NYS OASAS Provider Q&A
On-Site Laboratory Testing Registration Requirements

1. **Question: What is CLIA?**

Response:
The federal government passed a series of laws and standards known as the Clinical Laboratory Amendments (CLIA) beginning in 1988 to ensure that all samples taken of materials from the human body met certain criteria that assured accuracy, reliability and timeliness. States are required to implement these laws and standards.

2. **Question: As an OASAS provider, am I a laboratory?**

Response:
Any provider, practitioner or other person that collects a sample and performs testing of that material from the human body "for the diagnosis, prevention, or treatment of any disease or impairment of the health of, human beings" is a laboratory. If you collect and test even one sample of blood, urine, or salvia at your program, you are a laboratory.

3. **Question: As an OASAS provider, do I need NYS Department of Health's authorization to conduct on-site laboratory testing (e.g. fingerstick glucose, urine pregnancy, drugs of abuse, dipstick urinalysis, breath alcohol)?**

Response:
Yes. OASAS providers interested in performing on-site laboratory testing must obtain approval from the Department of Health's Clinical Laboratory Evaluation Program.

4. **Question: What type of laboratory approval should I apply for? How long is approval good for, and how much does it cost?**

Response:
Providers interested in performing on-site laboratory testing must register as either a **Limited Service Laboratory** or a **NYS Clinical Laboratory** depending on the testing performed, and the devices used to do that testing.

Limited Service Laboratory
Providers interested in performing on-site laboratory testing using test devices categorized by the Food and Drug Administration (FDA) as Waived must apply for a Limited Service Laboratory Registration Certificate. A certificate is good for two years. The initial application and reapplication fees are $200.00:

Application materials to obtain a Limited Service Laboratory Registration certificate are available at: https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs

NYS Clinical Laboratory

Providers interested in performing on-site laboratory testing using test devices categorized by the FDA as Non-Waived (Moderate or High complexity) must apply for a NYS Clinical Laboratory Permit. A permit is good for one year. The initial application fee is $1,100.00:

Application materials to obtain a NYS clinical laboratory permit are available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit

5. **Question: What are the most common tests performed by OASAS providers?**

Response

According to a recent survey, breath alcohol, drugs of abuse, glucose, pregnancy test (urine) & saliva alcohol were the most common tests reported. Providers should understand what they are testing for and how they are using test results. For example, testing urine for the presence of drugs (or other substances) is drugs of abuse testing, not urinalysis.

6. **Question: How do I know if the test device that I am using for drugs of abuse, glucose, pregnancy, etc. testing is an FDA Approved CLIA Waived test device for use under a Limited Service Laboratory Registration Certification?**

Response:

To determine if your test device is an FDA Approved CLIA Waived test device:

a) Check the manufacturer's package insert. It may state that the device is *CLIA Waived*. Otherwise, contact the manufacturer via the 800 number found in the package insert.
b) Contact the distributer where the test device was purchased.
c) Search the FDA database of approved test devices: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

