



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 14, 1998

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CN CAN N6A 1P4

Dear Dr. Yeh:

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

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

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

Enclosure

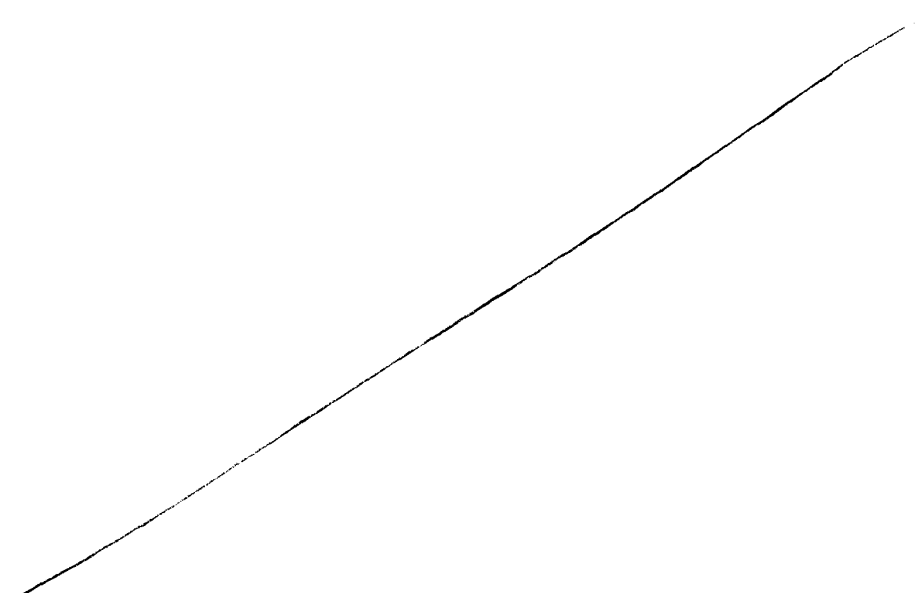
cc: Project Files/M1



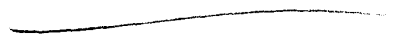


The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

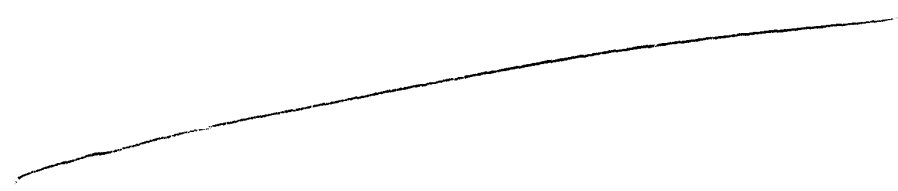
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Records Audit



**Section H. Personnel**

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**Section I. Reagents**

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**Section J. Quality Control and Standards**

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**Section K. Reporting**

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**Section L. Equipment and Maintenance**

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**Section M. Immunoassay**

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**Section N. Gas Chromatography/Mass Spectrometry**

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# RESEARCH TRIANGLE INSTITUTE

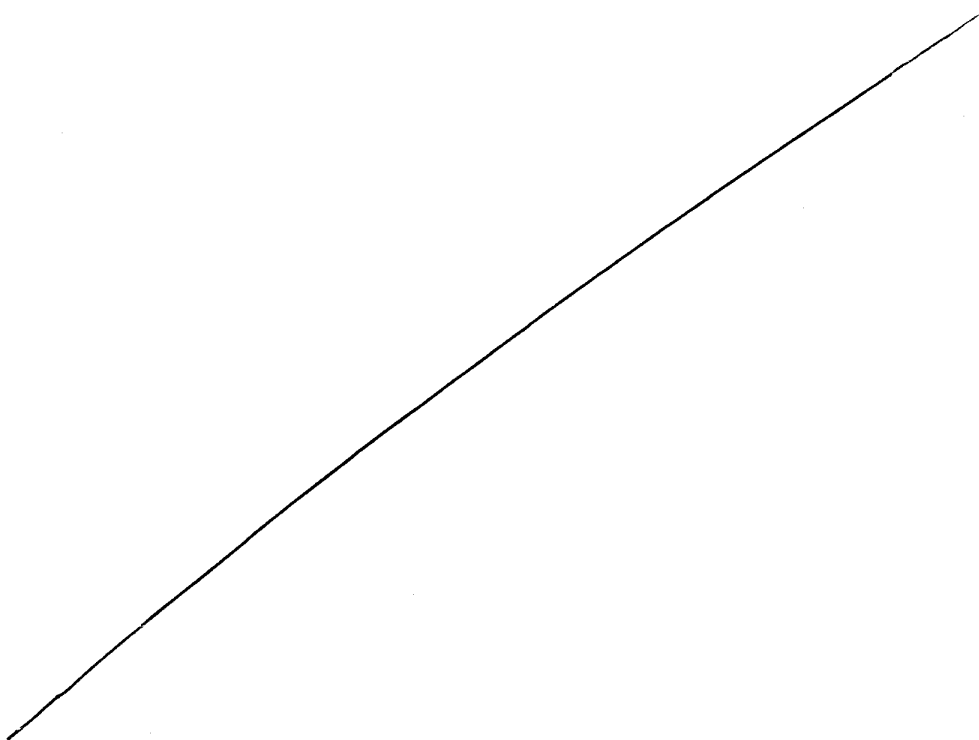
National Laboratory Certification Program

