

Validity Testing Information Part I

Laboratory Name: VA medical Center Forensic Toxicology Laboratory
Address: Chem-113 / 1 Veterans Drive
mpls, MN 55417
Responsible Person: Dr. Jasbir Singh (Printed Name)

[A large diagonal line is drawn across the page, likely indicating that the document is void or has been cancelled.]

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Renee E. Burke AIT RP for 10-4-00
Signature, Responsible Person Dr. Jasbir Singh Date

Renee E. Burke AIT RP
Printed Name, Responsible Person

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for each DOT regulated specimen that was reported either adulterated or substituted:

- Specimen ID number
- Laboratory Accession Number
- Date of receipt
- Date reported
- Reported result (i.e., adulterated or substituted)
- Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

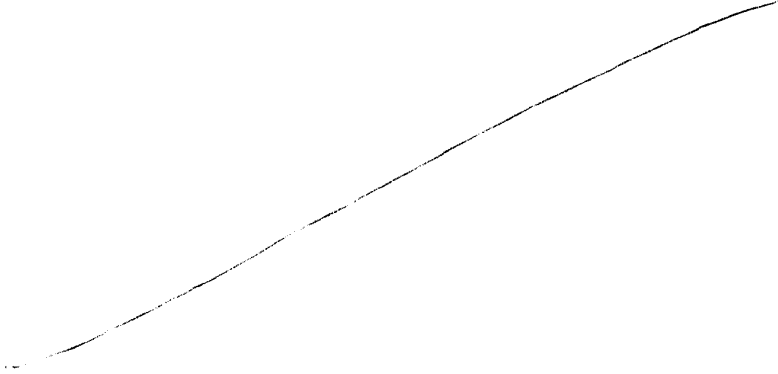
I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

J Singh
Signature, Responsible Person

10/13/00
Date

Jasbir Singh Ph.D
Printed Name, Responsible Person

Minneapolis Veterans Affairs Medical Ctr Forensic Toxicology Lab



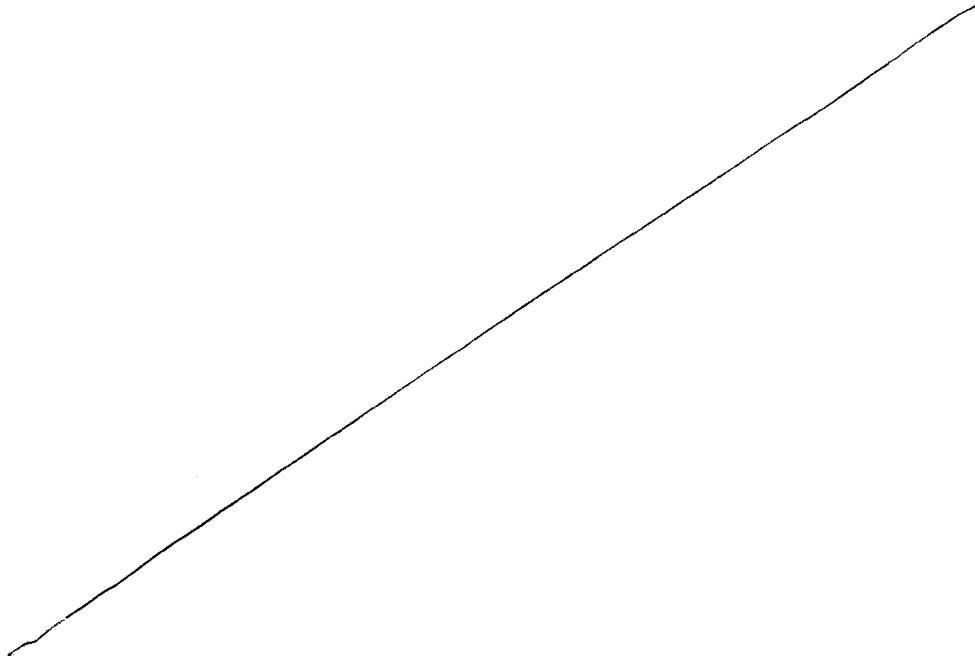


January 5, 2001

0239
Dr. Jasbir Singh
Minneapolis Veterans Affairs Medical Center
Forensic Toxicology Lab (Mail Stop 113)
1 Veterans Drive
Minneapolis, MN 55417