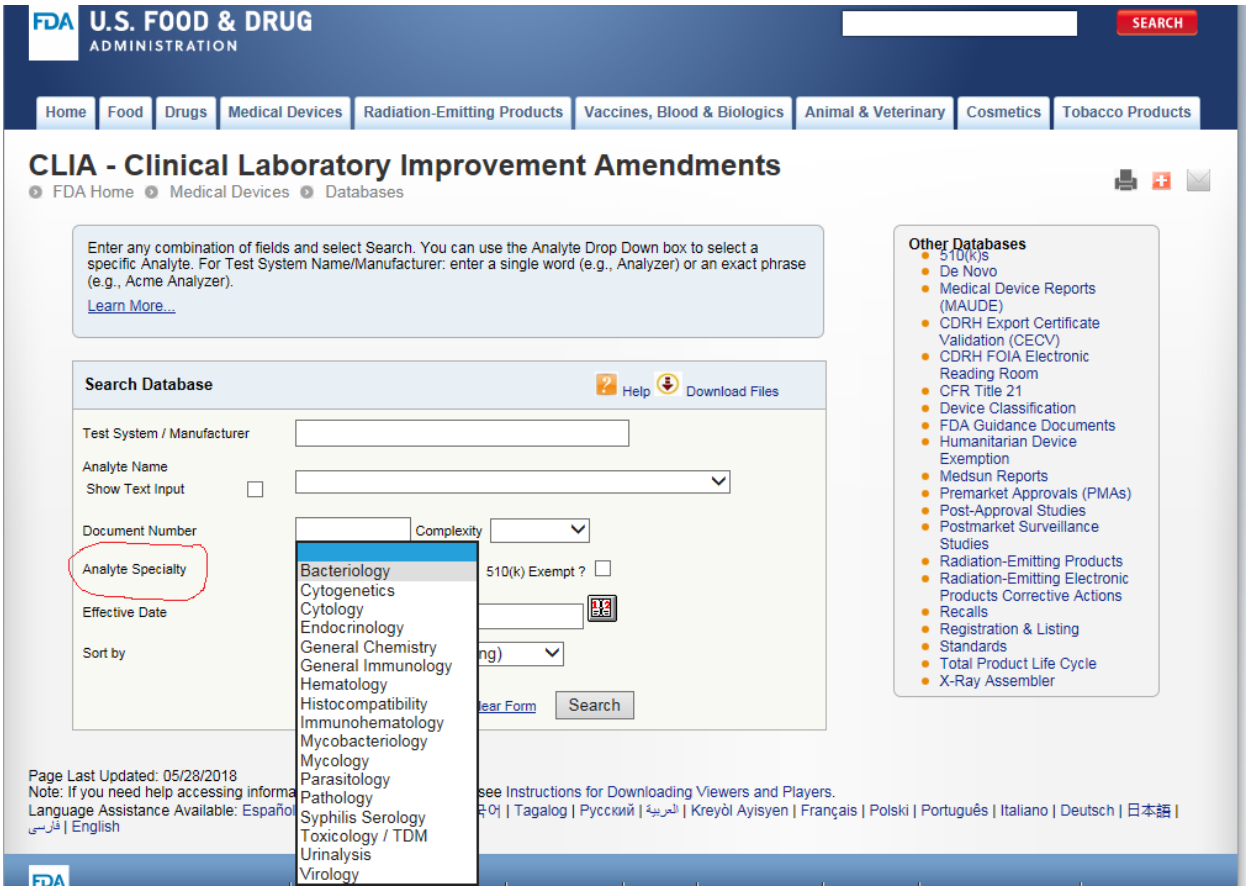
If the test device that you wish to use is not categorized as "Waived," then you may not use it under a Limited Service Laboratory Registration and you must apply for a NYS Clinical Laboratory permit.

7. **Question: How do I search the FDA database for approved Waived test devices at** https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

