

DRAFT

The NELAC Institute Presents:

SUGGESTED PROCEDURES FOR

LOQ



TNI plays well with Others...

These suggested procedures are compliant with NELAC and TNI standards, and can provide a dataset suitable for other Quantitation Limit protocols, including:

- Detection/Quantitation Federal Advisory Committee procedure
- Office of Water MRL
- Texas PQL
- DoD QSM v4.1



TNI DEFINITION - LOQ

Limit of Quantitation

The minimum levels, concentrations, or quantities of a target analyte that can be reported with a specified degree of confidence.



What is a TNI LOQ?

I see some yellow pollen on the stamens below. This magnification is at my *Limit of Detection (LOD)*. If it were any smaller I wouldn't see the pollen.



How **many** pollen particles do I see? (quantitate?)

I think maybe 3...



TNI DEFINITION - LOQ

I wasn't really sure at 2x how many pollen particles there were. But at 5x I am sure I am reliably quantitating

Magnification - 5x



LOD is 2x (I can see it)

LOQ is 5x (I can reliably quantitate)



Exceptions for LOQ

An annual LOQ verification **is not required** if the LOD was already determined or verified annually on *that* instrument.



Requirements :

All sample processing steps must be included in the determination of the LOQ



Requirements :

An LOQ verification study **is not required** for any component or property for which spiking solutions or quality control samples are not available or otherwise inappropriate.



Such as pH or temperature.



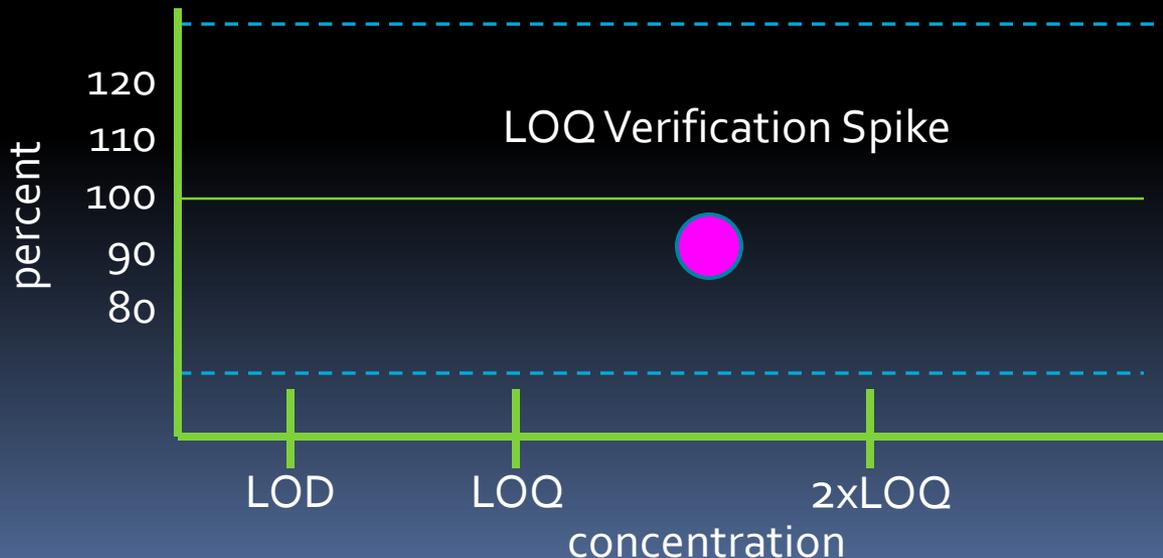
Requirements:

The LOQ verification sample:

- Must be spiked at 1-2 times the claimed LOQ,
- And recovery must be within established control limits.

Limits	50 – 150%
Result	94%

VERIFIED



Requirements:

The LOQ verification sample:

- Must be spiked at ~ 2 times the claimed LOQ,
- And recovery must be within established control limits.

YOU GET TO SET THE LIMITS FOR THE LOQ VERIFICATION SPIKE !!

