Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
Empire State Plaza
Albany, NY 12237
E-mail: CLEPLTD@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

INITIAL LIMITED SERVICE LABORATORY REGISTRATION APPLICATION INSTRUCTIONS

Please follow the instructions carefully since submission of incomplete applications will delay processing and issuance of the registration. **NOTE: You must enclose a $200.00 application fee payment with your application. This fee is mandatory and non-refundable. Your check or money order should be made payable to: New York State Department of Health.** The check or check stub should indicate the laboratory's name.

Volunteer ambulance services as defined in Article 30 of the Public Health Law and operated under Section 209-B of the General Municipal Law shall be exempt from the requirement to pay the $200.00 application fee. Fee waiver eligibility is verified by the Bureau of EMS.

Volunteer ambulance services seeking a fee waiver must submit a copy of the most recent *Application for EMS Operating Certificate, form DOH-206* that was filed with the Bureau of EMS, as well as a copy of your current EMS Operating Certificate. The document may be obtained through the Bureau of EMS Central Office Operations Unit at 518-402-0996, or through the Bureau of EMS website at: http://www.health.ny.gov/professionals/ems/.

A. BACKGROUND AND GENERAL INFORMATION

The New York State Department of Health's Clinical Laboratory Evaluation Program has been authorized under Section 579 of Article 5, Title V of the Public Health Law to provide oversight to facilities performing waived and/or provider-performed microscopy procedures in New York State. These facilities are considered Limited Service Laboratories and must register with the Department as described in this registration package in order to obtain a federal CLIA number and authorization to perform patient testing. **Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of test per registration may be eligible to apply for a multi-site CLIA number.**

B. PHYSICIAN OFFICE EXCEPTION

The only facilities that are exempt from Limited Service Laboratory Registration are private physician office laboratories (POLs) operated by individual practitioners or as part of a legally constituted, independently owned and managed partnership or group practice, or the independent practice of a nurse practitioner operating under a practice agreement with a licensed physician. The tests performed must be conducted by the providers or by their own employees, utilizing their own reagents and instrumentation, solely as an adjunct to the practice of medicine for their patients. Laboratories that meet the criteria above for a POL must apply to the Physicians Office Laboratory Evaluation Program (POLEP) in order to receive a CLIA number. Information and applications may be obtained by emailing POLEP at clia@health.ny.gov.

Laboratories which are set up as a joint venture of several practitioners, partnerships or practices and practices which are owned, managed and/or operated by managed care organizations, hospitals or consulting firms do not qualify for the POL exemption and must obtain a Limited Service Laboratory Registration. If you have any question about whether a permit is required, contact our program via e-mail at: CLEPLtd@health.ny.gov.

C. ADDITIONAL RESOURCES

Technical support is available from our program to assist Limited Service Laboratory staff in implementing a quality testing program within these facilities. An additional resource available to Limited Service Laboratory staff is a document published by the Centers for Disease Control and Prevention (CDC) in November 2005 entitled "Good Laboratory Practices for Waived Testing Sites." This publication is available on the CDC website at: http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

COMPLETING THE REGISTRATION APPLICATION

Please note that the authority for the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request personal information from you, including identifying numbers such as federal Employer Identification Number (EIN), and the authority to maintain such information, is found in Section 5 of the New York State Tax Law. Disclosure of this information by you is mandatory. These numbers are routinely used only as identifiers within our Program. They may only be released for tax administration purposes and other purposes authorized by the Tax Law. The administrator of the Clinical Laboratory Evaluation Program is responsible for maintaining the records of such information. The administrator can be reached by writing to the Clinical Laboratory Evaluation Program at the address indicated at the top of this page.

1. CLIA STATUS AND APPLICATIONTYPE

CLIA Number: If you have already obtained a CLIA certificate number, please indicate the number in the area provided. If you do not already have a CLIA certificate number, one will be assigned to your facility.

Multi-Site Network Registration: Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of tests per registration may be eligible to apply for a Limited Service Laboratory Multi-Site Network Registration and Multi-Site CLIA number. One location must be designated as the primary location; this application should be completed for that site. To include secondary locations, complete and include with this application a Limited Service Laboratory Registration Notification to Add Permanent Testing Location to Multi-Site Network Registration (form, DOH-4081MS). Note that the laboratory director listed on this application will be responsible for all sites operating under a Limited Service Laboratory Multi-Site Network Registration and Multi-Site CLIA number.

2. GENERAL LABORATORY INFORMATION (Note: If you are completing this application for the primary site in a multi-site network, provide the information for that site).