May 28, 1999

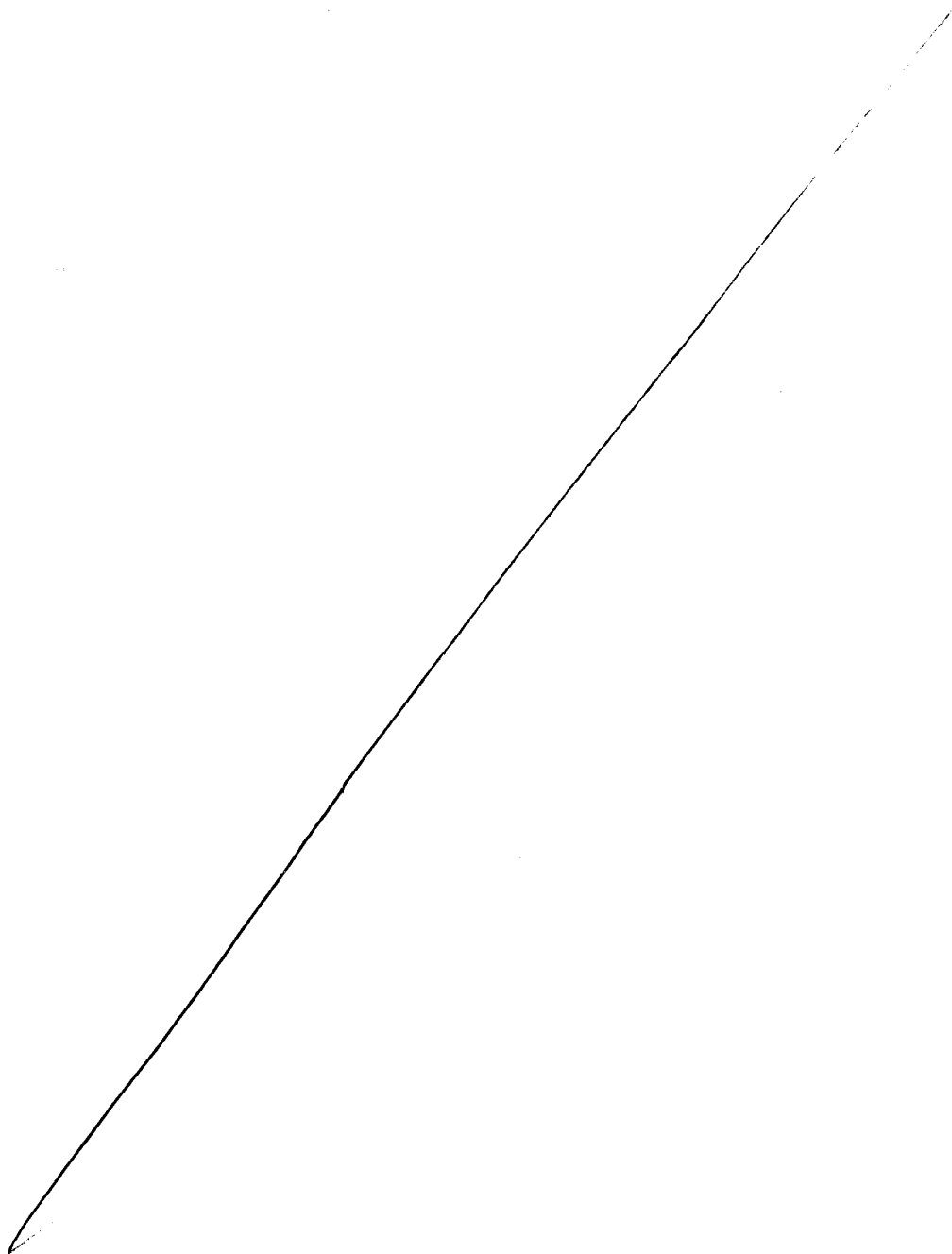
0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

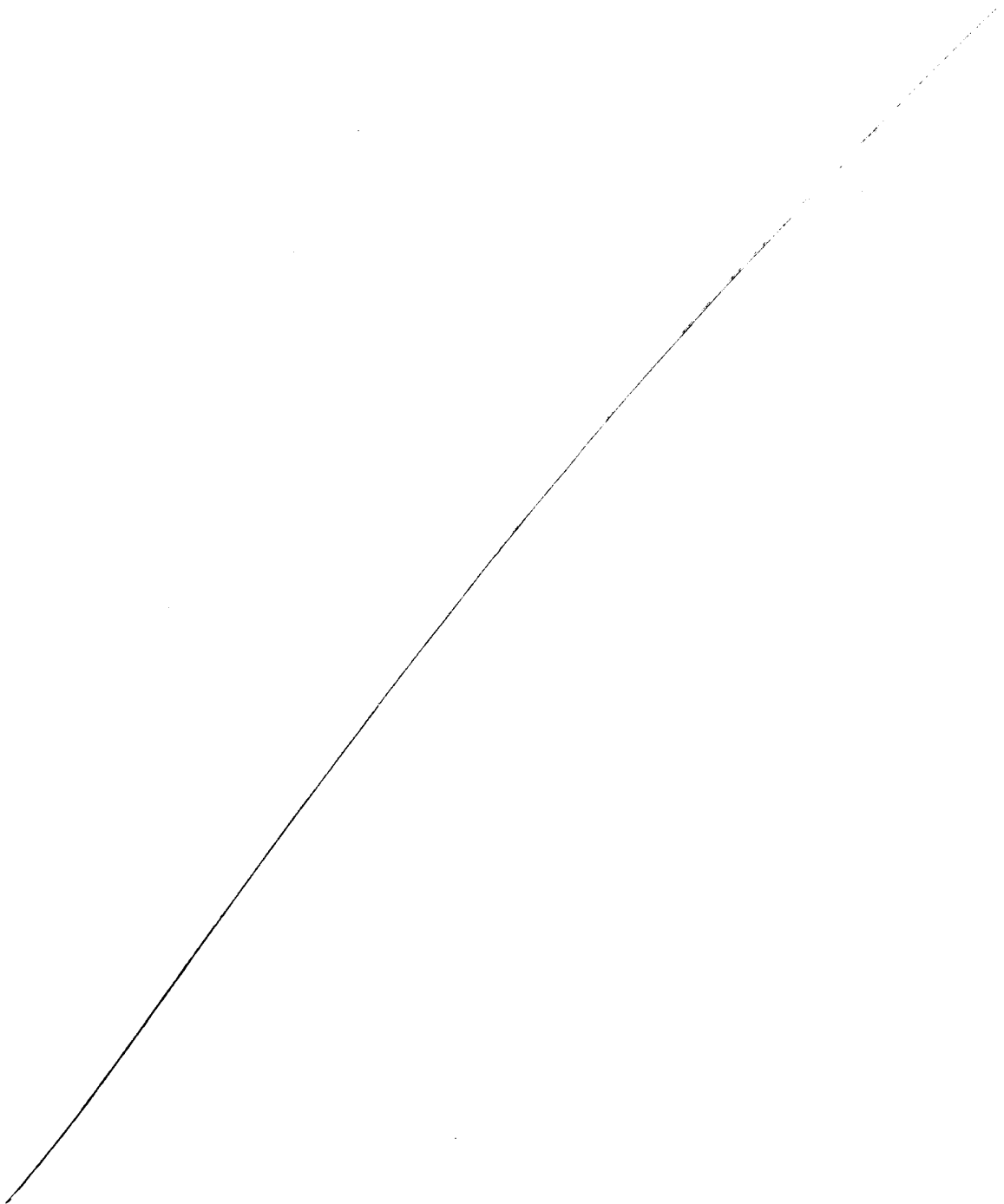
Dear Dr. Yeh:

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. However, the following issues were raised:

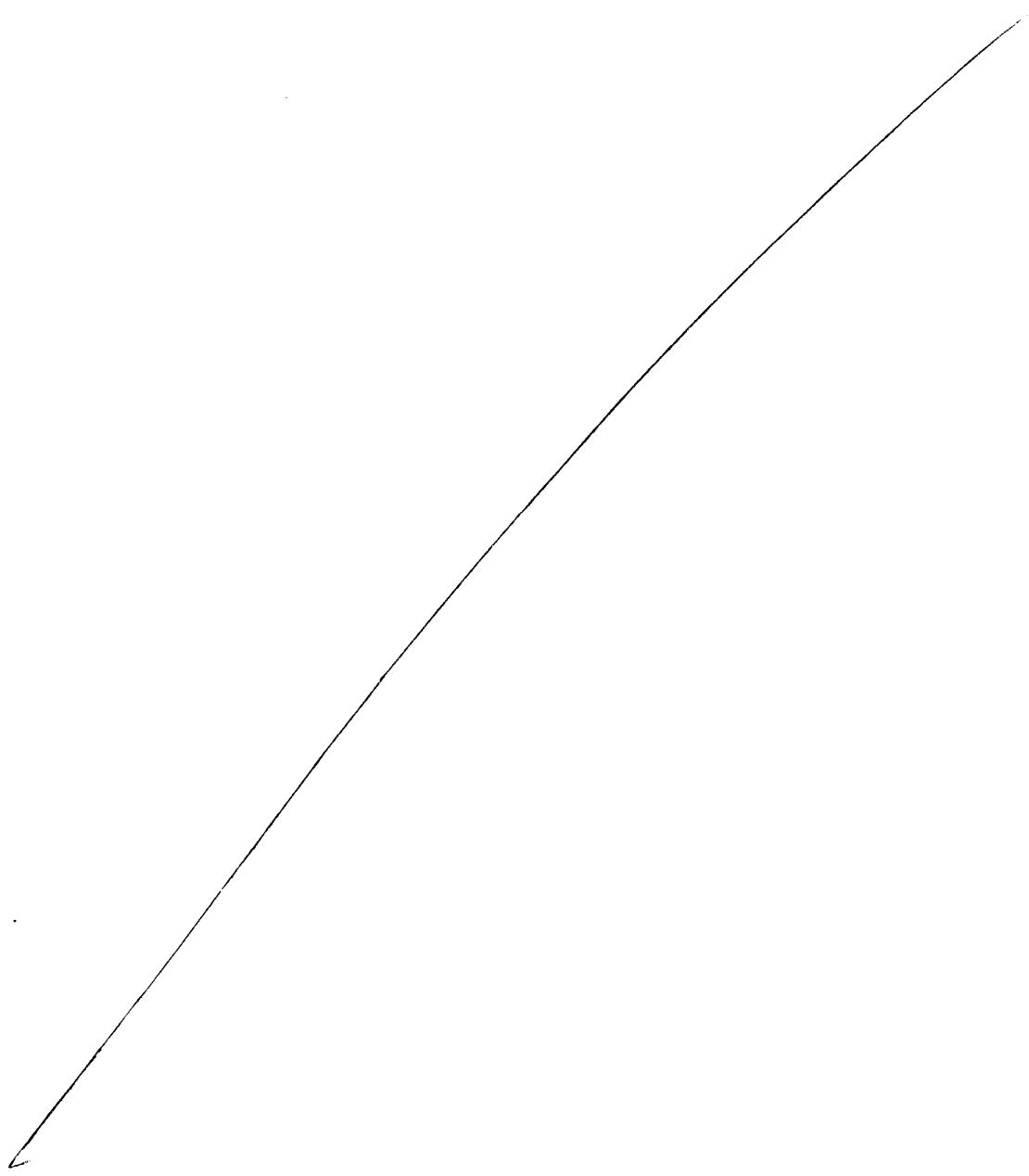


Dr. Yeh  
May 28, 1999  
Page 2 of 5





Dr. Yeh  
May 28, 1999  
Page 4 of 5



**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 section F above. In responding to these issues, please organize the material in your document in accordance with the item numbers as listed in this**



Dr. Yeh  
May 28, 1999  
Page 5 of 5

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,



*for* Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M2

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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: 0898  
Document No. Final

Laboratory: Gamma-Dynacare Medical Laboratories

Location: London, ON

Document Reviewed:     Application Form  
                               Inspection Report #M2                      Date: 18 March 1999  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

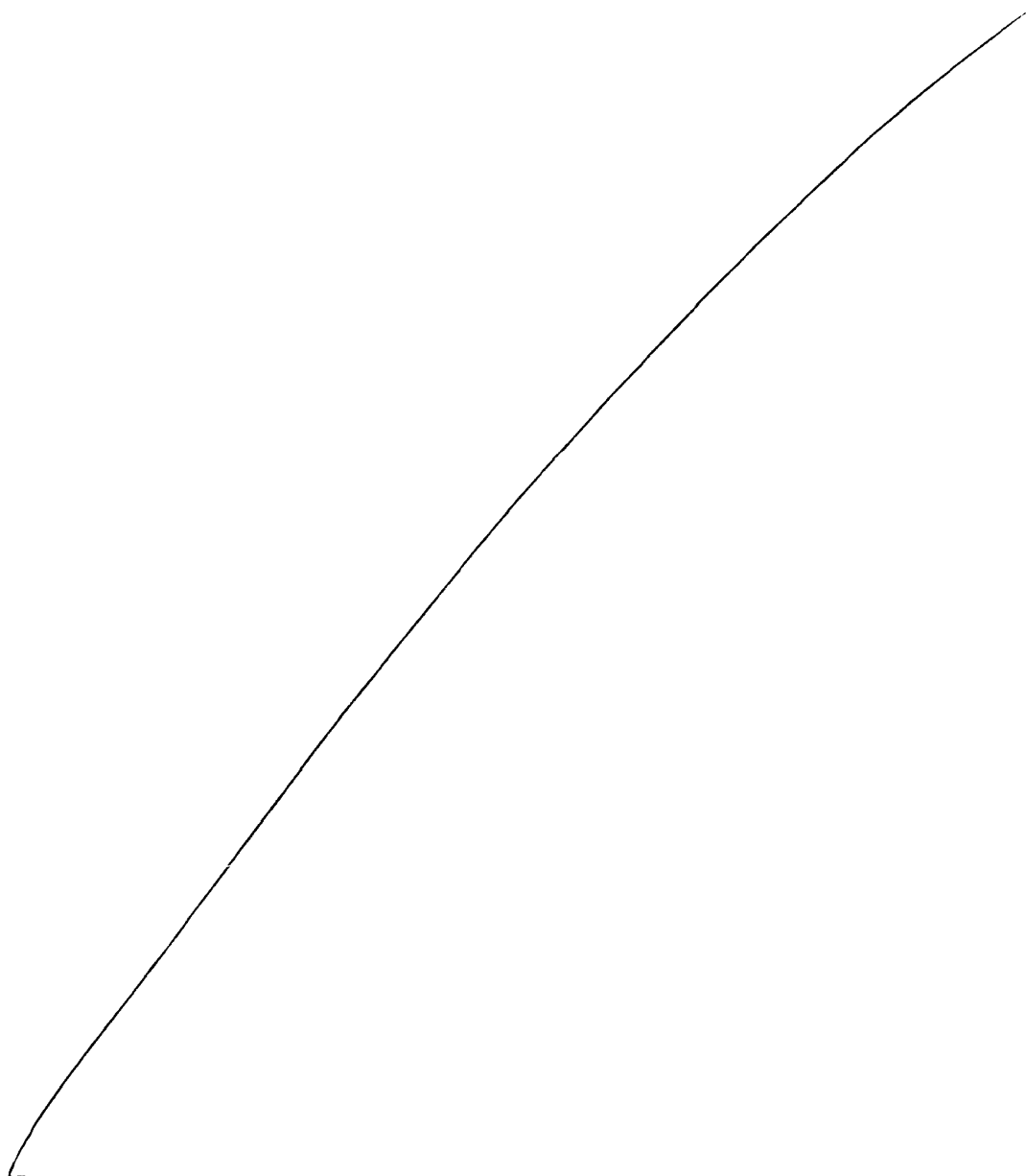
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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:

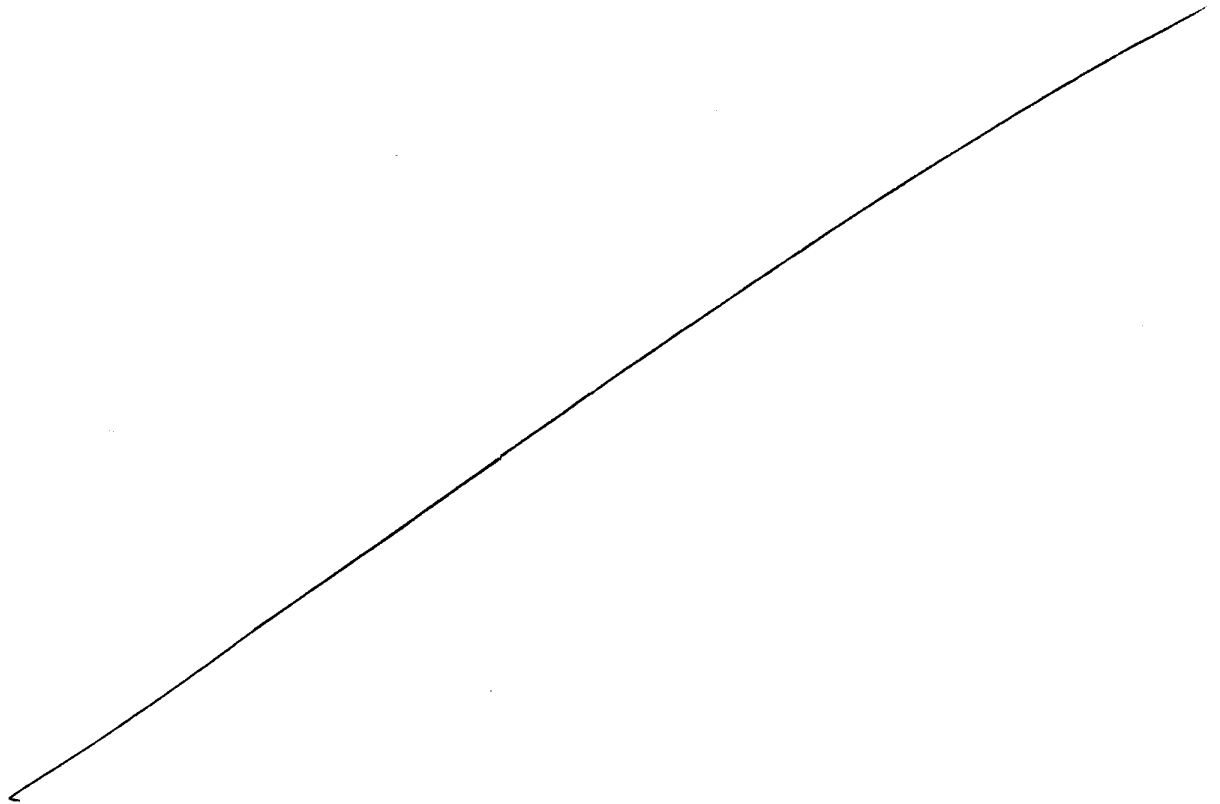
Section E. Standard Operating Procedures - Procedures Manual



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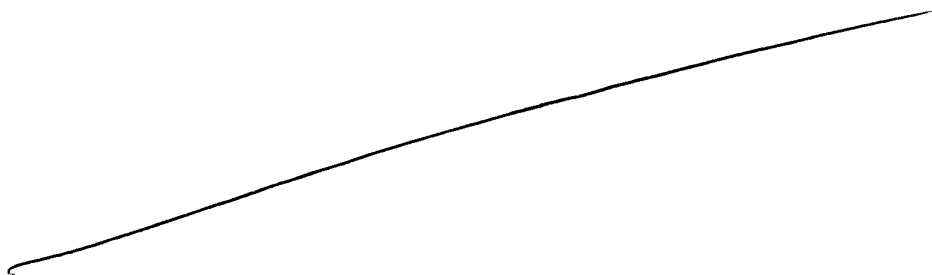
Section F. Chain-of-Custody, Accessioning, and Security

