



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 26, 1999

0030
Mr. Richard E. Struempler
Mr. Gordon Nelson
ARUP
500 Chipeta Way
Salt Lake City, UT 84108

Dear Mr. Struempler and Mr. Nelson:

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. The following issues were raised:

E. The Standard Operating Procedures section

F. The Chain of Custody, Accessioning, and Security section

Mr. Struempfer
Mr. Nelson
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H. The Initial Tests section

I. The Confirmatory Tests section

J. The Records Audit section

N. The Personnel section

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 issue in item F4 above. Once the issue has been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the

Mr. Struempler
Mr. Nelson
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laboratory's certification be continued. The laboratory must also review the enclosed critique and take all appropriate corrective actions before 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/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0030
Document No. Final

Laboratory: Associated Regional and University Pathologists, Inc.

Location: Salt Lake City, UT

Document Reviewed: Application Form
 Inspection Report #M16 Date: 3 December 1998
 Other _____

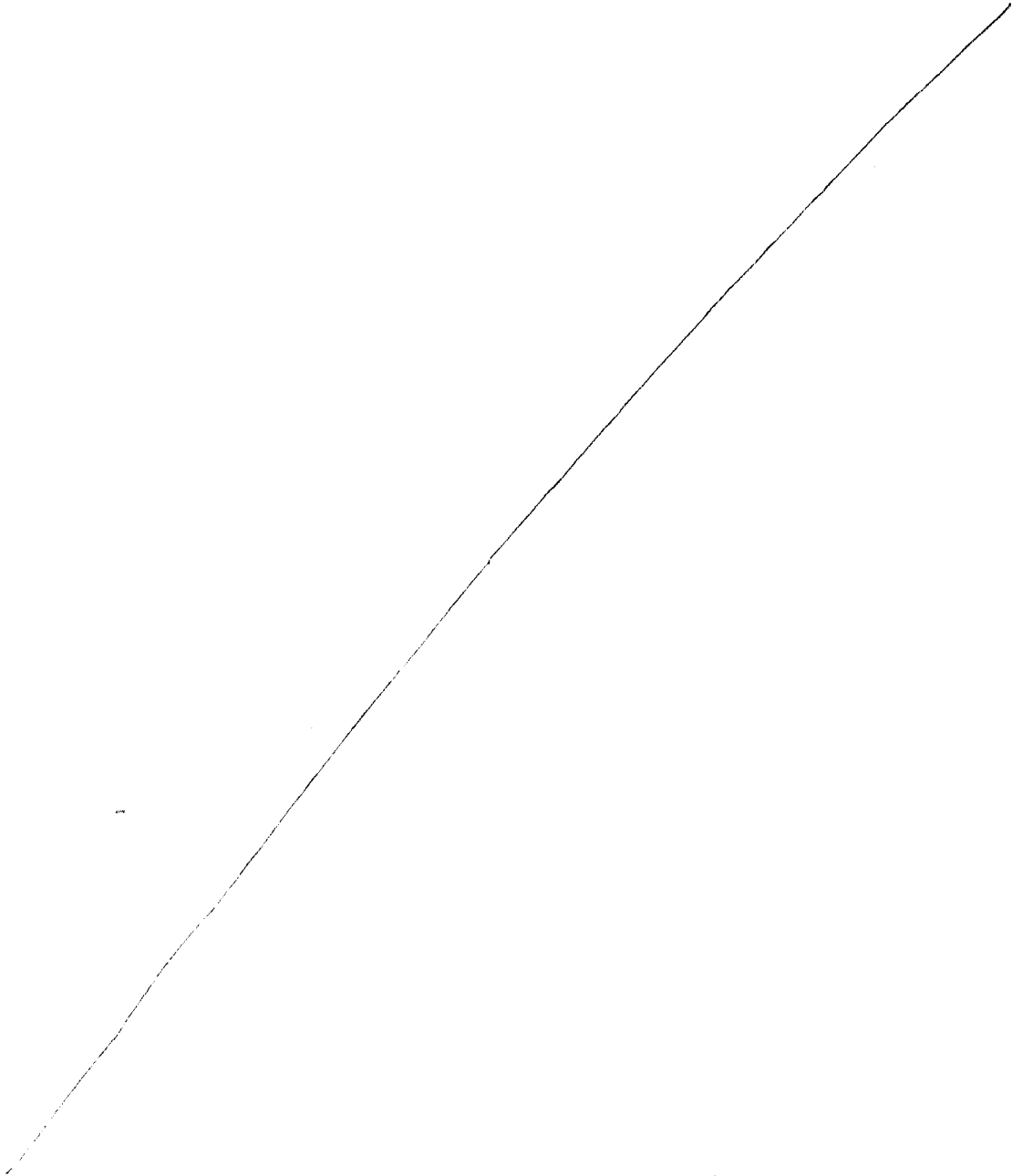
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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 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



ARUP[®]
Laboratories

received
2/21/99 DD

500 Chipeta Way, Salt Lake City, Utah 84108 (801)583-2787 Fax (801)581-0378

25 February 1999

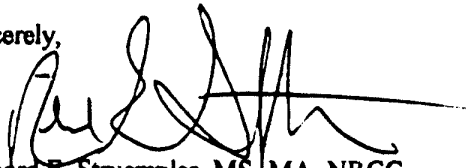
Deborah J. Denson
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

The following information is provided in response to your letter of 26 January 1999, and the critique of the sixteenth maintenance inspection under the National Laboratory Certification Program. |

If you have any questions or if I can be of further assistance, please call me at 801 583-2787, extension 2255, or Gordon Nelson at extension 2486.