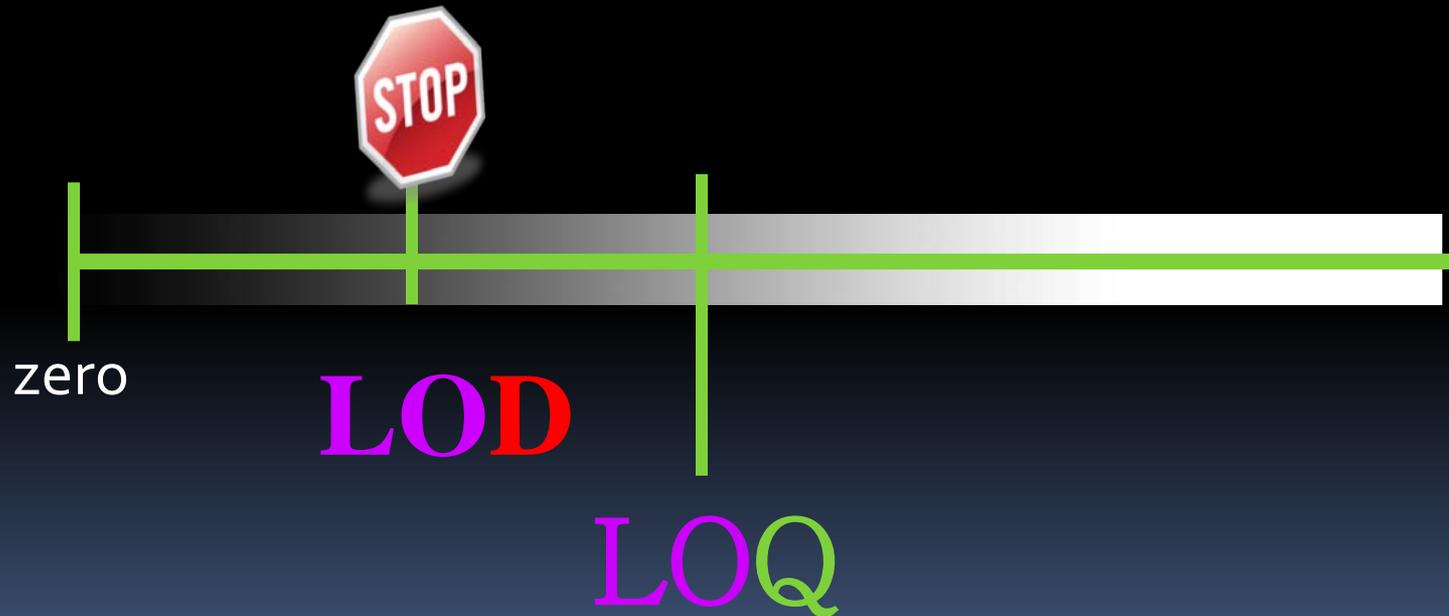
Limits Whatever is reasonable!
Result 94%



Requirements :

When an LOD is determined or verified by the laboratory, the LOQ shall be above the LOD.

Translation: They can not be the same number





If you don't require an LOD, then you don't have to check that your LOQ is greater than your LOD!



Requirements: What?

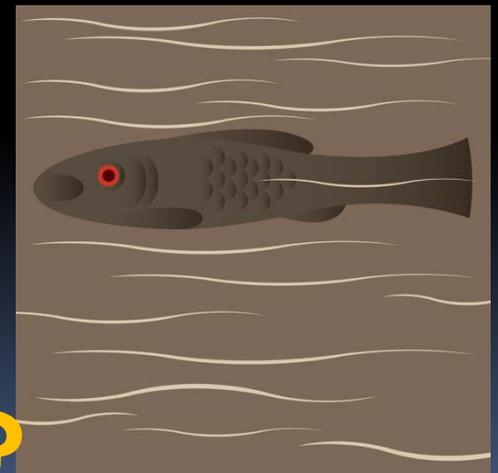
Verify LOQ annually

...In each quality system

matrix AND for each

technology...

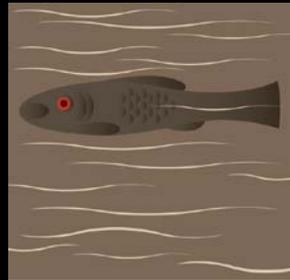
ON EACH INSTRUMENT??



Requirements:

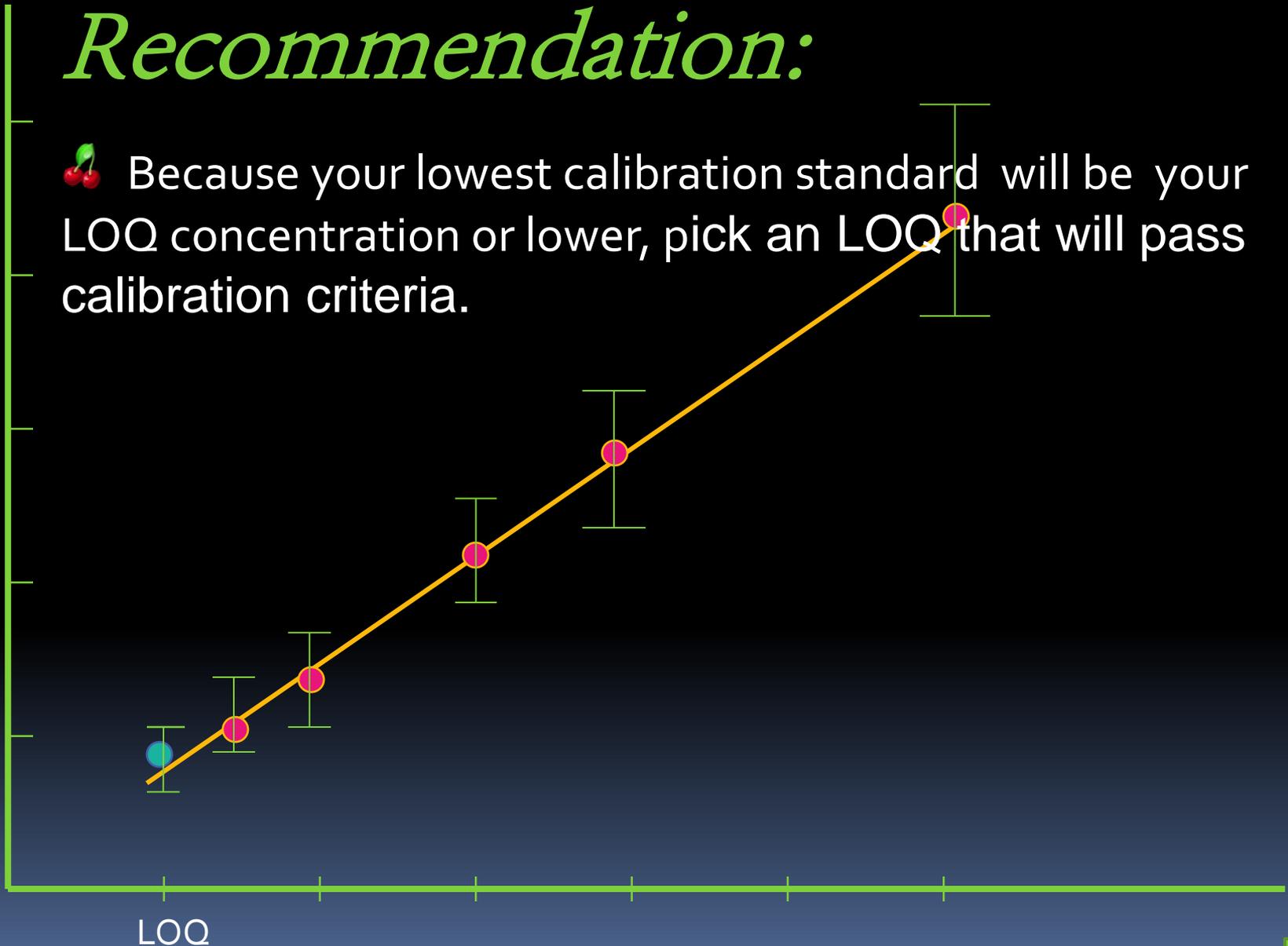
Document your procedures for LOQ determination and verification for each quality system matrix type.

Please be sure to check the appropriate TNI module for analysis-specific LOD or LOQ requirements



