

**Clinical Laboratory Evaluation Program
Management of NPL Requests
July 2011**

New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Part 58-1.10 (g) of 10NYCRR) require that all specimens obtained within New York State be tested by a laboratory that holds a New York State clinical laboratory permit, including test-specific approval when required. Test-specific approval is not required for tests designated as FDA-cleared, approved or exempt. Notification to add such tests to the laboratory's test menu is still required. Due to the rarity of many diseases, testing for all potential conditions may not be available from permit-holding laboratories or there may be adequate justification for use of a specific laboratory that does not hold a permit. In these cases, the department's approval must be received prior to submitting a specimen collected in New York State for testing by a non-permitted laboratory or a permitted laboratory that does not hold approval for that particular test. The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests. The following policy and algorithm is proposed to manage the non-permitted laboratory (NPL) test request process.

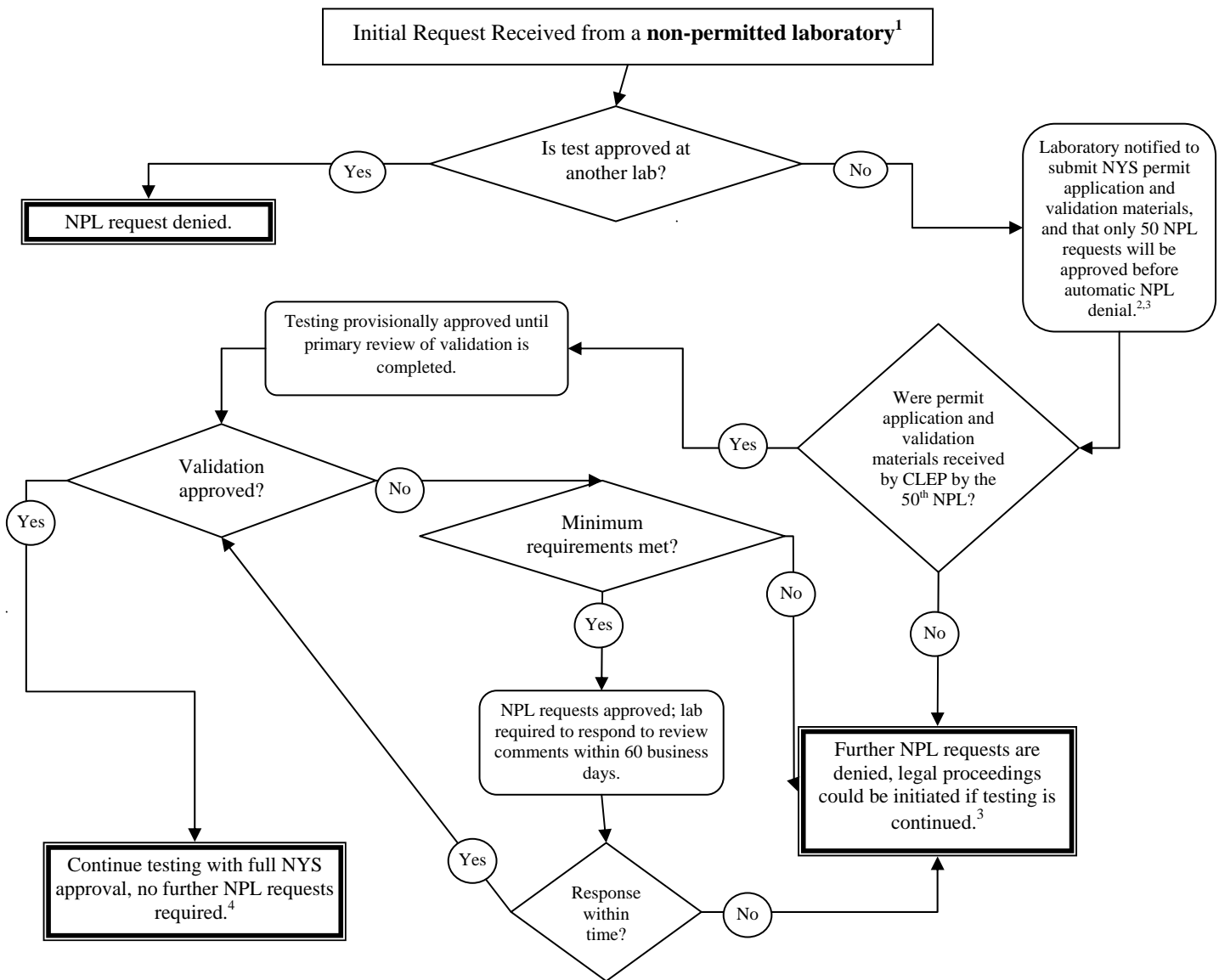
The algorithm is based on the following:

- New York State has adopted the CLIA interpretive guidelines published by the Centers for Medicare and Medicaid Services for the establishment and verification of performance standards (§493.1253(a)). Laboratories are required to verify or establish performance specifications for any test system. However, submission for review of Standard Operating Procedures Manuals and validation for any test system used by the laboratory prior to April 24, 2003 is not required, unless specifically requested. The laboratory must provide documentation for review during the on-site survey to demonstrate that the test was in use in the laboratory prior to April 24, 2003.
- Clinical validity is defined as the proven ability of an assay to reliably identify a specific condition in a test subject.
- Unique availability refers to those tests performed using a method not offered by another laboratory or tests carried out using an approach that differs substantially from a NYS approved assay.
- Continuity of care is an acceptable justification for an NPL request for a certain test that requires subsequent testing to be performed at the same facility and on the same instrumentation to allow relevant comparisons of test results over time. The necessity for continuity must be well-established and justified for the test being requested.
- Sample integrity is only an acceptable justification for NPL request approval in the following situations:
 - the sample would have to be split to allow testing at another facility that is approved to perform the test and such splitting would put the specimen at risk of compromise.
 - the sample must be tested within a defined timeframe to provide accurate results and shipping of the specimen to another facility approved to perform the test would delay the receipt of the sample beyond this timeframe. Laboratories should be cognizant of the specimen integrity requirements prior to sending the specimen to a laboratory that does not hold approval to perform the test. **Please note: Reference laboratories must have mechanisms in place to avoid unnecessary delays that would affect specimen integrity when seeking approval for a restricted permit.**
- Refusal of another laboratory to accept preprocessed samples (e.g. isolated DNA or RNA) is not a sufficient justification for an NPL approval if the sample could have been split without jeopardizing timely testing.

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- Minimum requirements must be met to approve a validation package. Examples of failure to meet the minimum requirements include:
 - lack of data demonstrating compliance with the minimum requirements as outlined in the department's validation submission guidelines (available on the website at www.wadsworth.org/clep);
 - the determination, based on published literature, of lack of clinical validity/medical relevance;
 - inadequacy of test design that would impact the intended test outcome (e.g. the test would not work as written in the provided standard operating procedure).

