

DRAFT

The NELAC Institute Presents

WHAT IS A TNIL LOD?



TNI Limit of Detection LOD

A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

LOD



TNI Limit of Detection LOD

It doesn't say anything about
quantitation - just detection

LOD



TNI LOD

The standards do NOT mandate HOW you determine your Limit of Detection .

They do say you need to verify the LOD by detecting a spike near the LOD.

LOD



LOD REQUIREMENTS FOR DETERMINATION

So, what do I have to do? Short and sweet please!



TNI Limit of Detection LOD

EL-V1M4-2009 1.5.2.1

If the laboratory is not reporting a value below the Limit of Quantitation, a Limit of Detection study is not required.

LOD



TNI Limit of Detection LOD

EL-V1M4-2009 1.5.2.1



The laboratory shall utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data.

LOD



TNI LOD

If a mandated method or regulation includes protocols for determining detection limits, these shall be followed.

Drill Sargent Bird Addresses the new recruits



Follow Regulation!



TNI LOD

The laboratory shall document how LODs were derived....



Documentation shall include the quality system matrix type.

All supporting data shall be retained.

LOD



TNI LOD

If the protocol for determining the LOD is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.



TNI LOD

All sample-processing and analysis steps of the analytical method shall be included in the determination or validation of the LOD.

LOD



TNI LOD



Determine the LOD for each analyte in the method using the quality system matrices.

LOD



TNI LOD

The LOD shall be initially determined for the compounds of interest in each method in a QS matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or the LOD shall be performed in the QS matrix of interest.



TNI LOD

An LOD shall be performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.



TNI LOD

The LOD, if required, shall be verified annually for each quality system matrix, technology, and analyte.



The LOD must be verified in order to be used.



We'll discuss verification in a separate presentation!



What does an LOD look like?

Let's use an example of a spectrum, where you are looking for a specific shade.

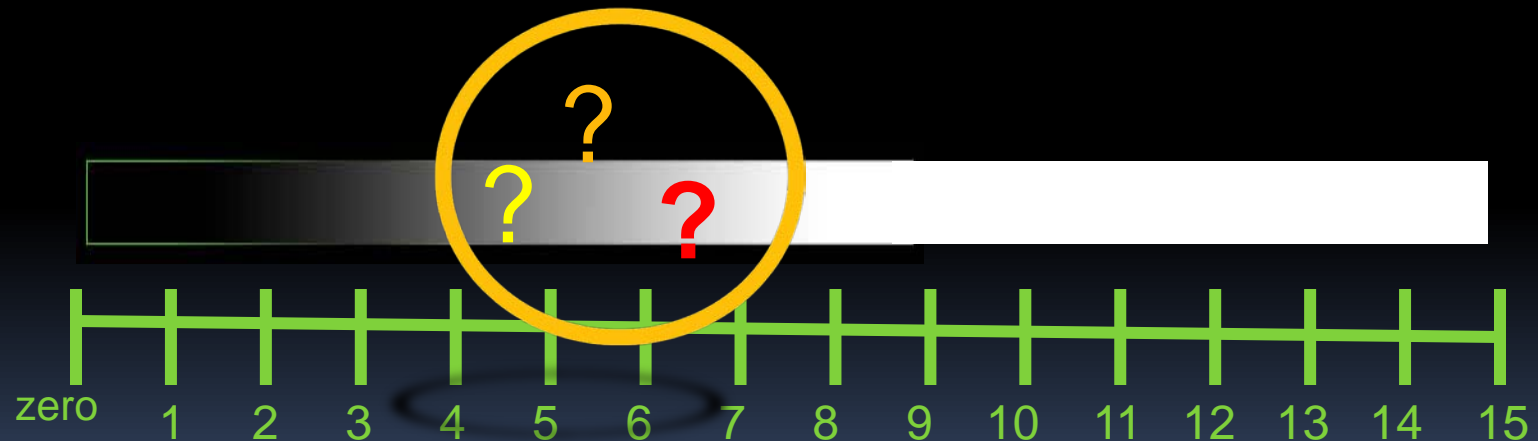


What does an LOD look like?

What does an LOD look like?

For example, suppose you are looking for **WHITE** in the example below. Not grey. Not black. White.

You could say anything above say, **9**, is definitely white.



Could these values be “white”??



