NQAC
Nestlé Quality Assurance Center
Dublin

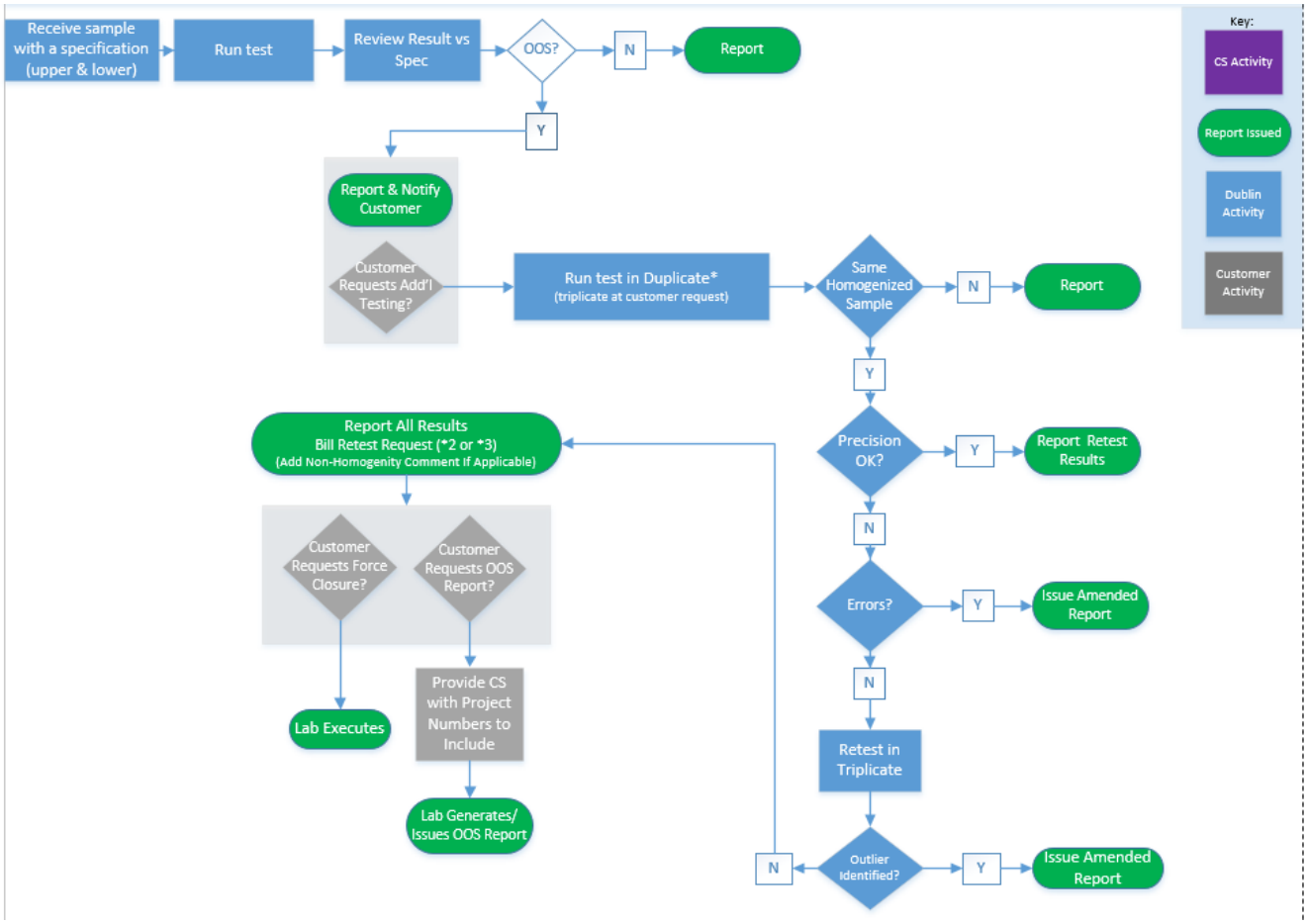
CHEMISTRY OUT OF SPECIFICATION PROCESS (OOS)

WHY SHOULD I ENROLL IN THIS OOS PROCESS?

The process is designed in order to provide additional data for customers receiving results which do not meet their expected levels and/or specifications on specified submissions. The concept is focused on additional testing; with the goal to provide a statistical evaluation of the result and determine the possibility of outliers.

Customers can enroll in this program by contacting our customer service team and registering your NQAC Customer ID Number for this process.

High-level process flow is outlined below:



Please note: additional charges may apply per above and this doesn't apply to micro testing.