Dear Dr. Singh:

The enclosed critique was developed from the inspection report associated with the December 14, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:



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. The laboratory must also review the enclosed critique and take all necessary corrective actions. All

Dr. Singh
Page 3 of 3
01/05/01

corrective actions must be implemented within 30 days receipt of this correspondence. **Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.** All corrective actions 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/svt239

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0239
Document No. Final

Laboratory: Minneapolis Veterans Affairs Medical Center

Location: Minneapolis, MN

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 14 December 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

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 I. Specimen Validity Tests

Section K. Records Audit

Section L. Certification and Reporting

Section O. Overall



DEPARTMENT OF VETERANS AFFAIRS

received
1/30/01 DC

January 29, 2001

In Reply Refer To:

Ms. Susan Crumpton.
Technical Analyst
National Laboratory Certification Program
Research Triangle Institute.
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

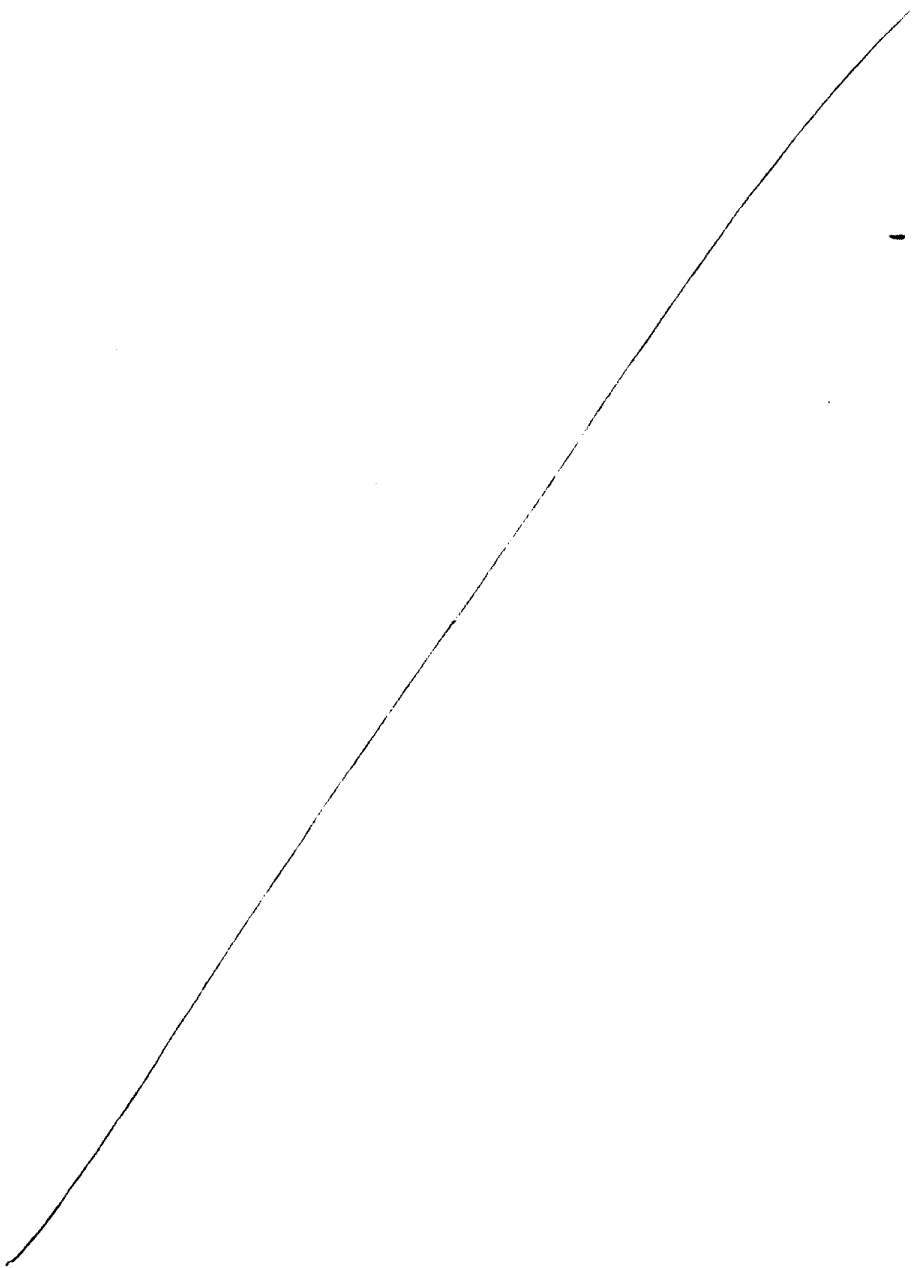
In reply to your critique of the specimen validity inspection that was performed on December 14, 2000, please find attached a copy of the response to the deficiencies. All corrective actions have been implemented and evidence of this has been provided. I trust that this will now satisfy the requirements of the program and I look forward to hearing from you in this regard.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jasbir Singh".