Laboratory Name: Indicate the legal name exactly as you wish it to appear on the Limited Service Laboratory Registration Certificate.

Federal Employer ID Number: Under the New York State Tax Law, you are required to provide your federal Employer Identification Number. A CLIA registration number cannot be issued without this information.

County/Borough: Indicate the New York State county or borough that the laboratory is physically located in.

Laboratory Address: The laboratory address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable.

Mailing Address: Indicate if the laboratory has a separate mailing address. Our office will use the mailing address for all correspondence with your facility.

Contact Person Name, Telephone Number and E-Mail Address: The contact person is the individual designated by the Laboratory Director as the liaison with our Program. This is the individual that you would like us to direct correspondence to and/or follow-up with should questions arise regarding any of the answers provided in your registration materials. If you are applying for a multi-site network registration, this individual will be the point of contact for all sites within the network.

Laboratory Telephone and Fax Numbers, E-mail Address: These sections are self-explanatory.

Days & Hours of Testing: Indicate the days and hours when laboratory testing will be performed.

Community Screening: Indicate whether your laboratory or laboratory network will perform testing at off-site community screening events. Under community screening, laboratory staff take testing equipment from the registered Limited Service Laboratory to an off-site location where testing will occur. At the end of the event, staff, equipment & records return to the registered Limited Service Laboratory location. Nothing can be left behind at the off-site testing location, otherwise a separate Limited Service Laboratory Registration will be required. Laboratories seeking approval to operate off-site community screening events must maintain a protocol describing in detail how laboratory testing will be performed.

3. LABORATORY TYPE

This information is needed to assign and maintain your CLIA certification. Indicate your laboratory type from the list provided. Please check the type that is most descriptive of your facility.

4. OWNERSHIP INFORMATION

All applications **must** list the name and address of the individual, partnership or corporation that owns or operates the laboratory or laboratory network. “Address of Principal Office” refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory. Government-operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator.

Small Business: A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.

Foreign Ownership/Control: Indicate whether the facility is partially or fully owned, or controlled by a non-United States-based government or entity.

5. AFFILIATION

If your facility is affiliated with a laboratory holding a New York State permit, please provide the name, address, and NYS laboratory permit PFI Number (if known). Affiliation refers to actual involvement in the technical performance of the testing performed at your facility, or common staff, supplies, etc. ***Do not report the name of your reference laboratory***.

MANAGEMENT

If the laboratory testing performed under this registration is provided under a management or consulting contract, indicate the name and address of the company that you contract with to perform this testing. ***Do not report the name of your reference laboratory***.

7. LABORATORY DIRECTORSHIP

Supply information concerning the individual designated as responsible for the technical and clinical direction of the laboratory testing within your facility and/or laboratory network.

The laboratory director designee must be a licensed health care practitioner (Physician, Podiatrist, Dentist, PA, NP, PharmD, RPh or CNM only) or a Ph.D. or D.Sc. holding a certificate of qualification.

Be Reminded:

- A Ph.D. or D.Sc. designee is not licensed health care practitioner and may not act as laboratory director in sites performing Provider-performed Microscopy Procedures (PPMP).
- A PharmD or RPh designee may only order *COVID-19* and/or *Influenza* testing. A separate alternate ordering source from another licensed health care practitioner is required for any additional tests.

Indicate if the individual holds a certificate of qualification. If the individual is a health care practitioner, a license number must be provided. ***NOTE: The laboratory director must include a copy of their current New York State Professional License (or in the case of a Ph.D or D.Sc. designee, a copy of their Certificate of Qualification) with the completed Limited Service Laboratory Registration Reapplication package.***

Indicate whether the individual is available to the facility and/or laboratory network on a full-time, or part-time basis during the days & hours when laboratory testing will be performed.

8. WAIVED TEST PROCEDURES REQUESTED

Indicate the *Waived* tests that you wish to perform and provide the combined estimated annual test volume for all *Waived* test procedures indicated. **Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration (FDA) as *Waived* for the purposes of CLIA '88. Non-DOT breath alcohol testing must be performed using an FDA approved IVD Over-The-Counter device. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated. Listings of waived tests are available at the following websites:

To Search By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm
To Search By Analyte: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm
To Search a Particular Kit/Mfr.: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
To Search FDA's IVD Over-The-Counter Lab Test Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm

Additional guidance with protocol development for lead, and/or rapid HIV testing is available at the following websites:

For Lead Testing: www.wadsworth.org/regulatory/clep/limited-service-lab-certs
For HIV Testing: www.health.state.ny.us/diseases/aids/testing/rapid/index.htm

9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED

Indicate the *Provider-performed Microscopy (PPM) Procedures* that you wish to perform and provide the combined estimated annual test volume for all PPM Procedures indicated. ***Provider-performed Microscopy (PPM) Procedures* includes tests personally performed as part of physical examinations by health care providers, licensed and currently registered in New York State, including physicians, dentists, podiatrists, physician assistants, nurse practitioners and certified midwives operating within the scope of practice for their profession and which have been designated as *PPM Procedures* by the Centers for Disease Control. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated.