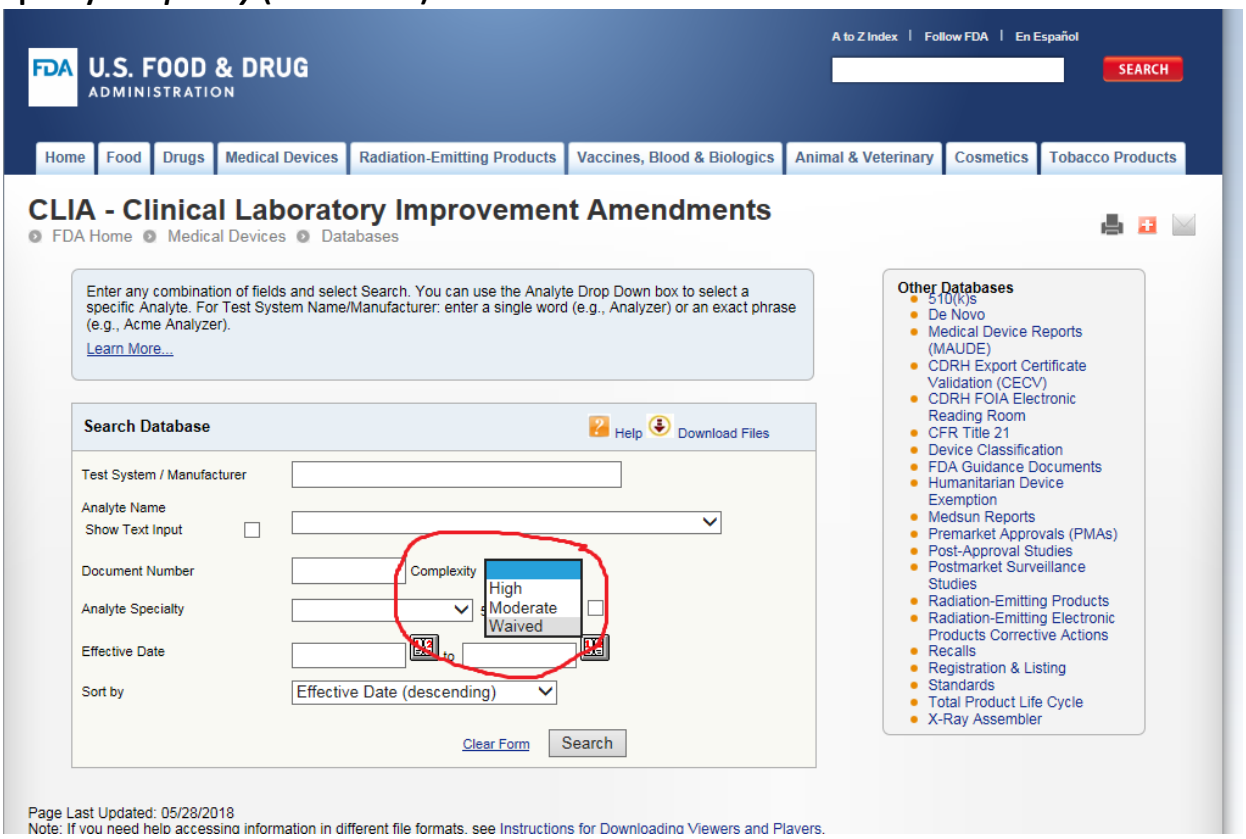
Response:

While you may search by Test System/Manufacturer Name if known, it may be easier to search by *Analyte Specialty* (ex: *Toxicology/TDM*), and Complexity (ex: *Waived*)

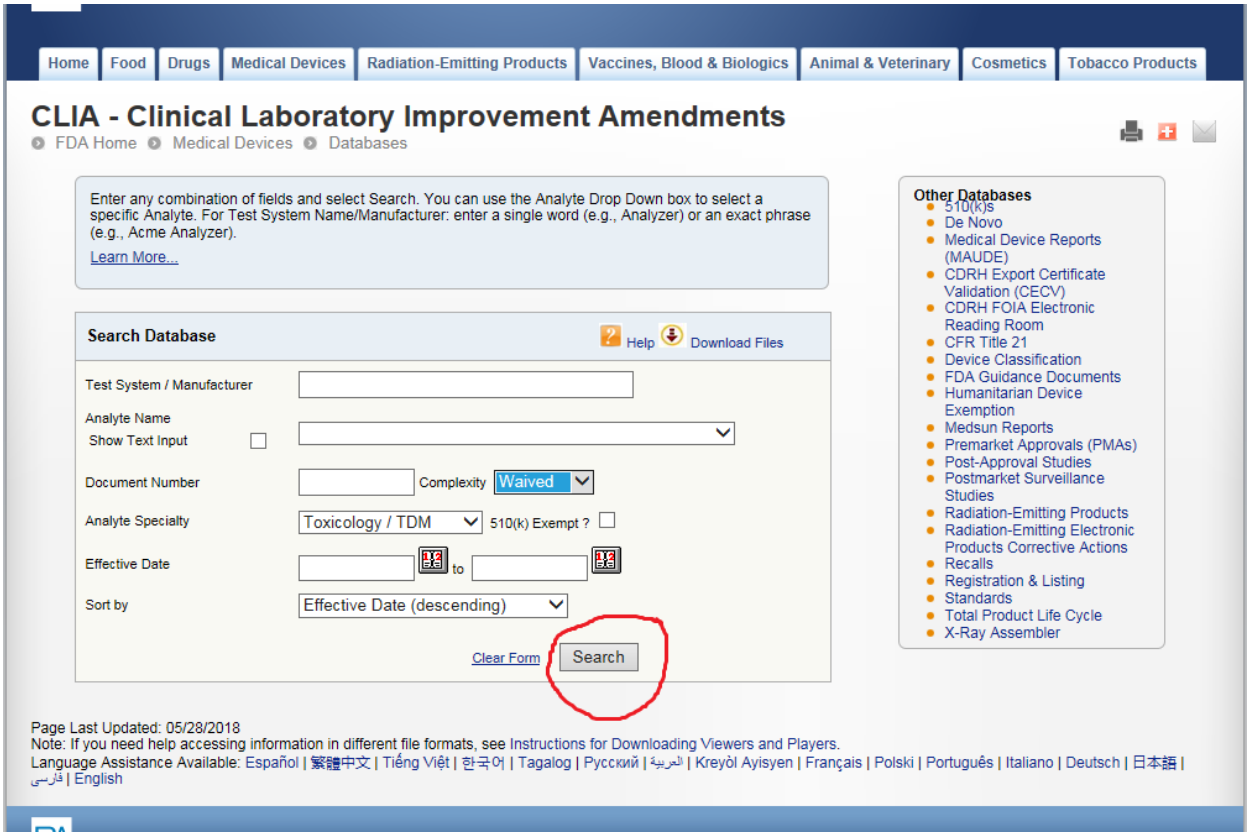
Select *Analyte Specialty* (ex: *Toxicology/TDM*)