Sincerely,



Richard E. Struempfer, MS, MA, NRCC
HHS Responsible Person/Forensic Toxicology Supervisor



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 4, 1999

0030
Mr. Richard E. Struempler
Mr. Gordon Nelson
ARUP
500 Chipeta Way
Salt Lake City, UT 84108

Dear Mr. Struempler and Mr. Nelson:

We have reviewed the material provided in your correspondence of February 25, 1999, submitted in response to issues raised during the sixteenth inspection of your laboratory as outlined in our correspondence of January 26, 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,

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M16





July 15, 1999

0030
Dr. Francis Urry
Mr. Richard E. Struempler
ARUP
500 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Urry and Mr. Struempler:

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 outcome of the laboratory's performance in this inspection is acceptable. Based on documents received from ARUP, it is our understanding that your laboratory ceased specimen testing as of 1 July 1999. Your laboratory has also indicated its intention to withdraw from the NLCP effective 15 July 1999. RTI will not require remedial action be implemented by your laboratory in response to the deficiencies cited in the enclosed critique. All outstanding issues concerning the accuracy and reliability of federally regulated drug testing at ARUP will be addressed as part of the remedial actions associated with the continuing special investigation.

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/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0030
Document No. Final

Laboratory: Associated Regional and University Pathologists, Inc.

Location: Salt Lake City, UT

Document Reviewed: Application Form
 Inspection Report #M17 Date: 3 June 1999
 Other _____

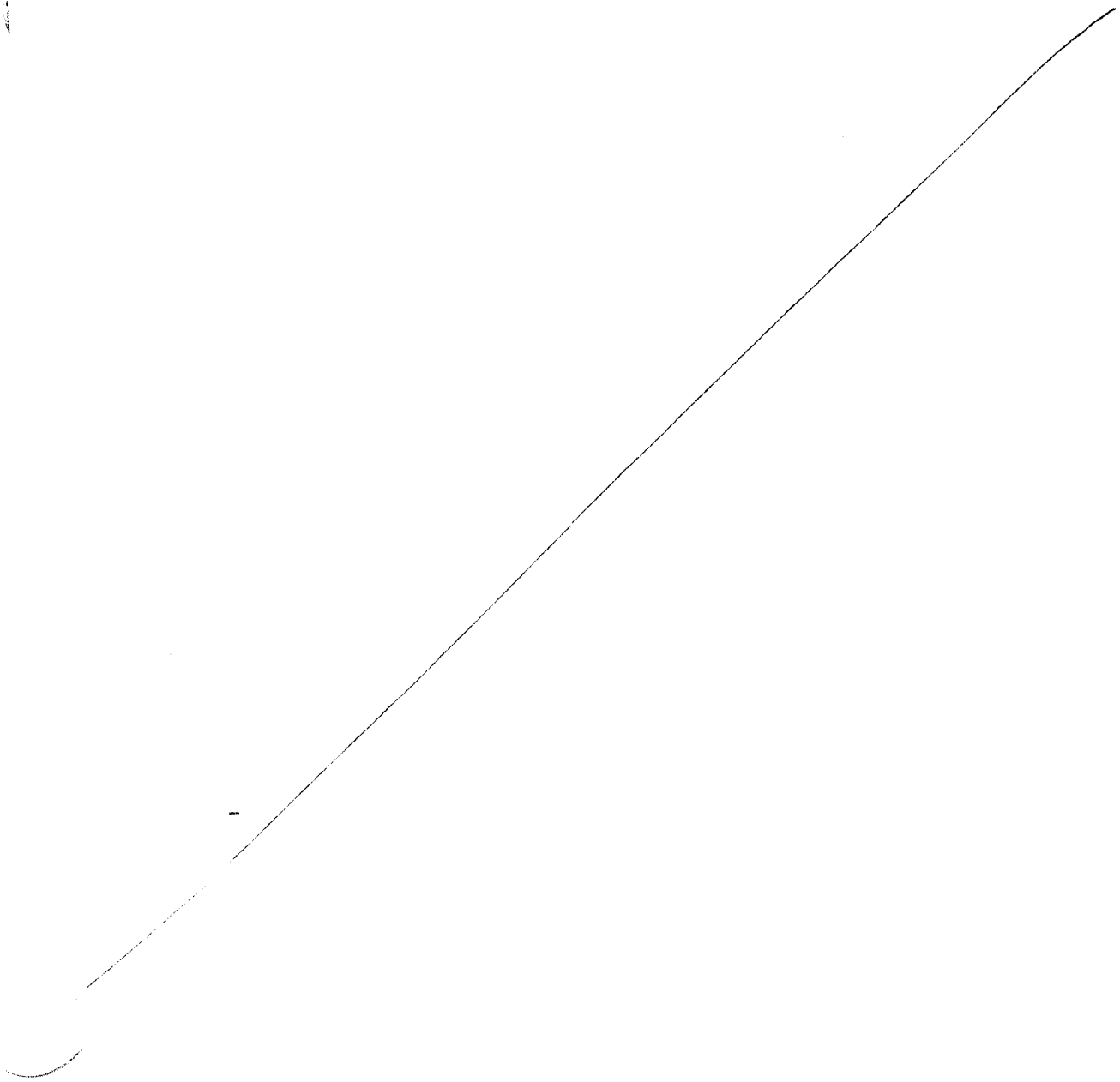
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

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