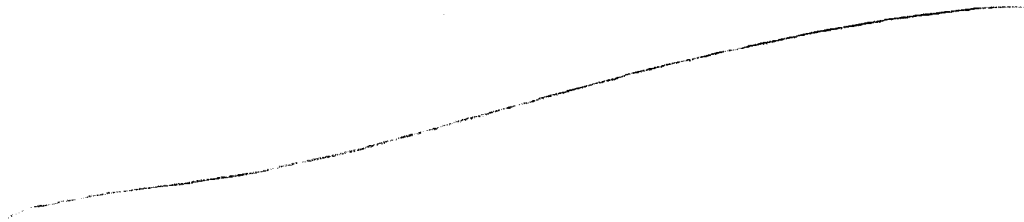
Section G. Quality Control



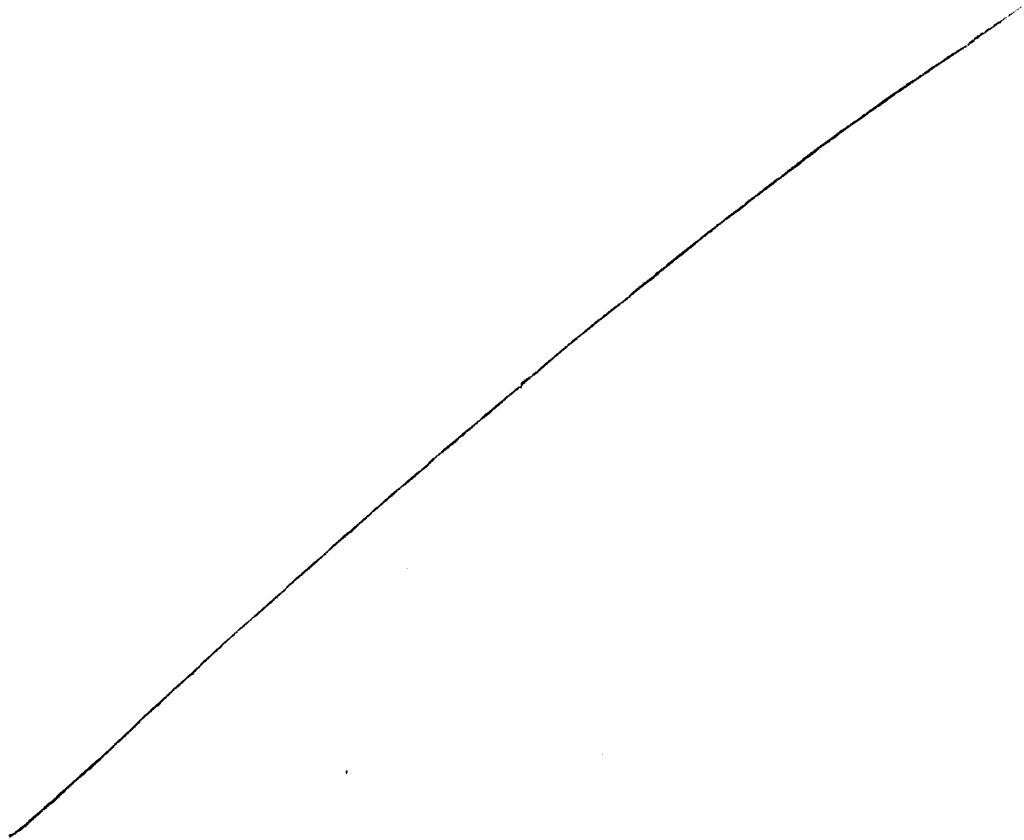
2

**Section H. Initial Tests**





**Section I. Confirmatory Tests**



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Section J. Records Audit

Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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received  
6/30/99 >R

1999 June 29

Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Post Office Box 12194  
Research Triangle Park, North Carolina 27709-2194  
U.S.A.

Attention: Deborah J. Denson, Inspection Analyst

**BY COURIER**

Dear Ms. Denson:

We acknowledge receipt of your letter of May 28, 1999 and submit for your review a summary of actions taken in response to the deficiencies noted on the inspection report of March 18, 1999.

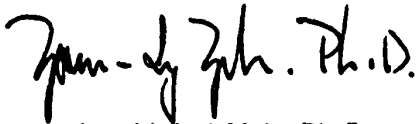
We have summarized the actions below. Documentation to support these statements (where applicable) is attached and is numbered to correspond with Laboratory Inspection Report questions.

Research Triangle Institute  
1998 June 29  
Page 2

If you have any questions, please do not hesitate to call.

Sincerely,

*Gamma-Dynacare*  
*Medical Laboratories*



Younn-Ing (John) Yeh, Ph.D.  
Clinical Chemist  
Director of Clinical Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

July 13, 1999

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

We have reviewed the material provided in your correspondence of June 29, 1999, submitted in response to issues raised during the second maintenance inspection of your laboratory as outlined in our correspondence of May 28, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory 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. at (919) 541-7043.

Sincerely,

A handwritten signature in cursive script that reads "Deborah J. Denson".

Deborah J. Denson  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M2

RESEARCH TRIANGLE INSTITUTE



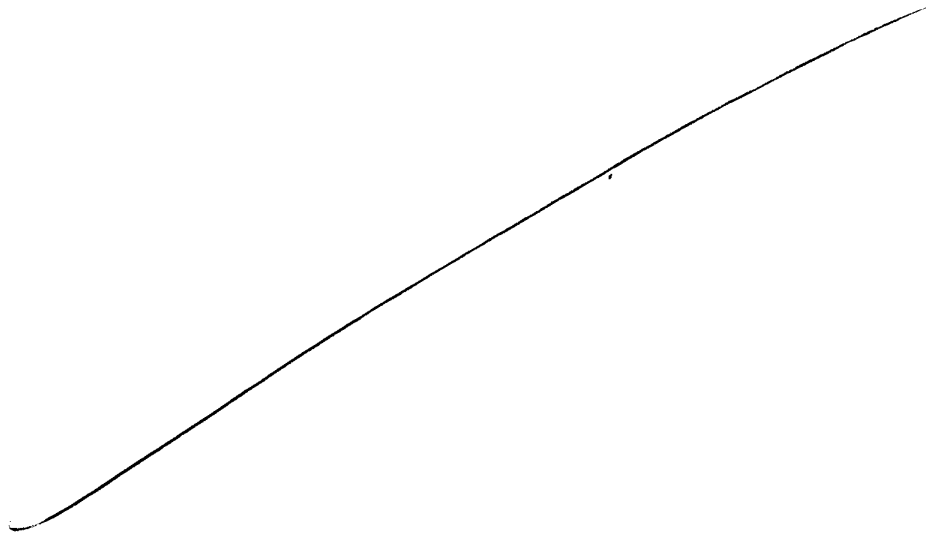
National Laboratory Certification Program