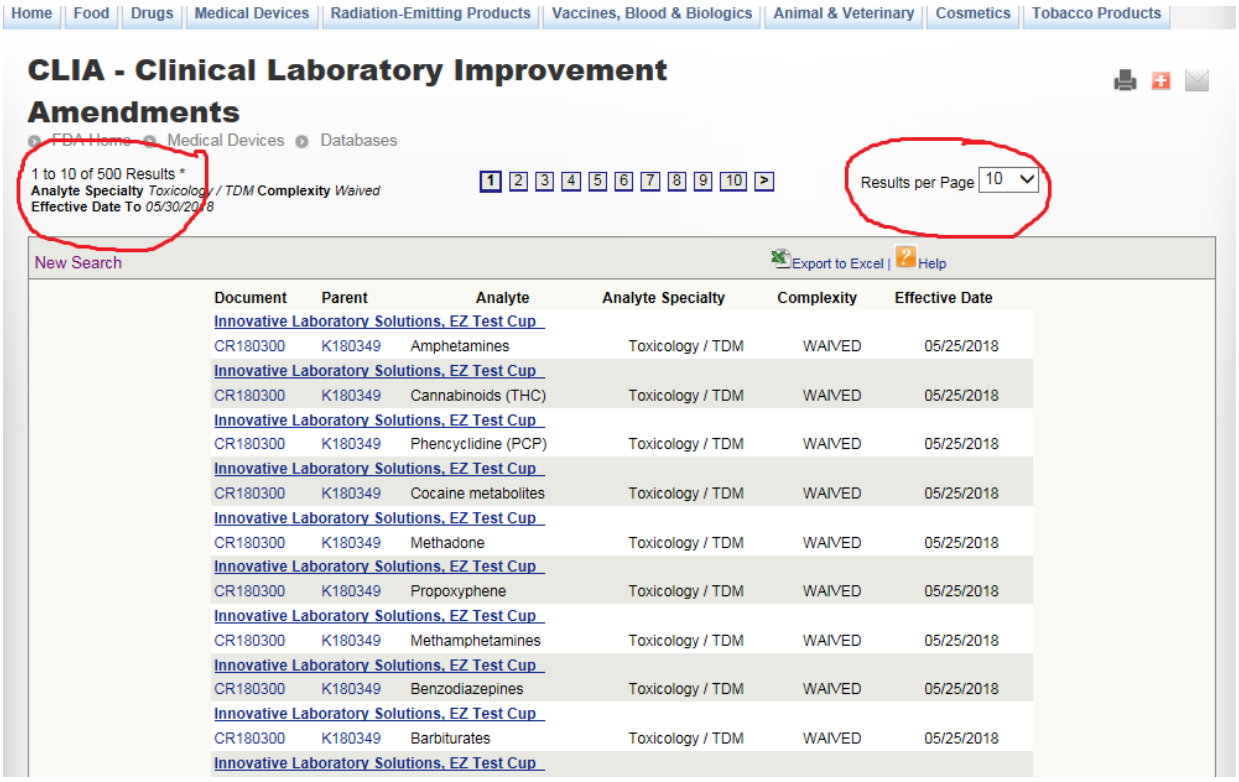
Specify *Complexity* (ex: *Waived*)



