



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 11, 2000

0355
Dr. William R. Lynn
LabCorp Occupational Testing Services, Inc.
7207 North Gessner Road
Houston, TX 77040

Dear Dr. Lynn:

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

Dr. Lynn
Page 2 of 3
08/11/00

The laboratory must submit 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.

Dr. Lynn
Page 3 of 3
08/11/00

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 Technical Analyst

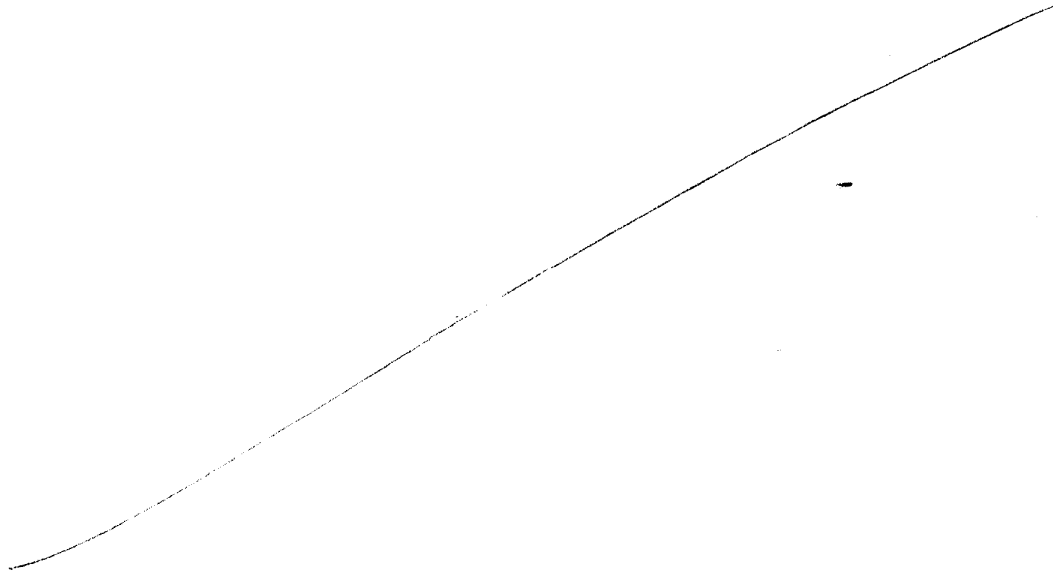
Enclosure

cc:

Project Files/355

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
SDC 8/18/00



Laboratory Corporation of America®
7207 North Gessner Road
Houston, Texas 77040

Telephone: 713-856-8288

August 17, 2000

Susan Crumpton
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms Crumpton:

The following remedial actions have occurred to correct and/or clarify issues raised during the initial inspection:

Section E 2

Section E 5

Section F 16



Section I 1b



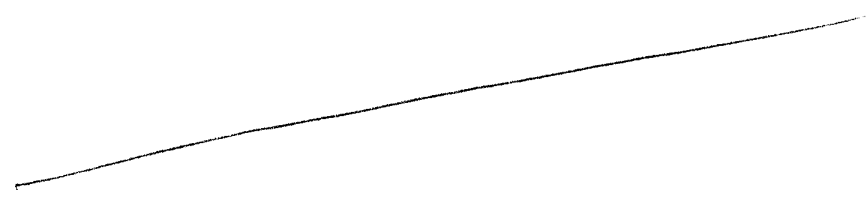
Section I 4d



Section I 18

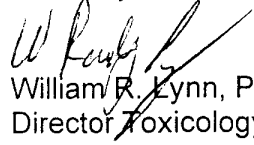


Section J 10.a



If you have any questions or need additional information please call me at 713-856-8288 x3653.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Lynn", written over the printed name.

William R. Lynn, Ph.D.
Director Toxicology



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 22, 2000

0355
Dr. William R. Lynn
LabCorp Occupational Testing Services, Inc.
7207 North Gessner Road
Houston, TX 77040

Dear Dr. Lynn:

We have reviewed the material provided in your correspondence of August 17, 2000, provided in response to issues raised during the initial inspection of your laboratory as outlined in our correspondence of August 11, 2000.

