NSF Standard(s) Impacted: NSF 50, Annex O

Background:

Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Issue Paper Number 146 raised technical questions about the shelf life portion of Standard 50, Section 19.2.6. This follow-up recommends that shelf-life testing be eliminated from the Standard.

The Standard works to fairly, and rigorously, confirm test performance. Section 19, however, attempts to make an absolute measurement of a system that, by its nature, is not absolute. From practical technical and manufacturing perspectives it has great potential to add cost and confusion, but not value, to the certification process.

Shelf-life determination is a science. The process starts with ideal conditions, various assumptions, and attempts to control for known variables. The result is a probability that the product will perform within the stated limits for the time. Importantly, that probability is specific to each chemical test.

Test kits are dynamic chemical systems; all testing technologies are affected by variables that can cause atypical results. For this reason the Standard cannot practically accommodate all the different conditions and amounts of testing required to truly confirm a shelf life.

Details are critical, especially when trying to confirm performance:

- Is the testing protocol compatible with how the shelf life was assigned?
- Is the stated shelf-life inaccurate, or was some variable introduced during storage or testing?
- Real-time stability results can vary between lots of the same product, so how many lots are enough for testing?
- Reagents degrade on a curve and not as an on-off event. This means the sampling method is critical. Does the protocol test enough samples to accurately describe the test behavior? To what level of confidence?
Even real time shelf life measurements vary. By its nature a shelf life period is a guide, a suggestion, a recommendation to help the user protect the performance of the product. It is not an absolute. Performance is key.

The Standard is designed to confirm that manufacturers release effective products with truthful claims. In consideration of the examples above, does the collected data really deliver a valid confirmation? Worse, since some organizations require particular certification levels, manufacturers who lose certification because of a testing artifact also stand to lose business opportunities on perfectly acceptable and effective products. Worse still, certification changes based on results delivered 18 months to 2 years (typical shelf life estimates) after the initial certification could cause great harm to established business relationships.

Decisions driven by the Standard must consider the real-life complexities of delivering a product to market. There must be a practical balance between actual manufacturing, NSF testing requirements, and the cost to meet the requirements.

It is impossible for a manufacturer to test for all the conditions a product will face. For decades manufacturers have understood this principle, and have used statements to alert customers; whether noting a “use by” date, a “best if used by” date, or a recommendation to get fresh reagent sets at the start of the season. Revising the standard to require this, or similar language, is a reasonable, and practical, approach. The real-life costs imposed by the Standard (testing, time, tracking, personnel) will be reduced, manufacturers will not risk damage from a situation out of their control, and end users will have a visible reminder that test kits do not last forever.

**Recommendation:**
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of strike-out and additions by highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration; etc.

1. Change the language in Section 19.2.6 as below:
Existing:

19.2.6 Shelf life

The shelf life for the reagents and components of a WQTD shall be at least as long as specified by the manufacturer when the reagents and components are tested in accordance with Annex O, Section O.14. When tested with reagents and components stored for the manufacturer specified shelf life (± 2 weeks), the accuracy, and repeatability of the WQTD shall meet the requirements of Annex O. After initial testing of the WQTD, it shall be stored in accordance with the manufacturer's instructions and retested at the manufacturer's prescribed shelf life (± 2 weeks) for compliance to these requirements in 49 and Annex O.

Proposed

Manufacturers shall add language followed by a date to denote the end of a period after which a WQTD is likely to demonstrate performance outside that mandated by the Standard. The language and date shall be added to the final packaging (e.g. box, bottle, pouch, or other) in which the WQTD is stored, so that the language is not separated from the testing reagents over the life of the test kit. Examples of acceptable language include “best if used by”, “use by”, “replace at start of season”, or other, as long as the end user can reasonably be expected to understand that optimal performance is less likely after such date.

2. Change the language in Annex O. section O.14 Shelf Life Testing as below:

Existing

To verify shelf life, open or use product as required for the above testing. Upon completion of use of product close/seal/turn off, and store in accordance with manufacturer's instructions or store at 50% relative humidity t 73 +/- 8oF (23 +/- 4oC) for the duration of the shelf life. After the shelf life time has elapsed, open/”turn on etc. and conduct testing with the product for the appropriate product types or parameters. If product does not comply, the manufacturer shall revise shelf life claims, storage conditions, etc. as appropriate.

Proposed

Replace with “omitted”, “removed”, or “revised”, as appropriate.
Supplementary Materials (photographs, diagrams, reports, etc.): If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

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Please submit to the Secretariat of the Joint Committee on: __________________________

Email completed form to the Standards Department: standards@nsf.org.

*Type written name will suffice as signature