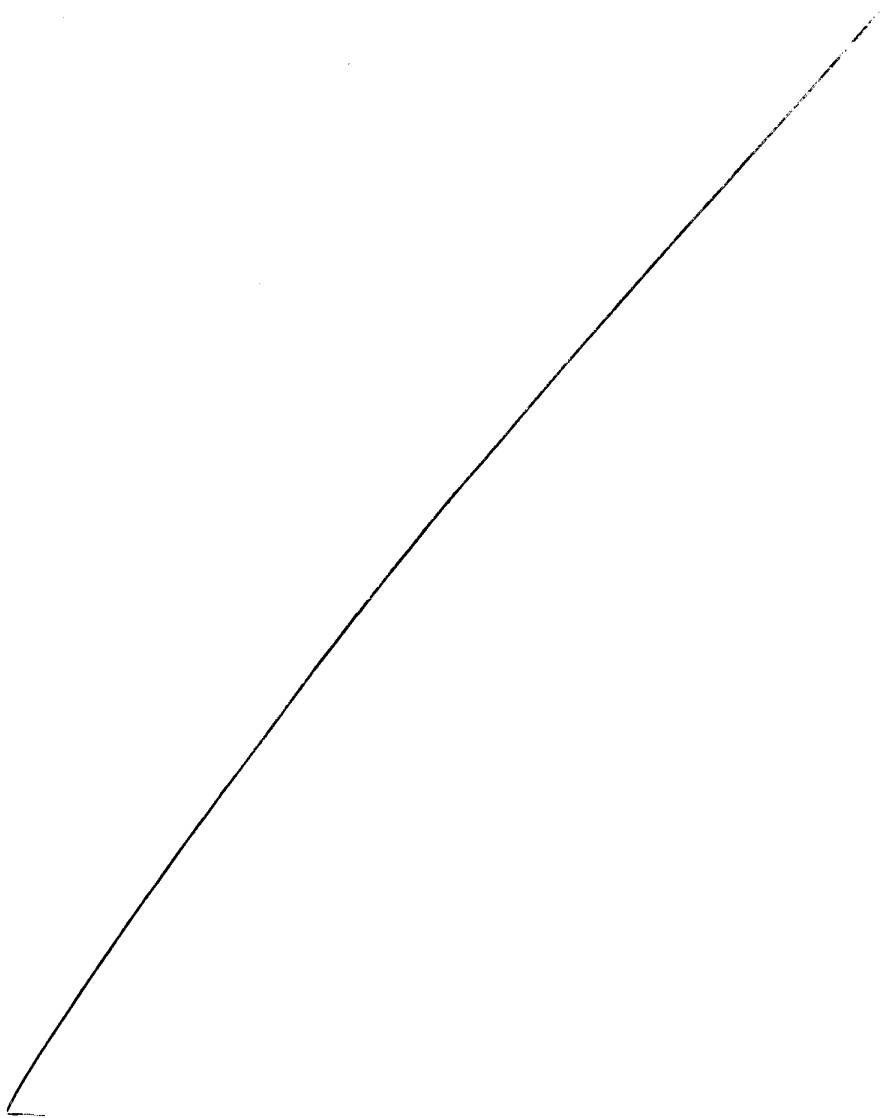
October 22, 1999

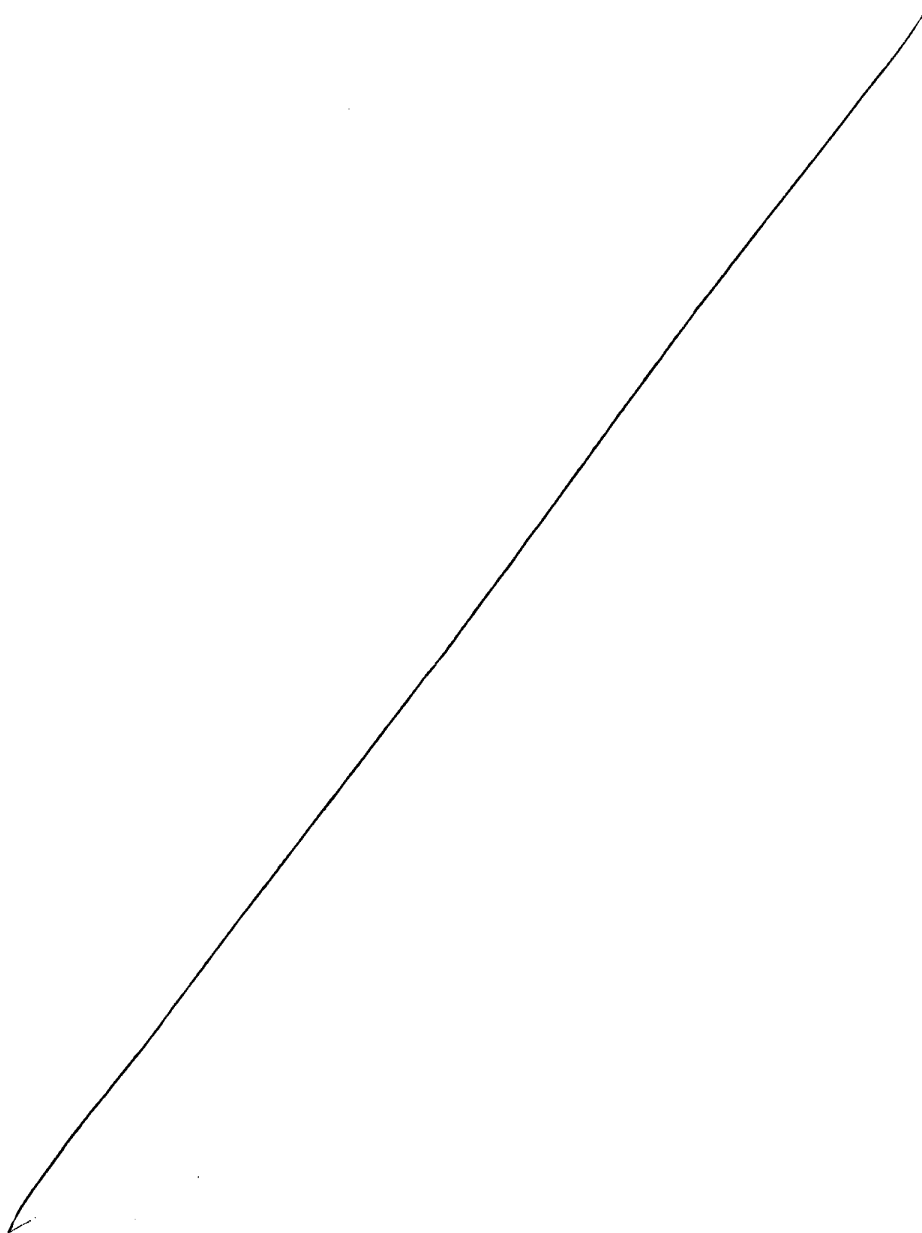
0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the third 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 take steps to correct the following issues raised:







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Many of the issues raised in this inspection were raised in the laboratory's previous inspection. It appeared that the laboratory did not take appropriate corrective actions in response to RTI's previous correspondence (see the May 28, 1999, cover letter and critique). Although RTI did not require a written submission regarding most of the issues in the previous inspection, the laboratory was directed to take appropriate corrective action and implement revised procedures within 30 days of receipt of RTI's correspondence. It is the Responsible Person's duty to ensure that appropriate and adequate corrective actions are taken to address deficiencies cited during NLCP inspections. The implementation of corrective actions is reviewed during the next maintenance inspection.

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 HHS that the laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

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

Sincerely,



Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M3

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0898  
Document No. Final

Laboratory: Gamma-Dynacare Medical Laboratories

Location: London, ON

Document Reviewed:  Application Form  
 Inspection Report #M3      Date: 23 September 1999  
 Other \_\_\_\_\_