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.

Details of the results of the laboratory's performance test samples have been provided under a separate correspondence. As indicated in the materials sent to you previously, a second inspection will be conducted at your laboratory as a follow-up to the initial certification process. This inspection will occur in about three months. After you have received your official certification letter from HHS, NLCP staff will contact you regarding inspection scheduling and payment.

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.

Sincerely,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Dr. John Mitchell
Project Files/1





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

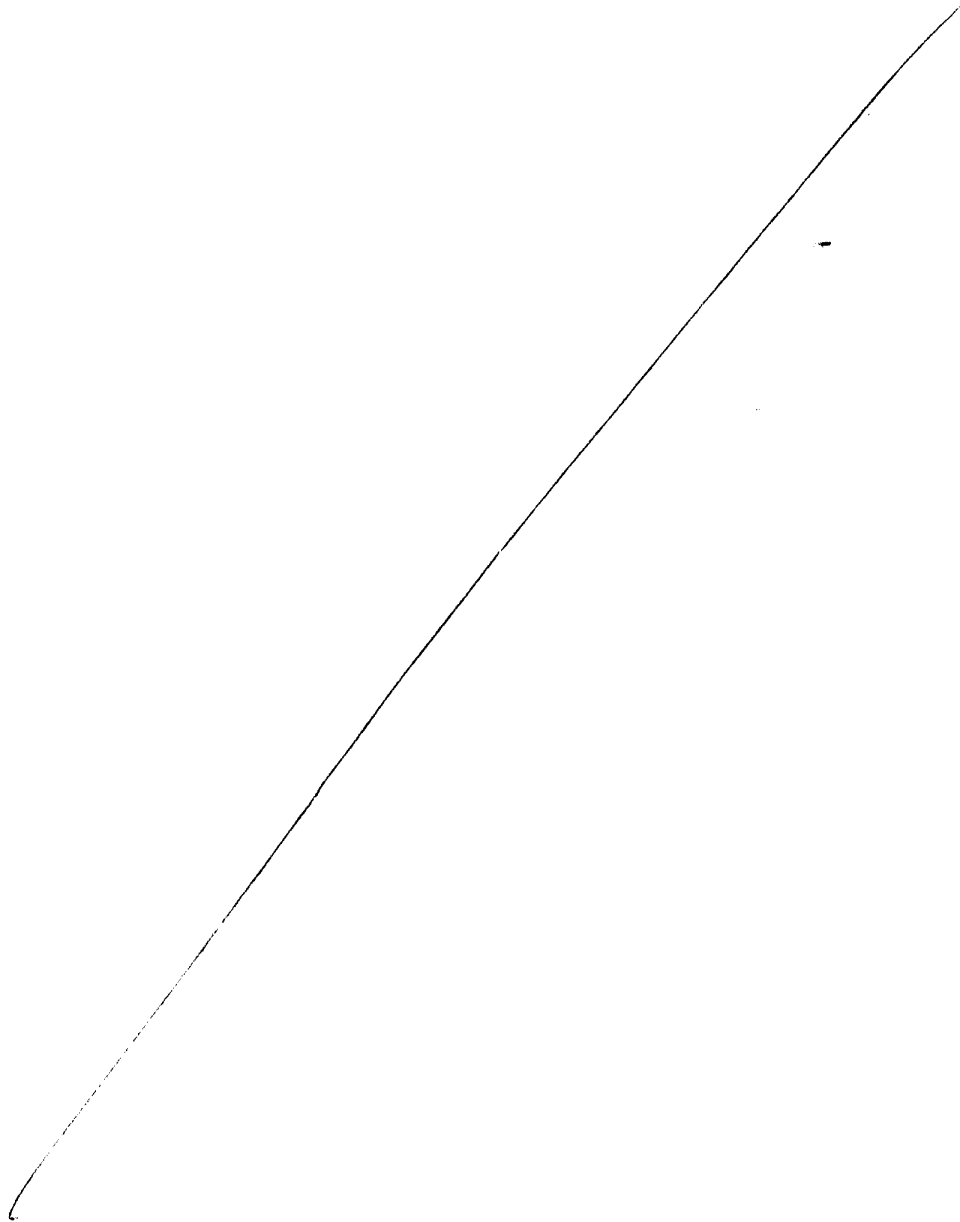
January 29, 2001

0355
Dr. William R. Lynn
LabCorp Occupational Testing Services, Inc.
7207 North Gessner Road
Houston, TX 77040

Dear Dr. Lynn:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the second (three-month) 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 clarify/correct the following issues raised:

Dr. Lynn
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01/29/01



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

Sincerely,

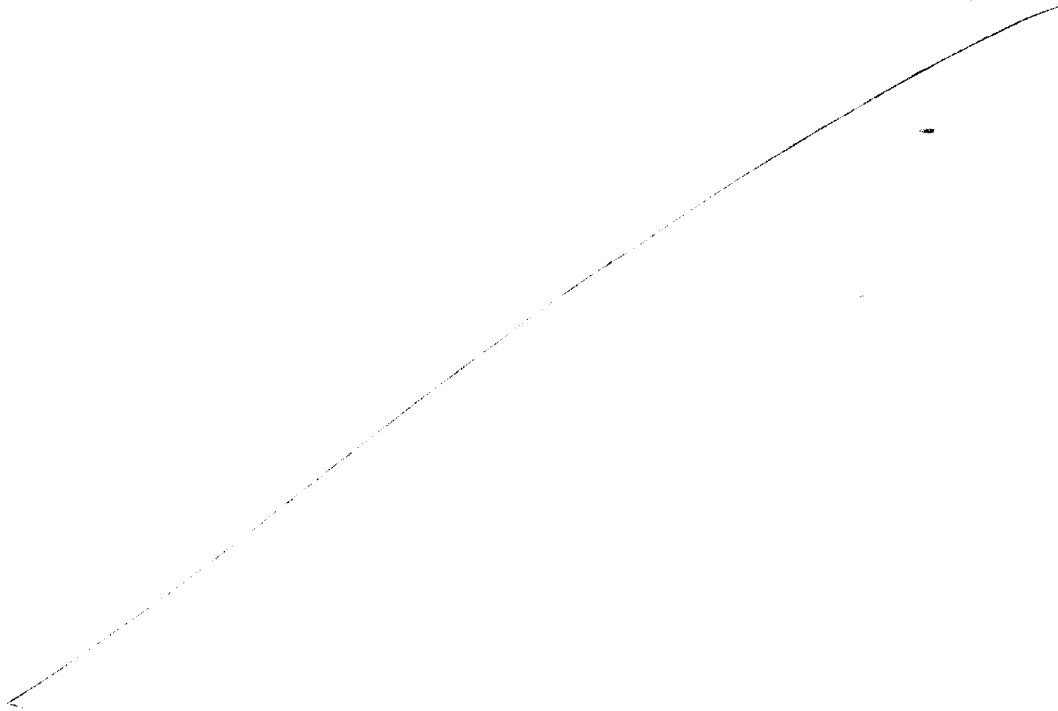

Susan Crumpton
NLCP Technical Analyst

Enclosure

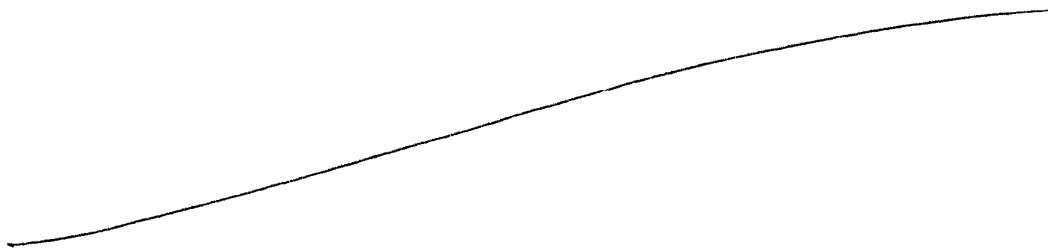