10. CERTIFICATION

This section must be completed & signed by the individual indicated in Section 7–Laboratory Directorship as responsible for the technical and clinical direction of your laboratory testing and the individual completing the application (if different from the Laboratory Director). **Please Note: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.**

OUR MAILING ADDRESS

Application documents must be returned to our office at the address below:

Regular Mail
Clinical Laboratory Evaluation Program
Biggs Laboratory
Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237

Express Mail
Clinical Laboratory Evaluation Program
Biggs Laboratory
Wadsworth Center
NYS Department of Health
Dock J - P1 Level
Empire State Plaza
Albany, NY 12237

LIMITED SERVICE LABORATORYREGISTRATION

Once the Limited Service Laboratory Registration application is approved, an initial registration certificate will be issued. The certificate will serve to verify your enrollment with this Program and will also provide documentation of your CLIA registration number. If you are applying for a multi-site network registration, registration certificates for all locations in the network will be sent to the primary location. Certificates are valid for two years from the date issued. Approximately three months before the registration expires, you will receive materials to renew your registration or multi-site network registration.

Registrants may only perform the tests listed on the registration certificate issued by the Department. Multi-site network registrants may only perform the tests listed on the registration certificate issued to the Primary Site.

CHANGES IN STATUS

Once approved, you must keep our Program informed of any changes which may affect your registration status (i.e. laboratory name, address, director, test menu, owner, additional testing sites, etc.). Be advised that Limited Service Laboratory registrations are void upon change in the laboratory location or the owner. In addition, registrants must inform our Program of any change in location or laboratory director within 30 days of the change. Limited Service Laboratory Change forms may be downloaded from our website at: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

SPECIAL NOTICE

The submission of incomplete and/or incorrect application materials will delay processing. Required information includes, but is not limited to the following:

- $200.00 Application Fee (*Volunteer Ambulances Services Refer to Page - 1 of the Instructions*);
- A Working E-Mail Address;
- A Copy of Laboratory Director's Current New York State Professional License;
- Estimated Annual Test Volumes for Waived and/or PPM Procedures;
- Name & Original Signature of Laboratory Director and Individual Completing Application. Signature stamps will not be accepted.

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Wadsworth Center
New York State Department of Health
Empire State Plaza
Albany, NY 12237
Telephone: (518) 402-4253 Fax: (518) 449-6902
E-mail: CLEPLtd@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

FOR OFFICE USE ONLY: ***I*** ___ ***R*** ___

Rec'd. _____

Fee No. _____

PFI: _____ Gaz Code: _____

CLIA No: _____

INITIAL LIMITED SERVICE LABORATORY REGISTRATION APPLICATION

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1. CLIA STATUS AND APPLICATION TYPE:

If your laboratory already has a CLIA number, please indicate here: _____

Type of Limited Service Laboratory Registration Requested (Select One):

☐ Single-Site Registration
☐ Multi-Site Registration (if you wish to add secondary testing sites, please complete form, DOH-4081MS)

If this is a new facility, indicate the projected opening date: _____

2. GENERAL INFORMATION: If applying for a multi-site registration, complete this information for the main site.

Laboratory Name (Limited to 70 Characters):	Federal Employer ID Number:
	County/Borough:

Laboratory Address (Physical Location of Laboratory):

City:	State:	ZIP Code:

Mailing Address (If Different From Physical Location):

City:	State:	ZIP Code:

Telephone Number:	FAX Number:	Contact Person Name (If Not the Laboratory Director):
Laboratory E-mail Address:		Telephone Number: E-mail Address:

Indicate the Days & Hours when testing will be performed (Please clarify hours as AM and/or PM):

MO _____ to _____ TU _____ to _____ WE _____ to _____ TH _____ to _____

FR _____ to _____ SA _____ to _____ SU _____ to _____

Indicate whether your laboratory or laboratory network will perform community screening events: ☐ No ☐ Yes