Jasbir Singh, Ph.D.
Director,
Forensic Toxicology Laboratory.

Corrective Actions.
Specimen Validity Inspection of December 2000.



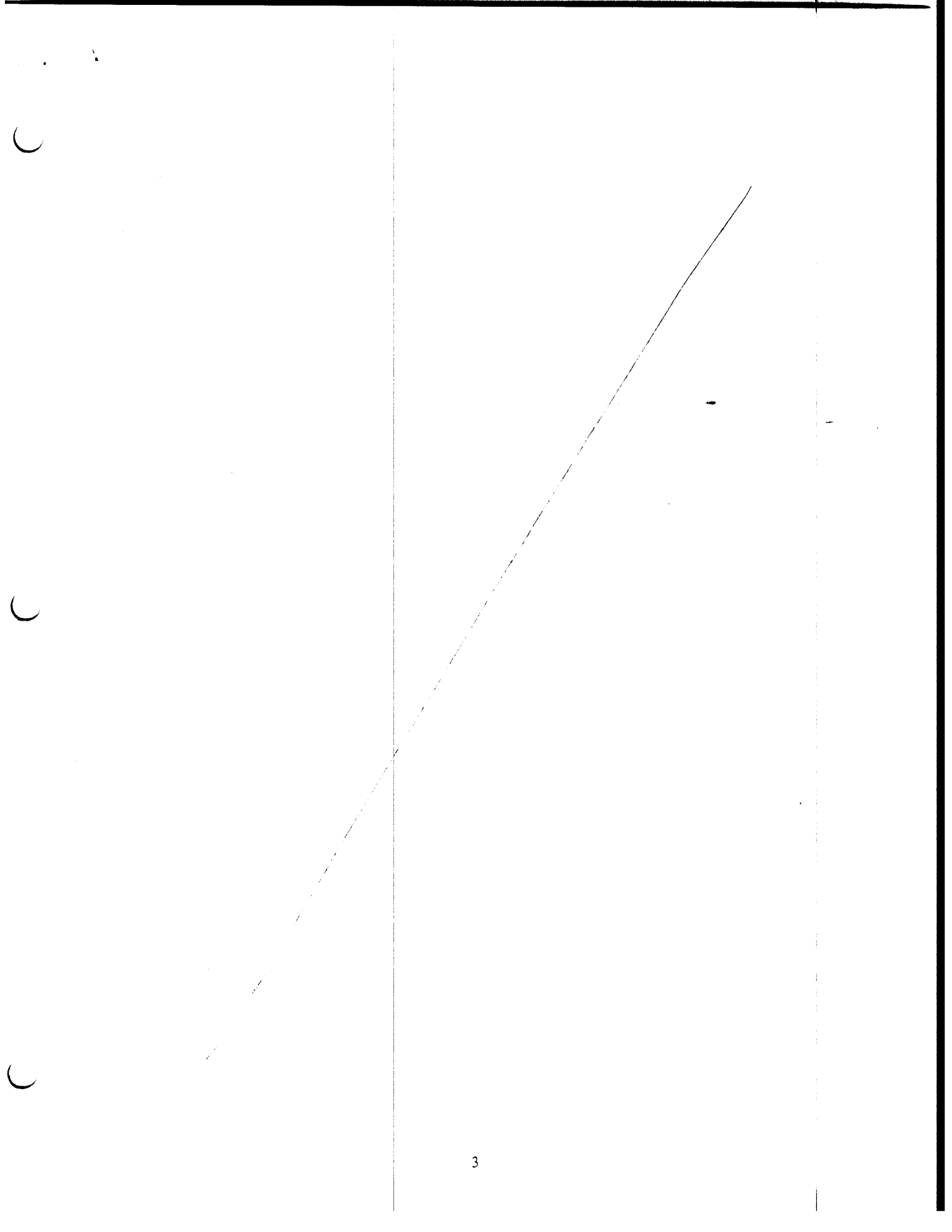
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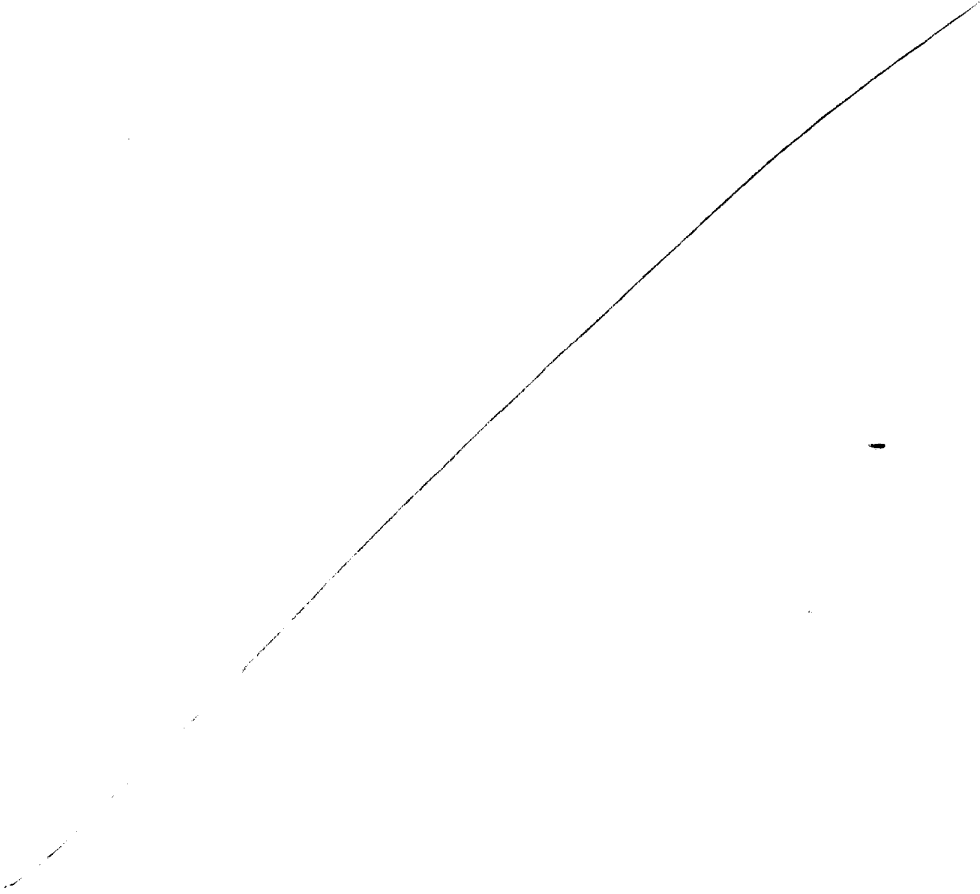
Attachment: P215

Section G. Quality control and Quality Assurance

Section I. Specimen Validity Tests

d





Section o. Overall



February 15, 2001

0239
Dr. Jasbir Singh
Minneapolis Veterans Affairs Medical Center
Forensic Toxicology Lab (Mail Stop 113)
1 Veterans Drive
Minneapolis, MN 55417

Dear Dr. Singh:

We have reviewed the material provided in your correspondence of January 29, 2001, submitted in response to issues raised during the December 14, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of January 5, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the laboratory must address the following issues raised during our review:

Dr. Singh
Page 2 of 2
02/15/01

The laboratory must submit, within 10 calendar days of receipt of this letter, documentation of corrective actions addressing the issues listed in this correspondence. All corrective actions must be implemented within 30 days of the receipt of this correspondence. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.***

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

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0239



DEPARTMENT OF VETERANS AFFAIRS

FEB 26 2001
received
SDC

February 23, 2001

In Reply Refer To:

Ms. Susan Crumpton.
Technical Analyst
National Laboratory Certification Program
Research Triangle Institute.
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

In reply to your communication dated 2/15/01 please find attached a copy of the response to the deficiencies. All corrective actions have been implemented and evidence of this has been provided.