cc: Project Files/355

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

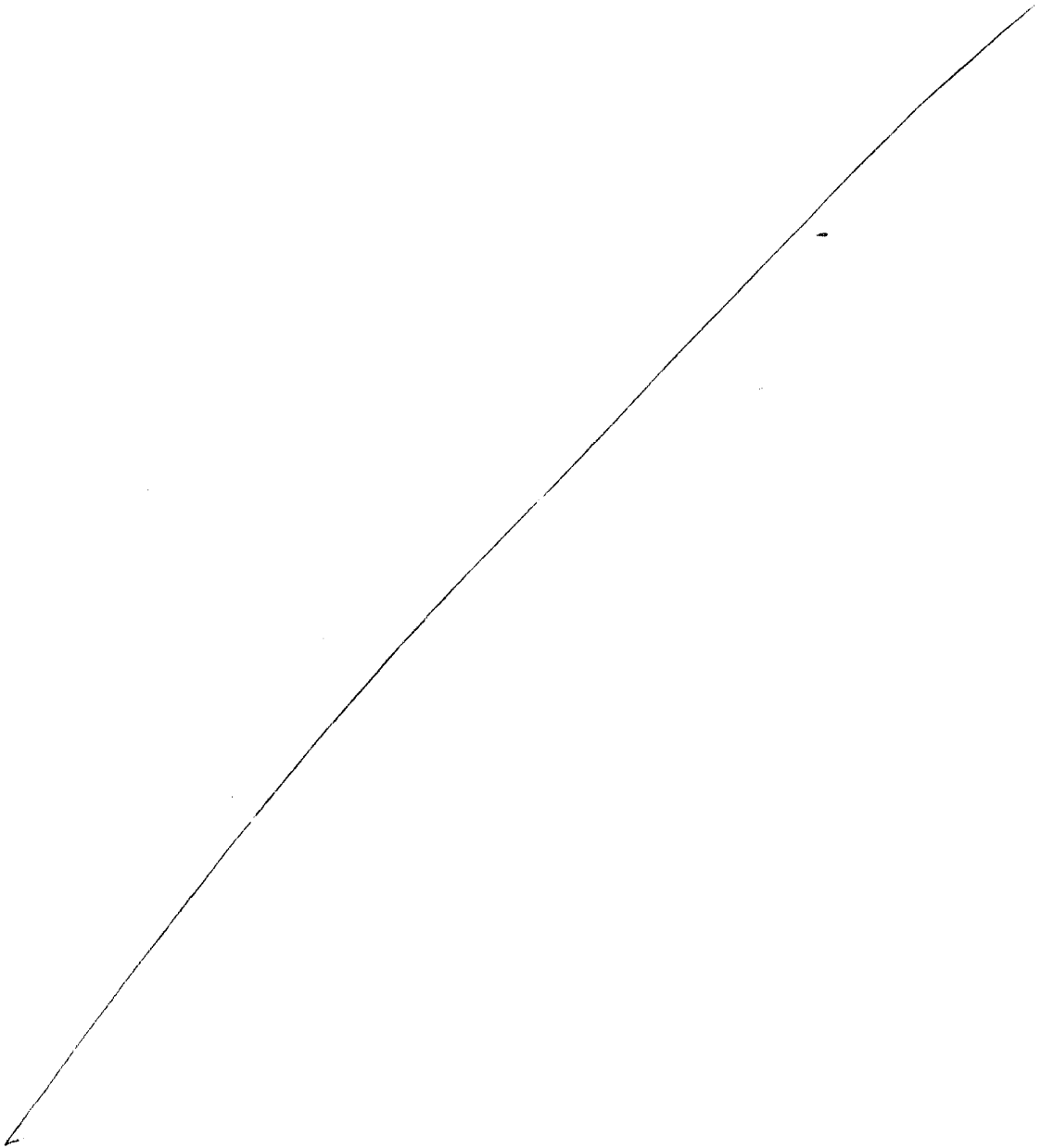
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control and Quality Assurance



Section H. Initial Tests

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