Status:  Highly Acceptable       Acceptable  
 Unacceptable       Failure

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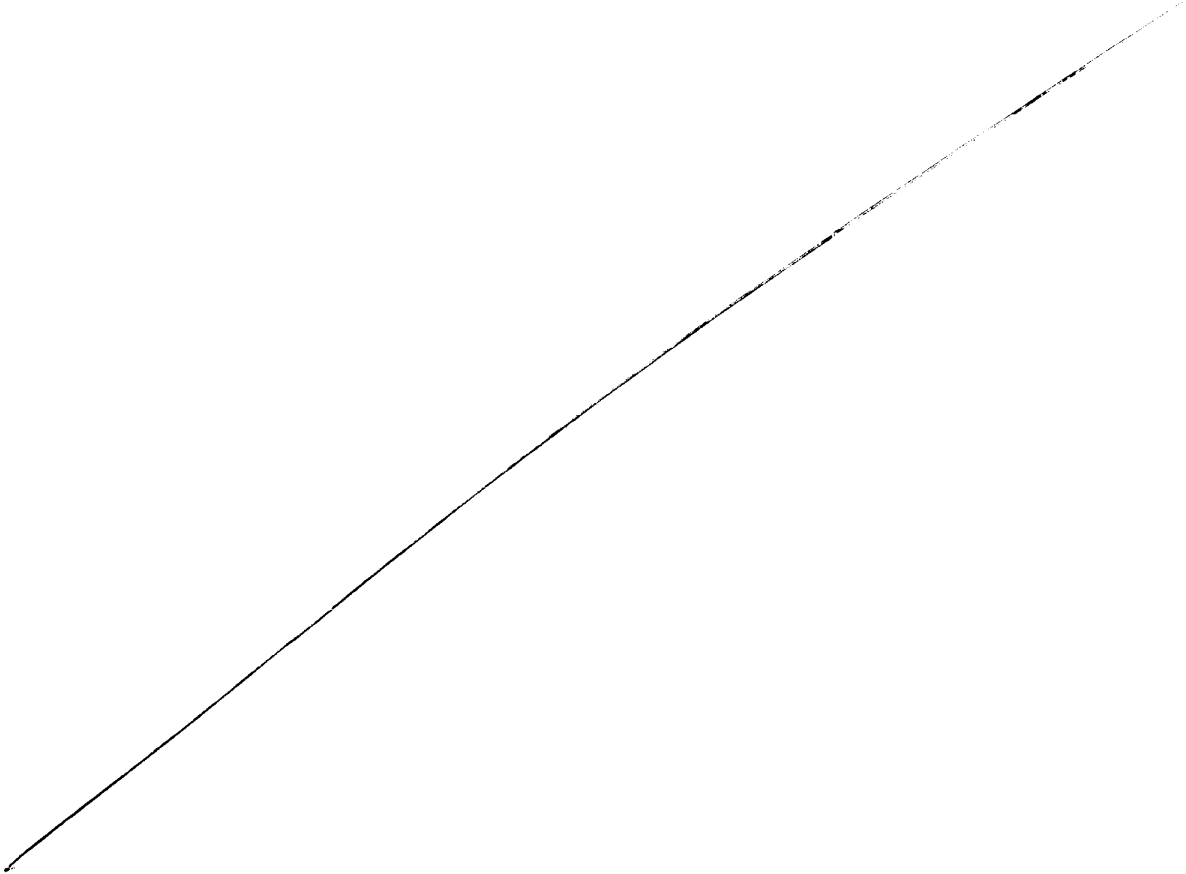
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

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Section J. Records Audit

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

Section N. Personnel

*Gamma-Dynacare*  
Medical Laboratories

received  
12/1/99 SDC

1999 November 19

Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Post Office Box 12194  
Research Triangle Park, North Carolina 27709-2194  
U.S.A.

Attention: Susan Crampton, NCLP Inspection Analyst

**BY COURIER**

Dear Ms. Crampton:

We acknowledge receipt of your letter of October 22, 1999 and submit for your review a summary of actions taken in response to the deficiencies noted on the inspection report of September 23, 1999.

We have summarized the actions below. Documentation to support these statements (where applicable) is attached and is numbered to correspond with Laboratory Inspection Report questions.

DOCUMENTS  
INCLUDED

**SECTION H: INITIAL TESTS**

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**SECTION I: CONFIRMATORY TESTS**

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**SECTION J: RECORDS AUDIT**

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**SECTION K: REPORTING**

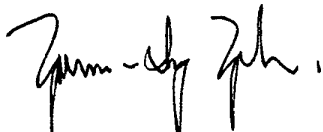
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**SECTION N: PERSONNEL**

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Sincerely,

***Gamma-Dynacare***  
*Medical Laboratories*



Yunn-Ing Yeh, Ph.D.  
SAT Director

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 20, 1999

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

We have reviewed the material provided in your correspondence of November 19, 1999, and December 10, 1999, submitted in response to issues raised during the third maintenance inspection of your laboratory as outlined in our correspondence of October 22, 1999, and discussed in our telephone conversations of December 7 and 9, 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 or were raised during our review of submitted material:



Dr. Yeh  
Page 2 of 2  
12/20/99

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

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

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/898





# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 20, 2000

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

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 highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Dr. Yeh  
April 20, 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 Technical Analyst

Enclosure

cc: Project Files/M4

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0898  
Document No. Final

Laboratory: Gamma-Dynacare Medical Laboratories

Location: London, ON

Document Reviewed:     Application Form  
                               Inspection Report #M4                      Date: 16 March 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable            Acceptable  
                               Unacceptable                Failure

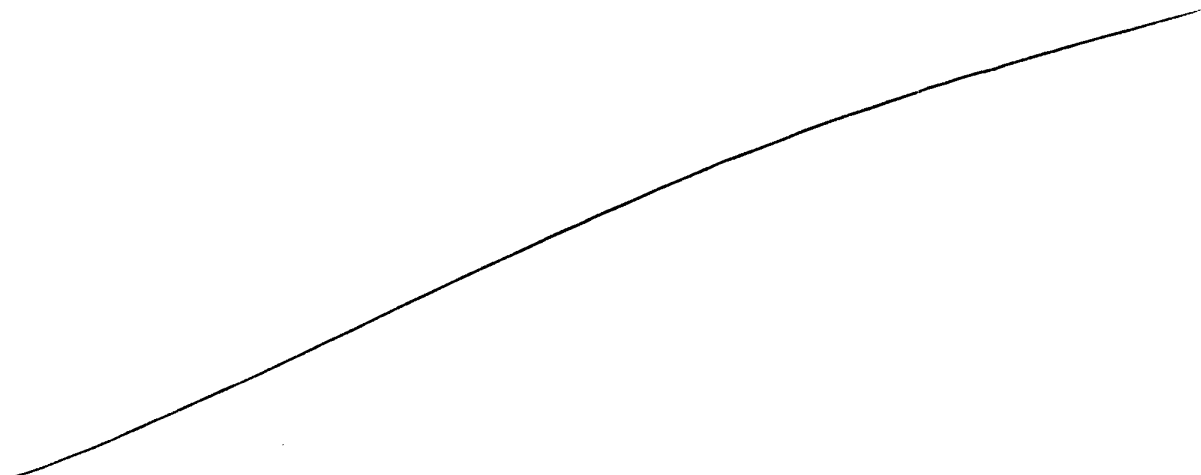
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

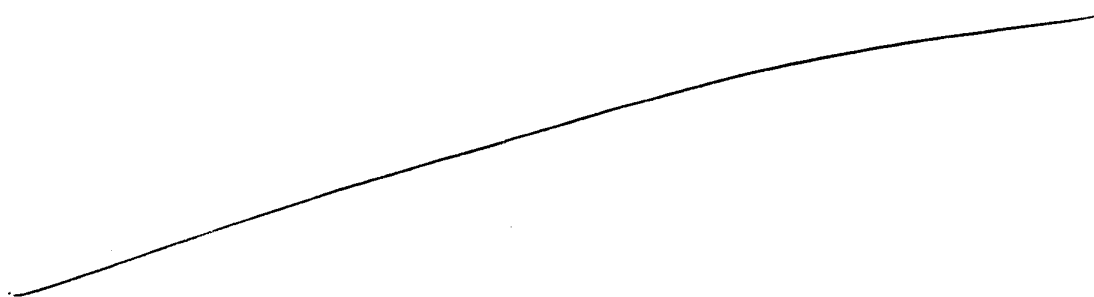
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