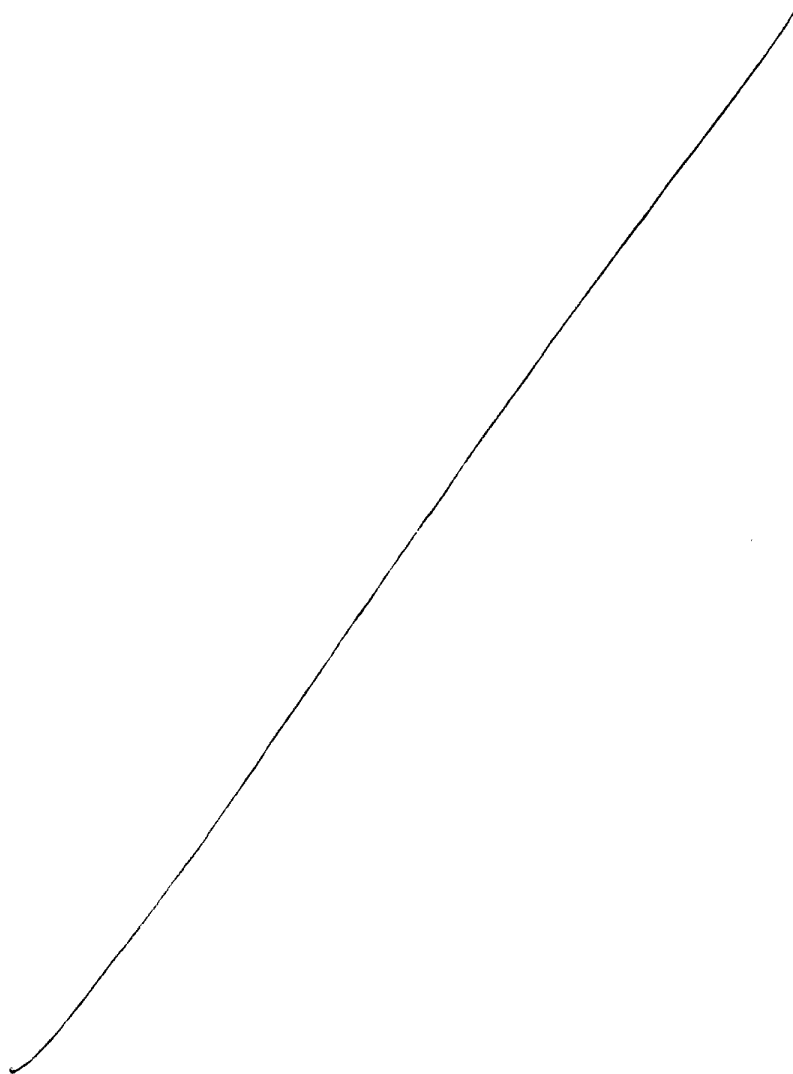
I trust that this will now satisfy the requirements of the program.

Sincerely,

A handwritten signature in cursive script, appearing to read "J Singh", is written above the typed name.

Jasbir Singh, Ph.D.
Director,
Forensic Toxicology Laboratory.

Corrective Actions.
Specimen Validity Communication from RTI 2/15/2001



March 1, 2001

0239
Dr. Jasbir Singh
Minneapolis Veterans Affairs Medical Center
Forensic Toxicology Lab (Mail Stop 113)
1 Veterans Drive
Minneapolis, MN 55417

Dear Dr. Singh:

We have reviewed the material provided in your correspondence of February 23, 2001, submitted in response to issues raised during your laboratory's December 14, 2000, specimen validity testing inspection and RTI staff's review of subsequent remedial correspondence, as outlined in our correspondence of January 5 and February 15, 2001. 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:

Dr. Singh
Page 2 of 2
03/01/01

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.***

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

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0239