3. LABORATORY TYPE: Select one from the list below that best describes your laboratory.

- ☐ 01-*24* Ambulance
- ☐ 02-*3B* Ambulatory Surgery Center
- ☐ 03-*02* Ancillary Testing Site in Health Care Facility/ Hospital Extension Clinic
- ☐ 04-*25* Assisted Living Facility
- ☐ 05-*26* Blood Bank
- ☐ 06-*3A* Community Clinic
- ☐ 07-*04* Comprehensive Outpatient Rehabilitation Facility
- ☐ 23-*06* Correctional Facilities
- ☐ 08-*3C* End Stage Renal Disease Dialysis Facility
- ☐ 09-*3D* Federally Qualified Health Center
- ☐ 10-*08* Health Fair
- ☐ 11-*07* Health Maintenance Organization
- ☐ 12-*08* Home Health Agency
- ☐ 13-*09* Hospice
- ☐ 14-*01* Hospital
- ☐ 15-*11* Independent
- ☐ 16-*12* Industrial
- ☐ 17-*13* Insurance
- ☐ 18-*14* Intermediate Care Facility for the Mentally Retarded
- ☐ 19-*15* Mobile Laboratory
- ☐ 20-*16* Pharmacy
- ☐ 21-*19* Physician Office
- ☐ 22-*20* Practitioner Other
- ☐ 24-*27* Public Health Laboratory
- ☐ 25-*3D* Rural Health Clinic
- ☐ 26-*17* School/Student Health Service
- ☐ 27-*18* Skilled Nursing Facility or Nursing Facility
- ☐ 28-*28* Tissue Bank/Repositories
- ☐ 29-*99* Other (Indicate): _____

4. OWNERSHIP INFORMATION: List the name and address of the individual, partnership or corporation owning or operating the laboratory or laboratory network. "Address of Principal Office" refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory or laboratory network.

Type of Control/Ownership (Check Only One Box From the List Below):

For-Profit (indicate):	☐ Individual	☐ Partnership	☐ Corporation	
Not-For-Profit (indicate):	☐ Religious Affiliation	☐ Private		
Government (indicate):	☐ City	☐ County	☐ State	☐ Federal

Name of Owner (if Sole Proprietorship) or Corporation:

Street Address of Principal Office of Owner (if Sole Proprietorship) or Corporation:

City:	State:	ZIP Code:

This Facility: A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.

☐ Is a small business ☐ Is not a small business

Foreign Ownership/Control: Does this facility have partial or full ownership or control by a non-United States-based government or entity?

☐ Yes (Indicate the country of origin for the foreign entity): _____ ☐ No

5. AFFILIATION: If your laboratory is affiliated with a laboratory holding a NYS laboratory permit, provide the name, address, and NYS laboratory permit PFI Number (if known). *Do not provide the name and PFI Number of your reference laboratory.*

PFI Number:	Name of Affiliated Laboratory:

Street Address:

City:	State:	ZIP Code:

6. MANAGEMENT: If the laboratory testing performed on-site in your facility is provided under a management or consulting contract, indicate the name, and address of the company you contract with to perform this testing. *Do <u>not</u> provide the name and PFI Number of your reference laboratory.*

Name of Management/Consulting Company:		
Street Address: ☐ ☐		
City:	State:	ZIP Code:

7. LABORATORY DIRECTORSHIP: Complete this section in its entirety for the individual providing technical and clinical direction of your laboratory testing.

First Name:	M.I.:	Last Name:

Do you currently hold a NYS Laboratory Director Certificate of Qualification? ☐ Yes (Indicate CQ Code): _____ ☐ No

Check Degree(s) and License(s) Held (Include a Copy of Current New York State Professional License):

☐ M.D. ☐ D.O. ☐ D.P.M. ☐ D.D.S. ☐ Ph.D ☐ O.D. ☐ D.Sc. ☐ NP ☐ PA ☐ CNM ☐ PharmD ☐ RPh

Indicate New York State Professional License Number: _____

Home E-mail Address:	Work E-mail Address:

8. WAIVED TEST PROCEDURES REQUESTED: Check off all waived tests that you intend to perform and indicate the estimated annual test volume for all waived tests to be performed.