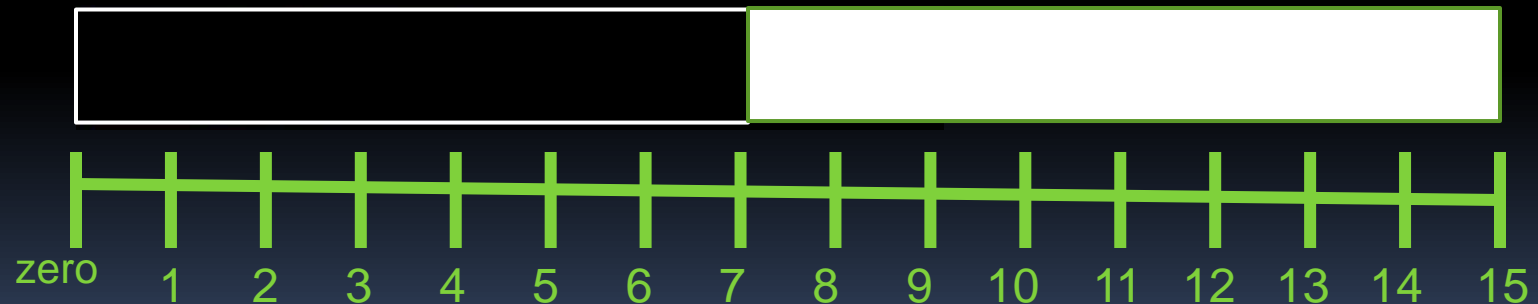
What does an LOD look like?

What does an LOD look like?

An LOD is not usually an easy
“black vs. white” decision...

It is where you can reliably detect white in a mix of white shades.

Not whitish-grey, not greyish-white, not mostly white.

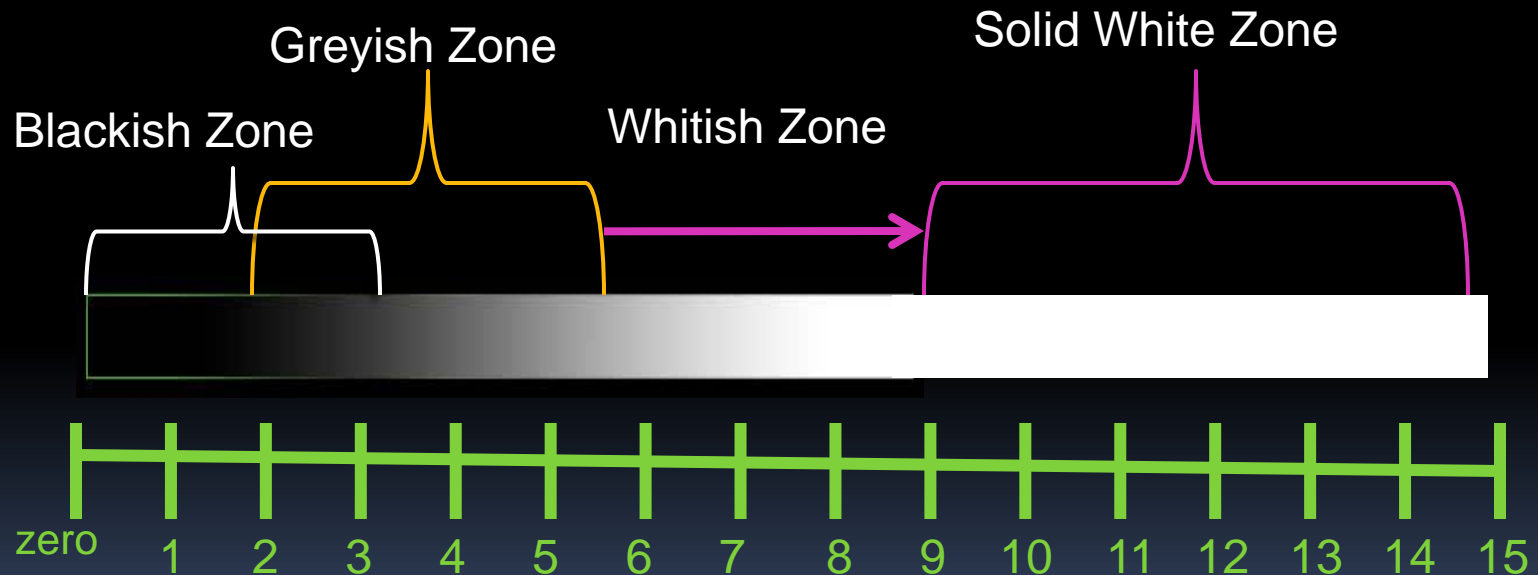


At the LOD, I decide that I can detect white.