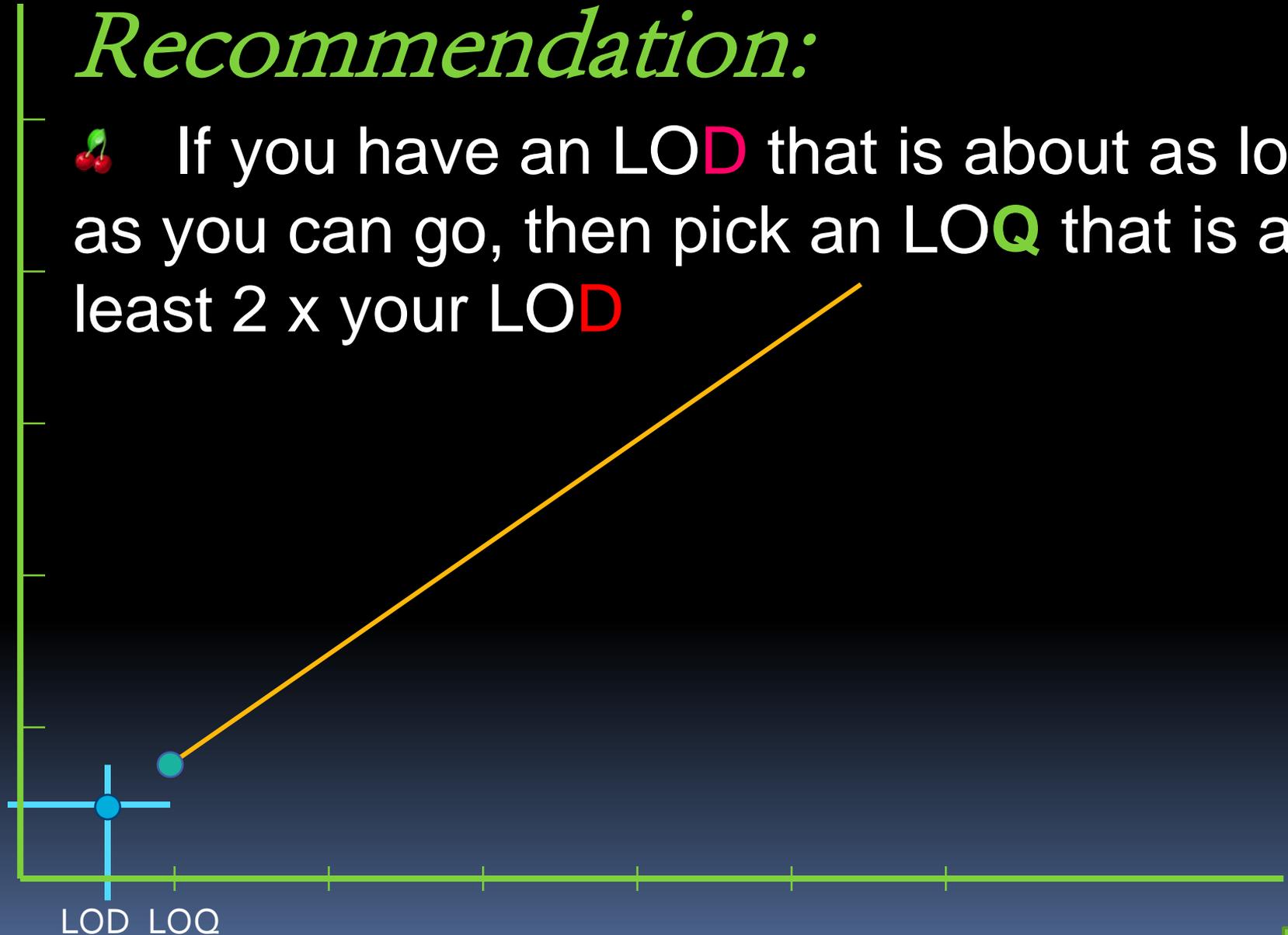
Recommendation:

🍒 Because your lowest calibration standard will be your LOQ concentration or lower, pick an LOQ that will pass calibration criteria.



Recommendation:

🍒 If you have an LOD that is about as low as you can go, then pick an LOQ that is at least 2 x your LOD



Q:

Can your LOQ be anything you want?

A:

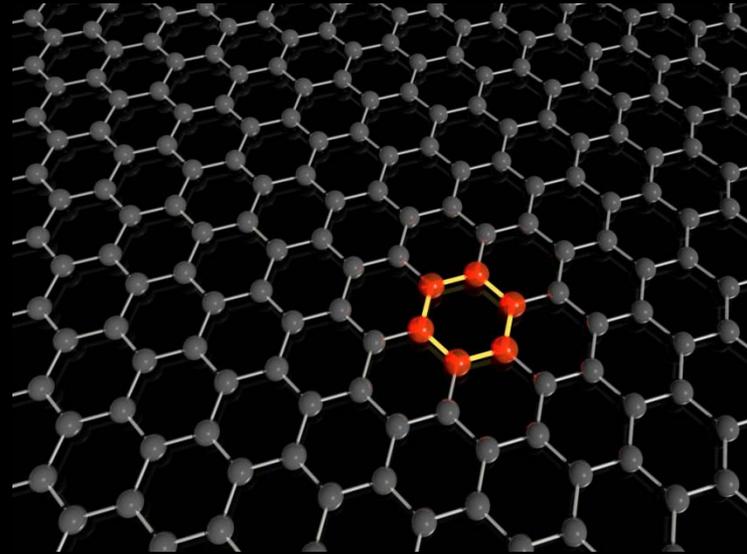
As long as it is greater than your LOD.



And it meets all client or program requirements...



Recommendation:



🍒 If you want to comply with other programs that require multiple spikes for verification, we recommend you first test with just one spike. If the LOQ was too low, you didn't waste time or money preparing the rest.



Recommendation:

To be compliant with other programs by analyzing multiple LOQ spikes, we recommend...

- 🍒 Analyzing at least 2 replicates on each instrument for a total of at least 7 replicates.
- 🍒 Replicates should not all be analyzed in a single batch – a more representative data set is obtained if the samples are spread over time.



Thought:



If you make an LOQ spike part of your routine quality assurance, you won't have to bother doing a separate study at the end of the year.



REVIEW: Your TNI LOQ wish-list

...something that
Something about
meets program
twice the LOD would
...on the And don't forget
and customer
different matrices or technologies.
requirements...
If this LOQ won't pass for that can be
(even though it's fitted on each
analyte), I may request a separate
would pass calibration
criteria and...





I haz questions!

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