☐ Adenovirus	☐ Creatinine	☐ Nicotine
☐ Aerobic/Anaerobic Organisms-Vaginal	☐ Drugs of Abuse	☐ Occult Blood
☐ Alanine Aminotransferase *(ALT)*	☐ Erythrocyte Sedimentation Rate *(ESR)*	☐ Ovulation Tests
☐ Albumin	☐ Ethanol	☐ pH
☐ Alkaline Phosphatase *(ALP)*	☐ Gamma Glutamyl Transferace *(GGT)*	☐ Phosphorous
☐ Amylase	☐ Glucose	☐ Platelet Aggregation
☐ Aspartate Aminotransferase *(AST)*	☐ Glycosylated Hemoglobin	☐ Potassium
☐ B-Type Natriuretic Peptide *(BNP)*	☐ HDL Cholesterol	☐ Pregnancy Test (*Urine*)
☐ Bacterial Vaginosis, Rapid	☐ Helicobacter Pylori	☐ Protime
☐ Blood Urea Nitrogen *(BUN)*	☐ Hematocrit	☐ RSV *(Respiratory Syncytial Virus)*
☐ Breath Alcohol *(FDA OTC Devices Only)*	☐ Hemoglobin	☐ Saliva Alcohol
☐ Calcium	☐ HCV, Rapid	☐ Sodium
☐ Calcium, Ionized	☐ HIV, Rapid	☐ Strep A Test (*Rapid*)
☐ Carbon Dioxide	☐ Influenza	☐ Thyroid-Stimulating Hormone *(TSH)*
☐ Chloride	☐ Ketones	☐ Total Bilirubin
☐ Cholesterol	☐ Lactic Acid *(Lactate)*	☐ Total Protein
☐ Creatine Kinase *(CK)*	☐ LDL Cholesterol	☐ Trichomonas, Rapid
☐ **COVID-19 *Antigen***	☐ Lead	☐ Triglycerides
☐ **COVID-19 *Molecular***	☐ Microalbumin	☐ Urinalysis
☐ **COVID-19 *Antibody***	☐ Mononucleosis	☐ Other: _____

	Indicate the combined estimated annual test volume for <u>all</u> Waived Test Procedures indicated above.

9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED: Check off all PPM Procedures that you intend to perform. NOTE: Only providers (physicians, nurse practitioners, nurse midwives and physician assistants) may perform testing.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Fecal Leukocyte examinations
- ☐ Fern tests
- ☐ Nasal smears for granulocytes
- ☐ Pinworm examinations
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
- ☐ Urine sediment examinations

	Indicate the combined estimated annual test volume for <u>all</u> PPM Procedures indicated above.

10. CERTIFICATION. I understand that by signing this application form, I agree to any investigation made by the Department of Health to verify or confirm the information provided herein or adjunctive to this application, and any investigation in connection with my laboratory registration, a complaint or incident report made known to the Department. Registration under this subdivision may be denied, limited, suspended, revoked or annulled by the Department upon a determination that a laboratory services registrant: (i) failed to comply with the requirements of this subdivision; (ii) provided services that constitute an unwarranted risk to human health; (iii) intentionally provided any false or misleading information to the Department relating to registration or performing laboratory services; or (iv) has demonstrated incompetence or shown consistent errors in the performance of examinations or procedures. If additional information is requested, I will provide it. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation.

Laboratory test registrants shall: (i) provide only the tests and services listed on the registration issued by the Department hereunder; (ii) advise the Department of any change in the registrant's name, ownership, location or qualified health care professional or laboratory director designated to supervise testing within thirty days of such change; (iii) provide the department with immediate access to all facilities, equipment, records, and personnel as required by the Department to determine compliance with this subdivision; (iv) comply with all public health law and federal requirements for reporting reportable diseases and conditions to the same extent and in the same manner as a clinical laboratory; (v) perform one or more tests as required by the department to determine the proficiency of the persons performing such tests; and (vi) designate a qualified health care professional or qualified individual holding a certificate of qualification pursuant to section five hundred seventy-three of this title, who shall be jointly and severally responsible for the testing performed.

By signing this application, I hereby attest that the information I have given the Department of Health as a basis for obtaining a Limited Service Laboratory Registration is true and correct, that I have read the relevant rules and regulations, and that I accept responsibility for the tests indicated in Section(s) 8. Waived Test Procedures Requested and/or 9. Provider-Performed Microscopy (PPM) Procedures Requested of this application.

Print Name of Laboratory Director	Signature of Laboratory Director	Date
Print Name of Person Completing this Form	Signature of Person Completing this Form	Date

SPECIAL NOTICE

Return this application and any accompanying documentation by <u>mail</u> only. The submission of incomplete and/or incorrect application materials will delay processing. Required information includes, but is not limited to the following:

- $200.00 Application Fee (*Volunteer Ambulance Services Refer to Page - 1 of the Instructions*);
- A Working E-Mail Address;
- A Copy of Laboratory Director's Current New York State Professional License;
- Estimated Annual Test Volumes for Waived and/or PPM Procedures;
- Name & Original Signature of Laboratory Director and Individual Completing Application. Signature stamps will <u>not</u> be accepted.