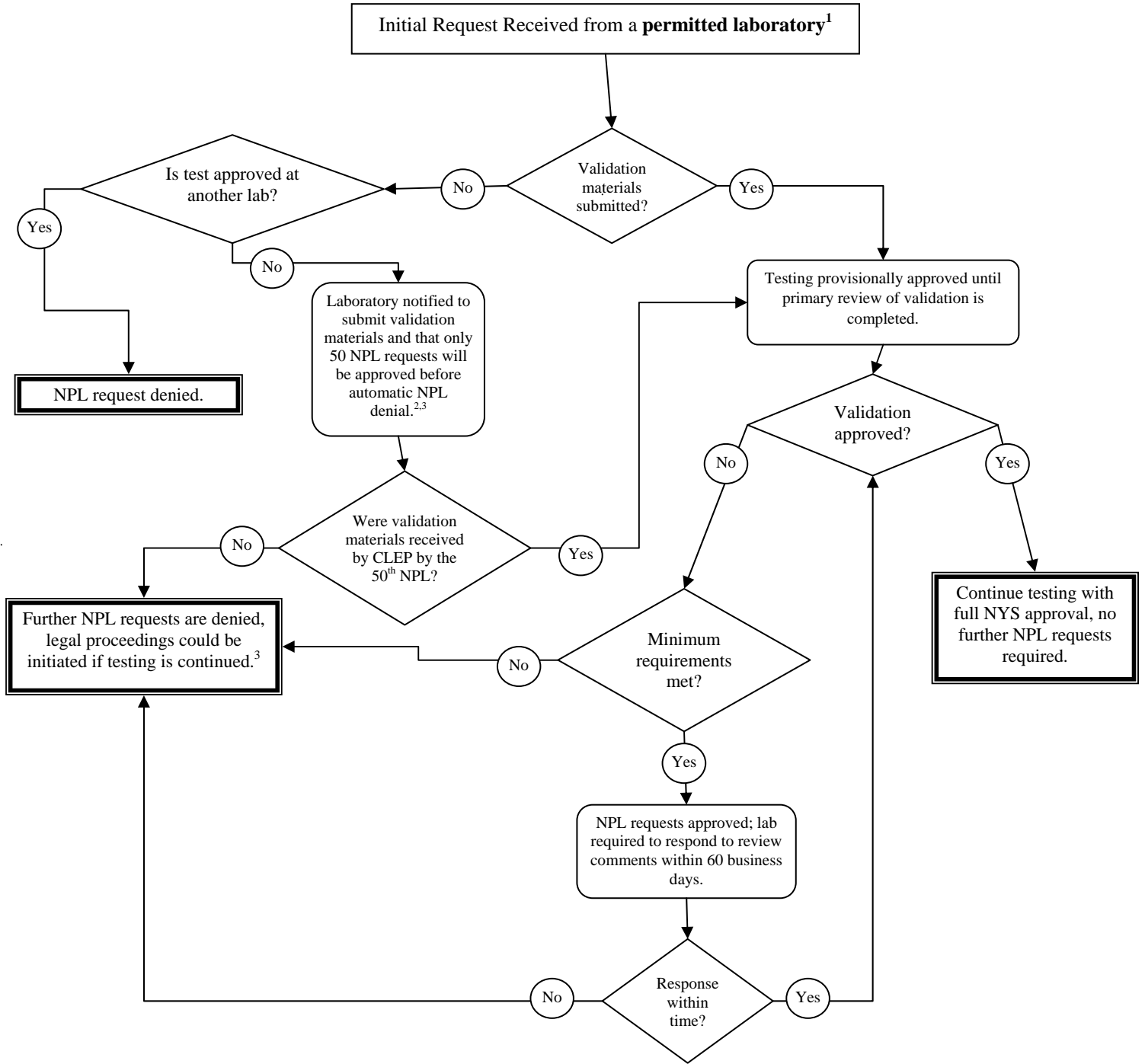
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Footnotes:

1. A non-permitted laboratory is a laboratory that does not hold a NYS clinical laboratory permit, or a NYS permit-holding laboratory that does not hold the appropriate testing category.
2. NPL requests may be denied based on documented lack of analytical and/or clinical validity.
3. NPL request approval may be granted when the test can be shown to be unique in its availability. Other considerations are continuity of care and sample integrity.
4. Assumes all other permit requirements have been met.

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Footnotes:

1. A permitted laboratory is a laboratory that holds a NYS clinical laboratory permit in the appropriate category of testing.
2. NPL requests may be denied based on documented lack of analytical and/or clinical validity.
3. NPL request approval may be granted when the test can be shown to be unique in its availability. Other considerations are continuity of care and sample integrity.