WHAT DO I NEED TO PROVIDE TO ENSURE SUCCESS?

1. The laboratory will need a clear minimum and/or maximum specification provided via submissions (ex: two value range or use of > or < or min or max).
2. If you do not provide clear product specifications and you are signed up for this process, our team will not follow the OOS process steps above. The submission will follow the routine testing and reporting process with no OOS emails sent.

WHAT SHOULD I EXPECT TO SEE WITH OOS ALERTS?

1. All submissions sent under your NQAC Customer ID Number will be designated as OOS alerts needed.
2. Our team will compare the provided min and/or max specification to the test results.
3. If the result is found as OOS per the specification, the customer service team will send an email alerting the report recipients what test is OOS so the next steps can be confirmed.
    - If a retest on a retained sample is needed.
    - If a new sample needs to be submitted to complete the investigation.
    - If an OOS investigation report is needed.
4. Results will automatically be reported.

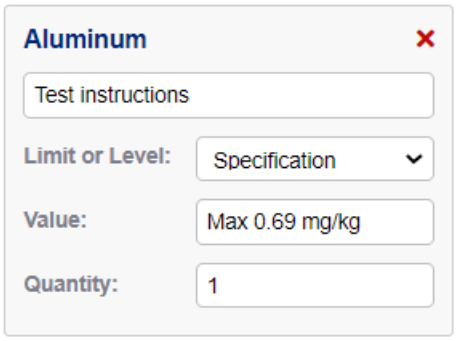
WHAT ARE THE LIMITATIONS/RISKS RELATED TO THIS PROCESS?

1. Process variation has been seen to also attribute to variance in analytical results. Because of this, the process cannot be applied to:

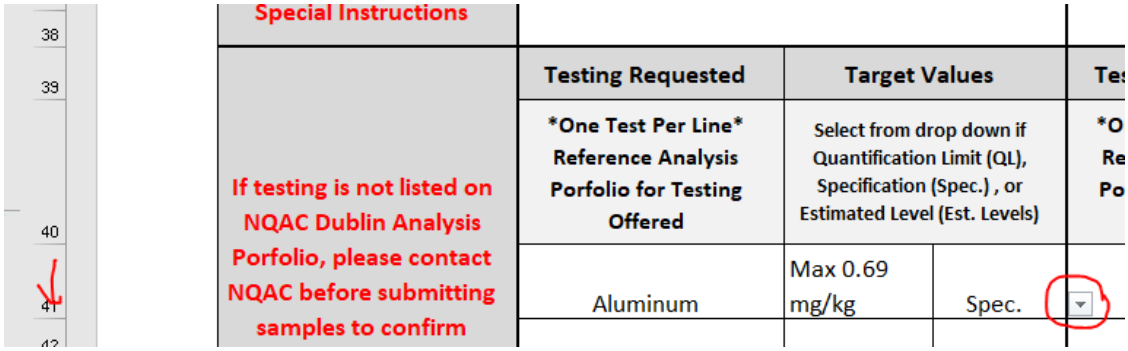
    - Situations where the original homogenized retain sample is no longer available for testing, it is not recommended to use only analytical reproducibility to evaluate statistical equivalence. Results may vary and be impacted by storage, shelf-life, time-point used and if these factors are not controlled must be accounted for when evaluating the results. When retests meet data acceptability requirements, they will be billed per our retest policy at listed price.
    - Original container: Another un-opened finished product container or a sub-sample which matches the original submission from the same time-point sent. Retest results have been proven to vary and may be impacted by storage, shelf-life, time-point used and if these factors are not controlled must be accounted for when evaluating the results.

HOW DO I ADD THIS CORRECTLY TO MY SUBMISSIONS?

1. **Online submissions:** choose specification in the "limit or level" and then enter the value, including units of measure. If more space is needed the utilize the test instruction to add longer specifications or more details.



2. **Manual submissions:** choose specification from the drop down and then enter the value including units of measure. If more space is needed adjust the row height to allow for additional space.



3. **SAP submissions:** add specifications into SAP as needed and this will flag on our side automatically.
4. **All Premix & Supplement/Raw Material Submissions for Minerals & Heavy Metals:** It is a requirement to provide a COA or estimated levels to allow for the proper method preparations.
    - If you are providing a COA, we request that you add "COA Included" in the special instructions so we can reference the paperwork easily.

Feel free to request support from our Customer Service team as we are here to assist you with setting up the process correctly and answering your questions!

ISO 17025 Accredited.

We receive, test and report seven days a week.

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