Once an *Analyte Specialty* and *Complexity* have been selected, hit *Search* button



The results of your query will be displayed based on the search criteria entered (Analyte Specialty *Toxicology/TDM* that have a test Complexity *Waived*). For easier viewing, you may wish to change the Results per Page from the default number 10 to 500 Results per Page:



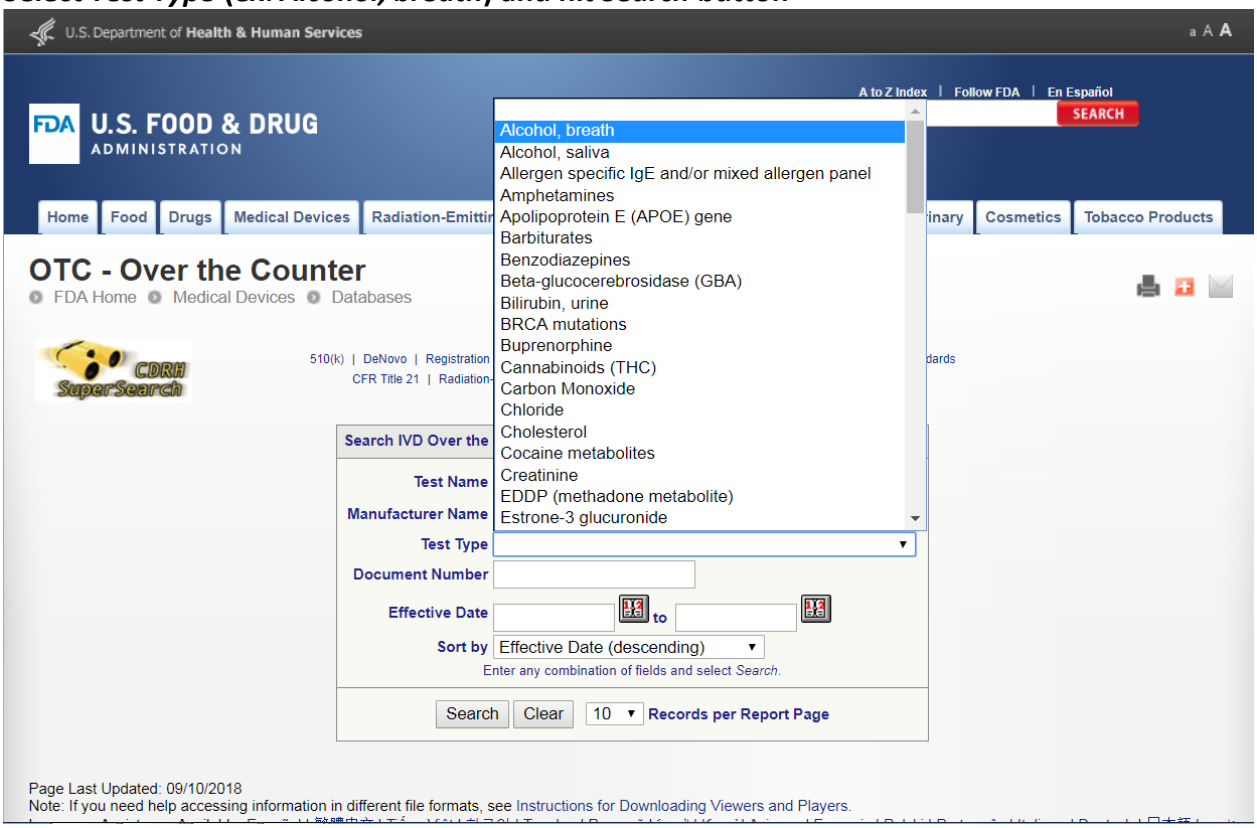
9. **Question: How do I know if my breath alcohol device is an acceptable FDA Over-The-Counter Device for use under a Limited Service Laboratory Registration Certification?**

Response:
Search the FDA Database for IVD Over-The-Counter Lab Test Devices at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm

