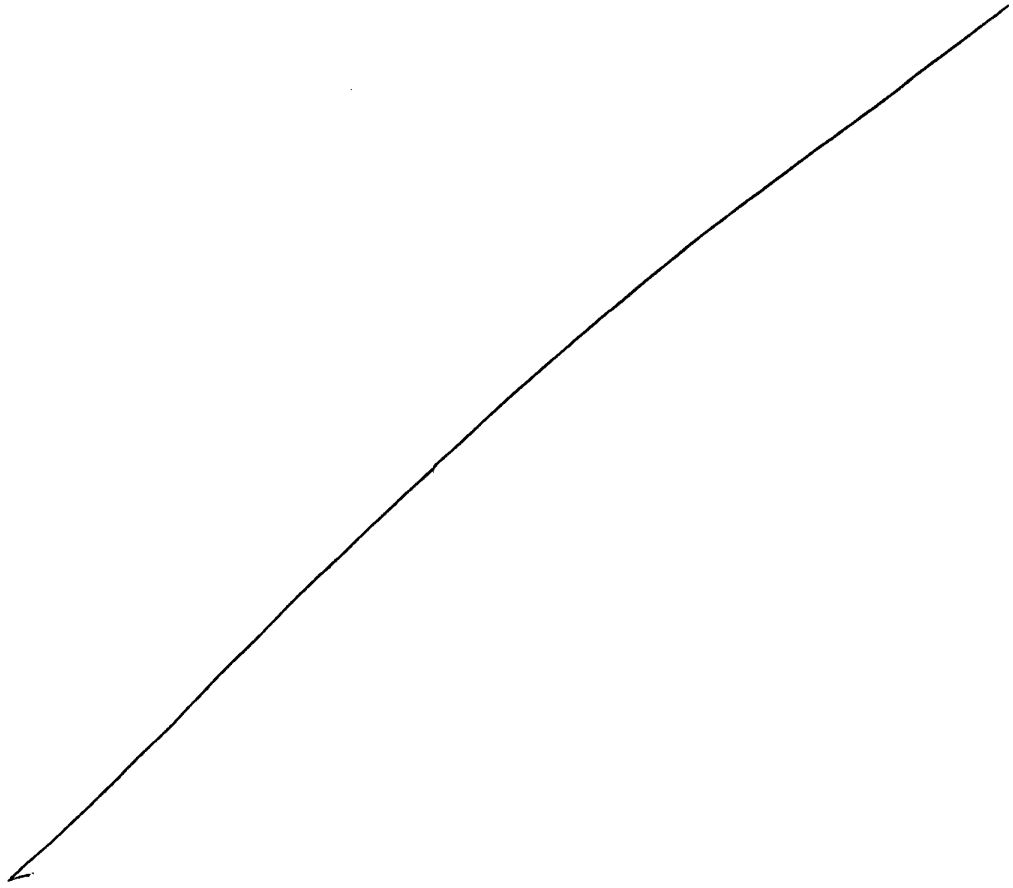
Liz Pratt, MT (ASCP)
Director, Service Operations

Rebecca Falance, SPHR
Director, Human Resources

Ms. Deborah J. Denson
Page 2 of 5
2/1/2001



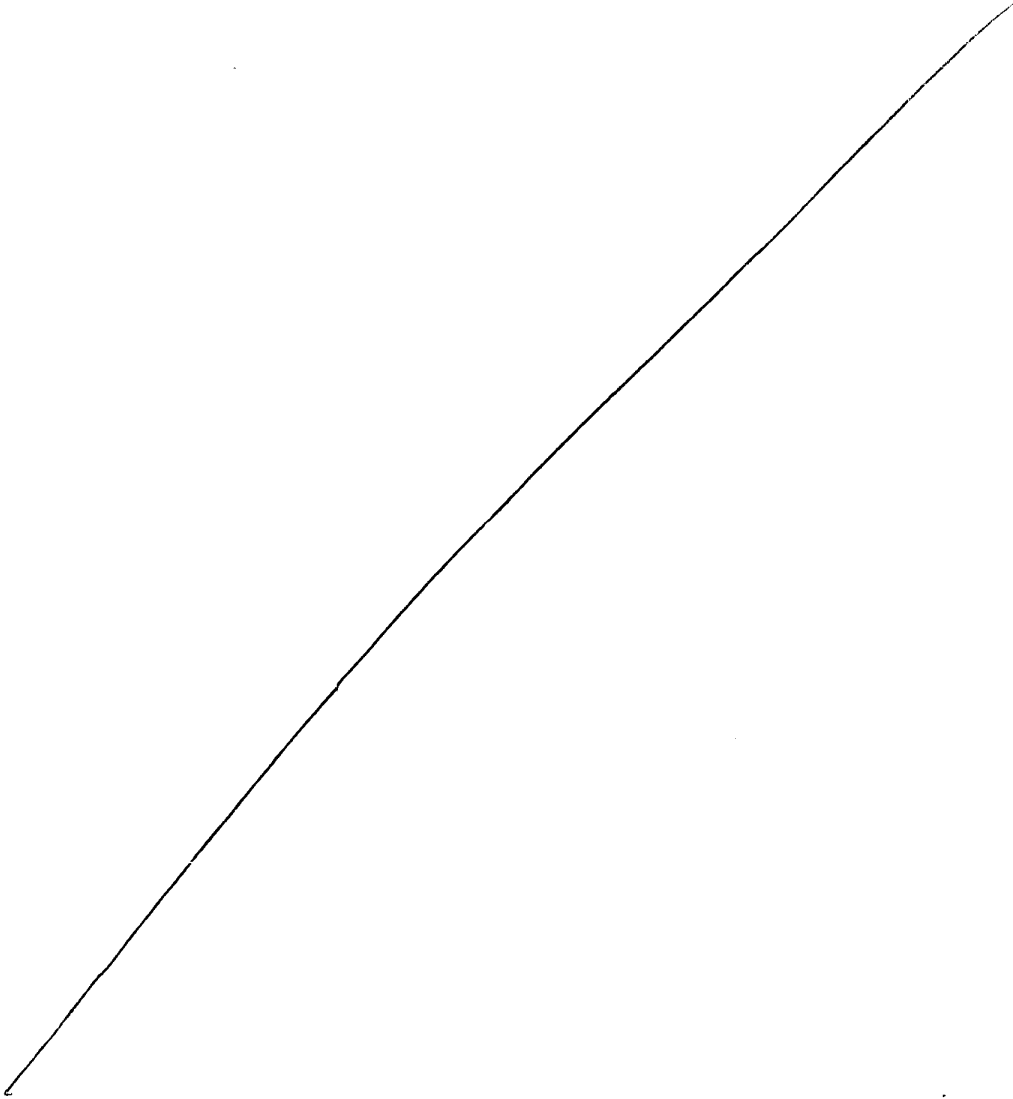
Ms. Deborah J. Denson
Page 3 of 5
2/1/2001