Section G. Quality Control



Section H. Initial Tests

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Section I. Confirmatory Tests

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Section J. Records Audit

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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RESEARCH TRIANGLE INSTITUTE

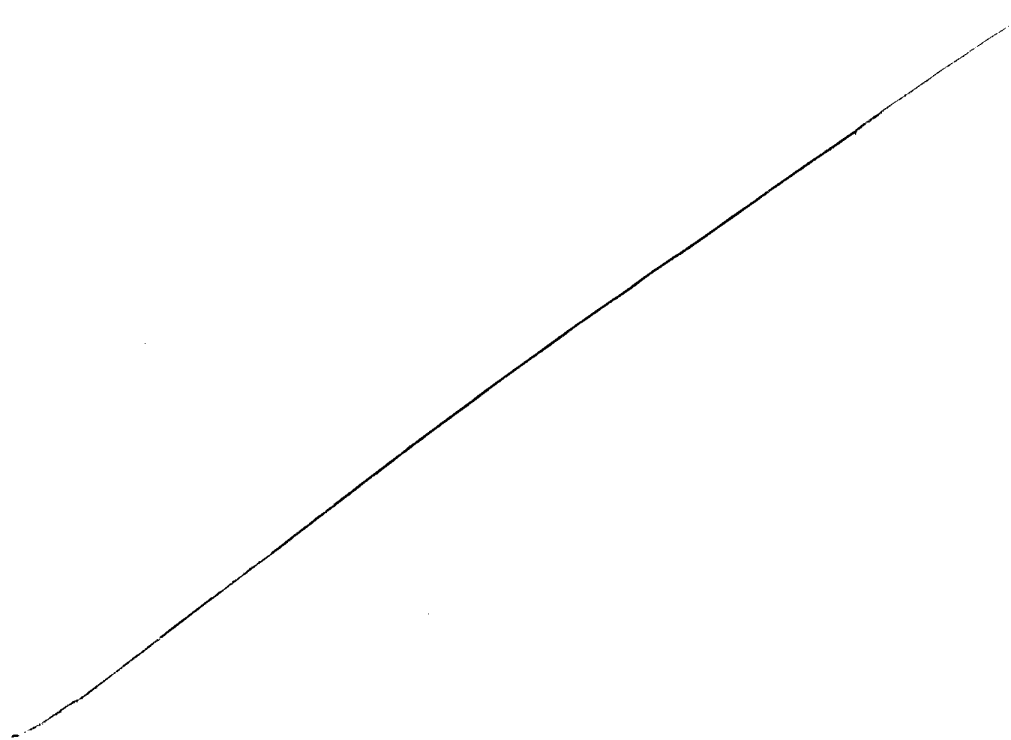
National Laboratory Certification Program

November 2, 2000

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

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 highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Dr. Yeh  
Page 2 of 2  
11/02/00

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/M5

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0898  
Document No. Final

Laboratory: Gamma-Dynacare Medical Laboratories

Location: London, Ontario

Document Reviewed:     Application Form  
                               Inspection Report #M5                    Date: 21 September 2000  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

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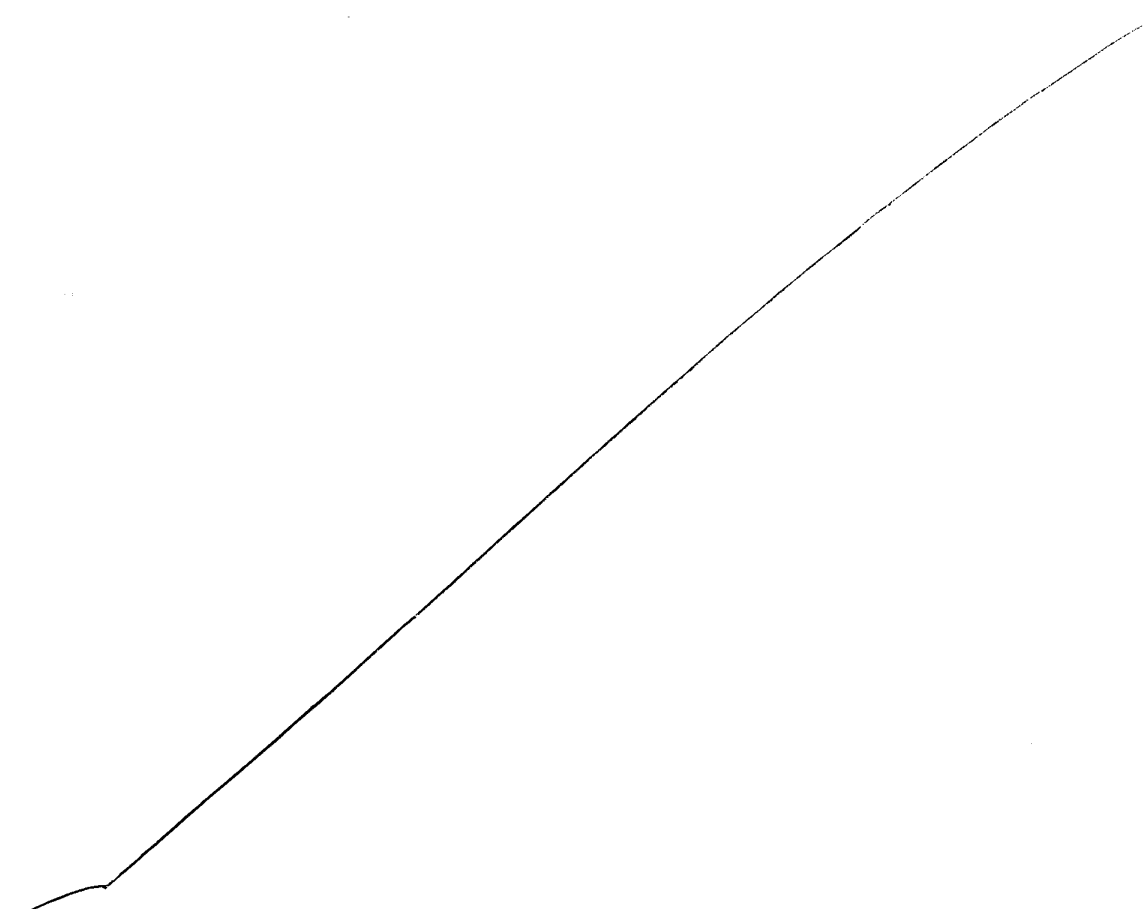
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There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.



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

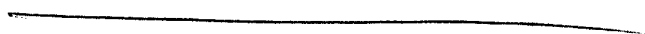
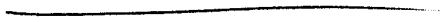
Section E. Standard Operating Procedures - Procedures Manual



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

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