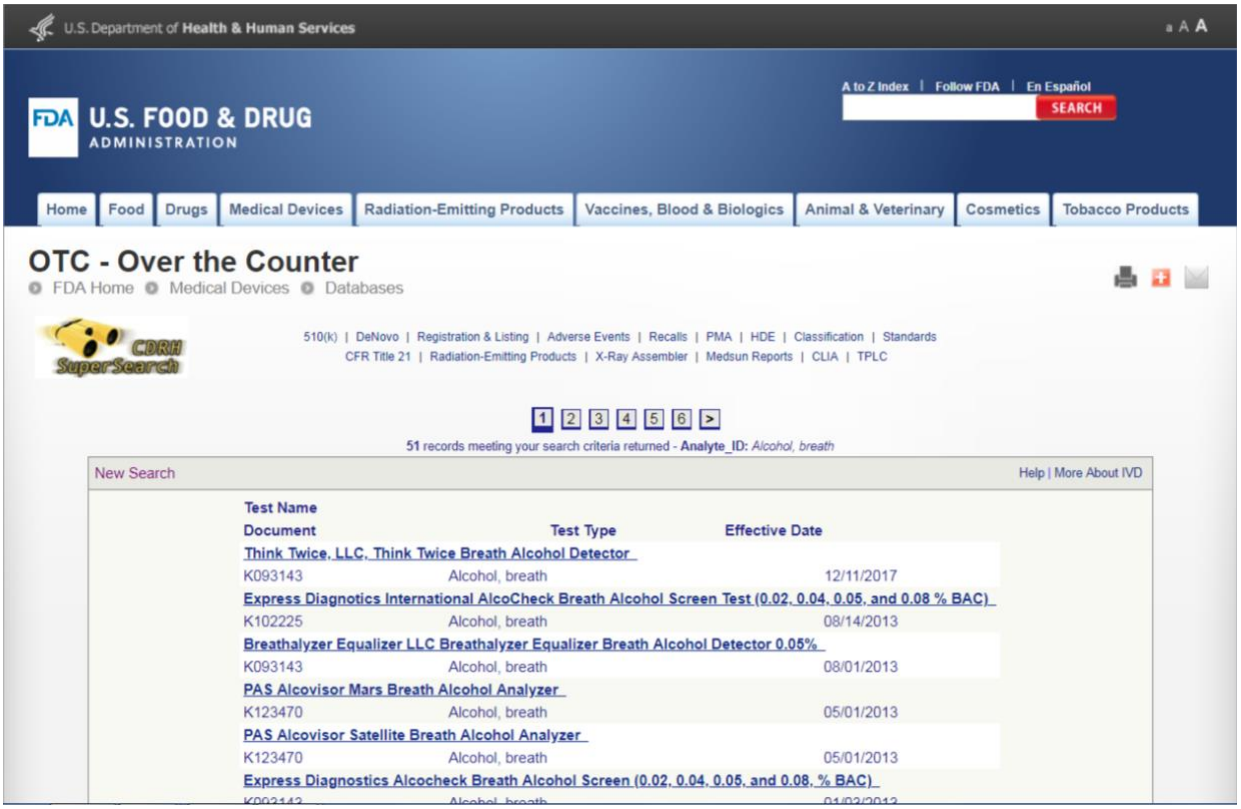
If the breath alcohol test device that you wish to use does not appear on the list under **Test Type: Alcohol, Breath**; it may not be used under a Limited Service Laboratory Registration and you must apply for a NYS Clinical Laboratory permit.

10. **Question: How do I search the FDA Database for IVD Over-The-Counter breath alcohol test devices at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm?**

Response:
Select *Test Type* (ex: *Alcohol, breath*) and hit *Search* button



The results of your query will be displayed based on the search criteria entered (Analyte ID: Alcohol, breath). For easier viewing, you may wish to change the Results per Page from the default number 10 to 100 Results per Page:



11. Question: Are there any special staff requirements to provide waived tests?

Response
Yes, testing staff must be trained by a qualified individual with knowledge of the testing procedure. Staff must perform the test as directed by the manufacturer, and in accordance established policies and procedures. Staff must be assessed for competency at least once per year thereafter.

12. Question: What happens if I submit an incomplete or illegible application?

Response:
Applications must be completed as required with no exceptions. The submission of incomplete and/or illegible applications will result in delayed processing.

For questions regarding this document please email: Legal@OASAS.ny.gov