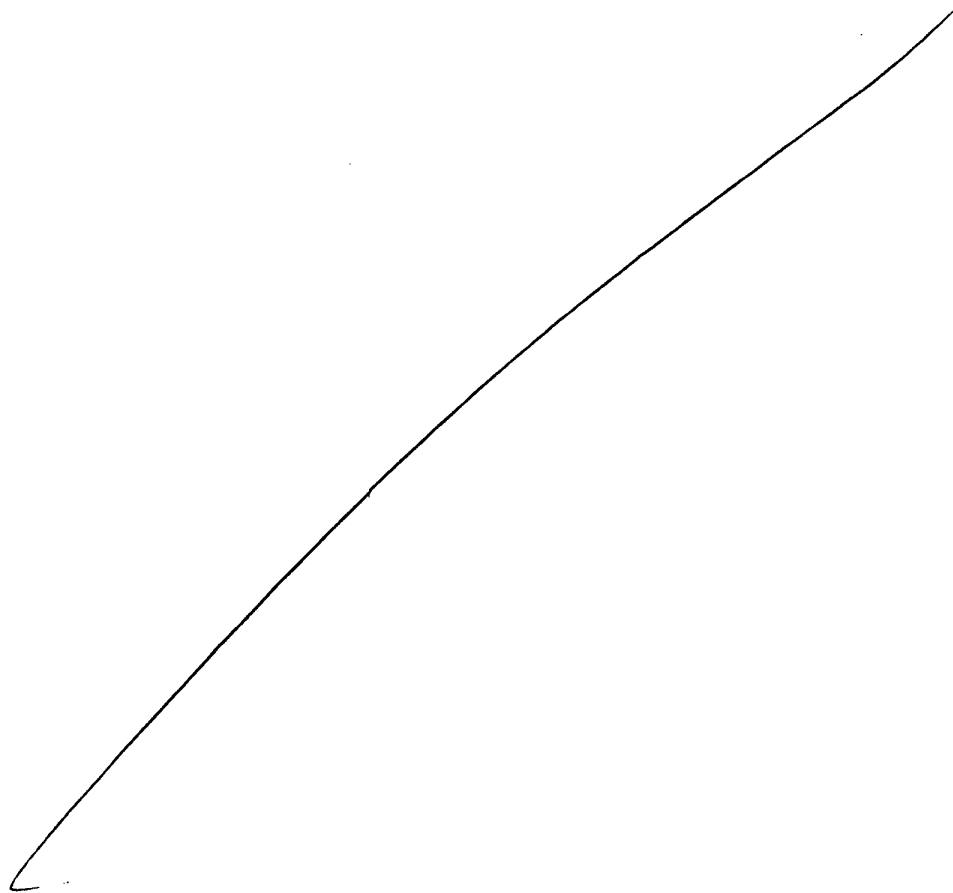
Ms. Deborah J. Denson

Page 4 of 5

2/1/2001



Ms. Deborah J. Denson
Page 5 of 5
2/1/2001



Sincerely,

A handwritten signature in cursive script that reads "Martin J. Brady".

Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 5, 2001

296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

We have reviewed the material provided in your correspondence of February 01, 2001 submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of December 27, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:

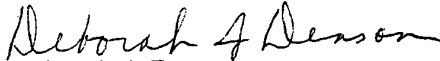
Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this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



Mr. Brady
February 6, 2001
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 R. Baylor at (919) 541-7043.

Sincerely,


Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/296