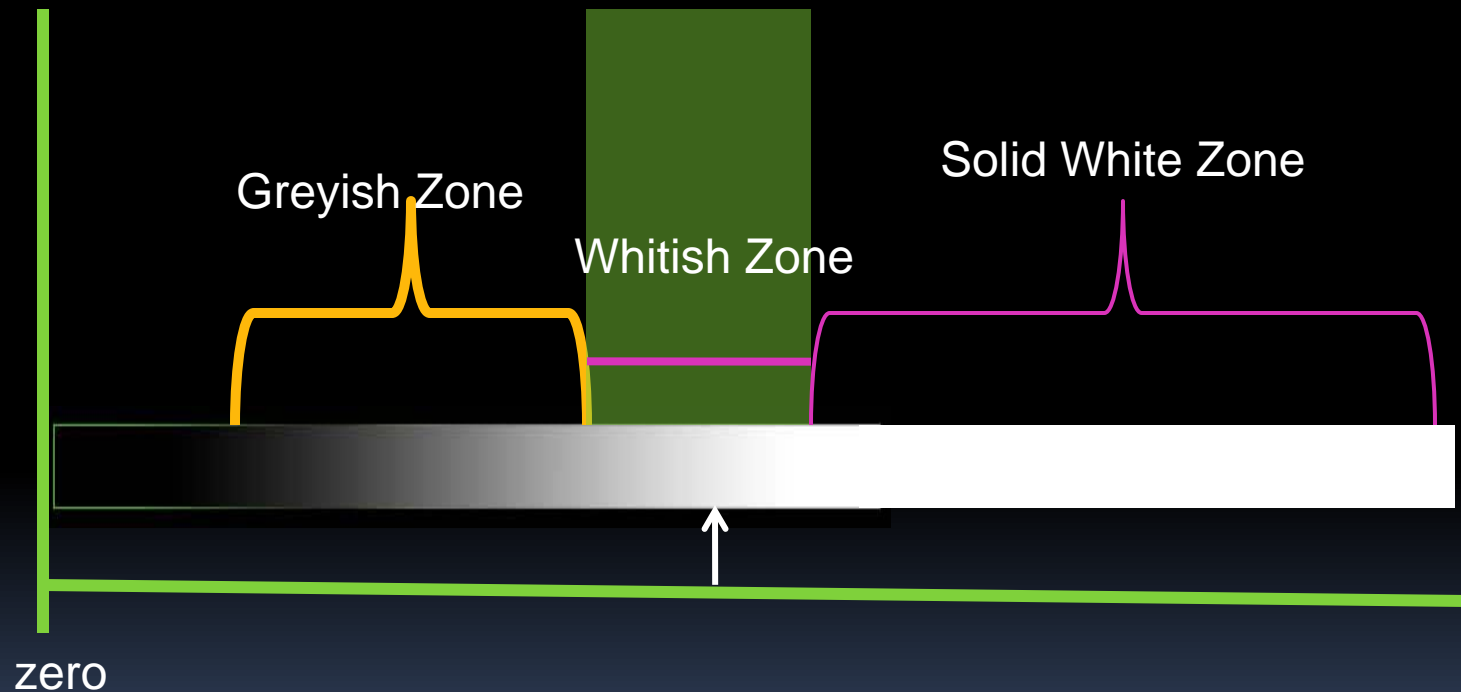


How low can you go?

To detect **white** at the absolute lowest value you can, the logical place to look is at the end of the **grey** zone. That should be where white starts!



The **MDL** from 40 CFR Part 136 is the point at which you are very sure you aren't measuring background (black).

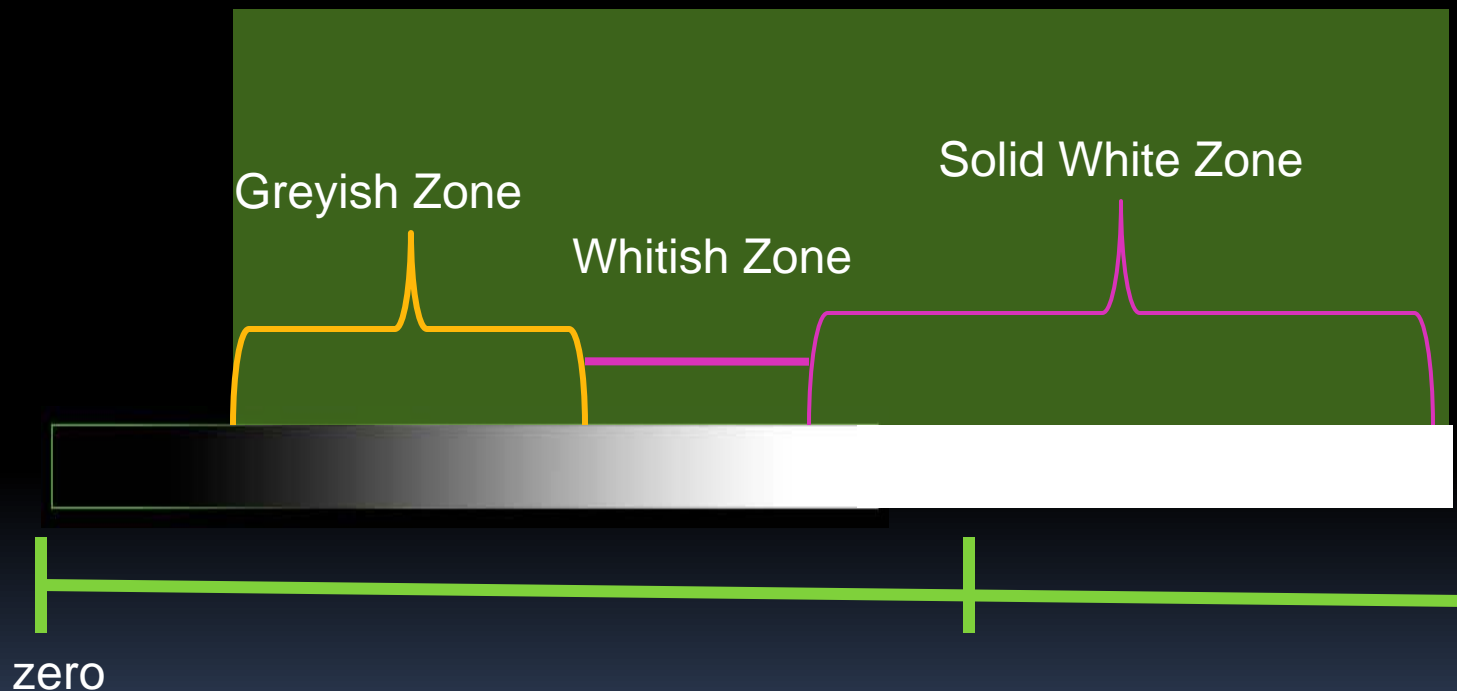


MDL will be a value in the whitish zone.

The LOD can be the same as the MDL if that choice is appropriate for your customers.



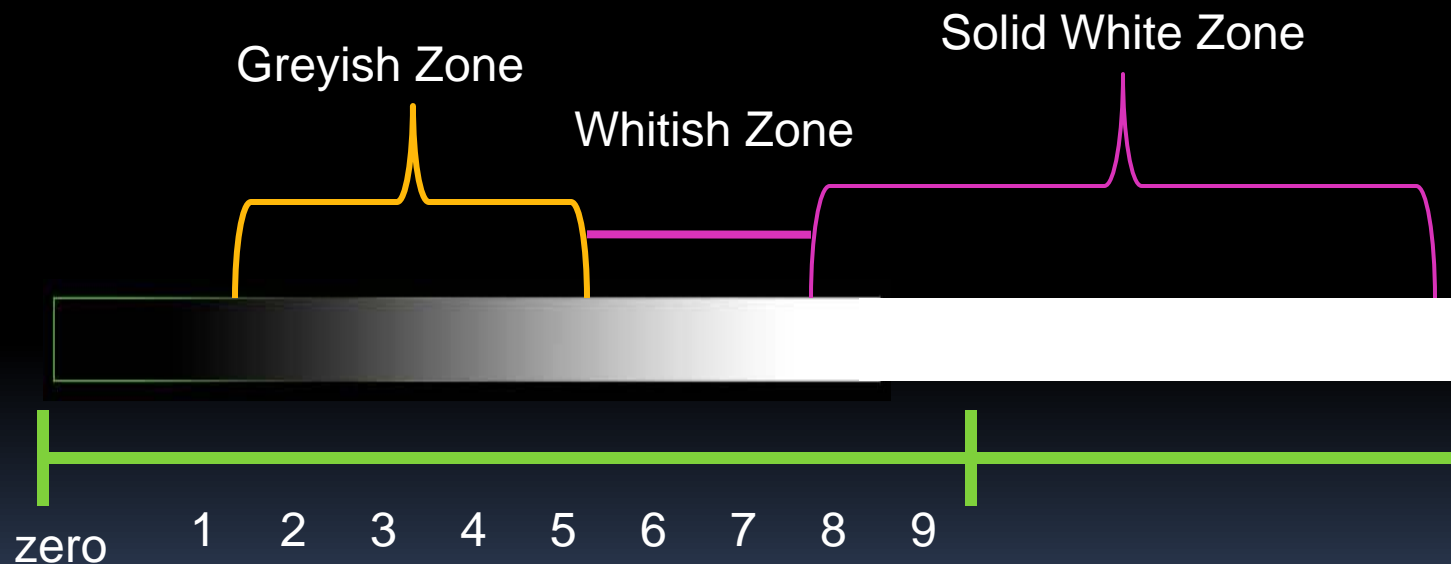
Unlike the MDL and L_C , the TNI
LOD can be anywhere “in the
grey or white zone”!*



* Because TNI does not define “reliably detected”, that is up to you!



LOD is wherever **YOUR** lab decides and verifies that an analyte can be reliably detected



But what about reliably quantitated? That is LOQ.

END