NSF Standard(s) Impacted: NSF 50 – Equipment for Swimming Pools, Spas, Hot Tubs, and other Recreational Water Facilities

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.

I strongly believe the shelf-life protocol needs to be examined because, as written, it cannot evaluate the accuracy of product shelf-life as it is typically assigned by manufacturers of consumer test kits.

It may be three or four months before a consumer test kit reaches its final purchase point or the end user. The manufacturer must have confidence that the packaging will protect the product until the consumer opens it. For this reason manufacturers of the types of diagnostic tests referenced in Standard 50 generally assign shelf life based on studies in a closed container.

Testing protocols can be quite specific. A manufacturer must understand their products and how they will be transported and used in order to choose the correct stability study protocol. Closed-bottle, open-bottle, and in-use stability testing, for example, require different assumptions and do not substitute for each other. Testing often occurs over multiple time frames (sometimes years) with multiple manufacturing runs.

Stability testing rests on the principle that chemicals, and their reactions, degrade with exposure to stress over time. “Stress” can be defined as conditions known to change the state or condition of the reactants. Heat and moisture are common stressors. Since pool water tests measure analytes in water one can consider them “activated” by contact with water. Typically the test packaging provides an environment designed to limit contact with water in liquid or vapor form. A product is exposed to ambient conditions the instant a package is opened; a package may go from a low of 3% relative humidity to ambient in moments. Depending on the conditions and length of the exposure the product performance may be affected.

Given the variation in testing environments and consumer attention to resealing a package, it can be difficult to assign a meaningful shelf life for opened product. It is not uncommon to see “close cap immediately”, “reseal after use,” “store in a cool dry place, away from direct sunlight,” or “use within” messages to the end user in an attempt to mitigate exposure.
Annex O, section O.14 Shelf Life Testing states:

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. Within a range of +2 wk of the expiration date/shelf life claim, 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.

The protocol, as written, raises important issues for manufacturers:

- The protocol could automatically invalidate the manufacturers’ shelf life assignment because the package seal is broken and the contents have been exposed. In no way does this question laboratory technique; it is a generally accepted principle that the rate of decline begins to increase the instant a bottle seal is broken.

- If tests perform poorly during shelf life testing is it because the shelf-life is inaccurate, or is it because the lab exposure during the original test, through no one’s fault, caused the materials to age prematurely? Revising a shelf-life claim can be difficult for manufacturers for the reasons mentioned above. In the case of failing results a manufacturer could lose certification not because of an inherent flaw, but because the strips are compromised.

- It is known that real-time stability results can vary between lots of the same product, so how many lots is enough for testing? Furthermore, since reagents tend to degrade more or less as a curve and not as an on-off event, then how do you know the two bottles available reflect the true performance?

- Since real-time stability data shows variation, at what point is the shelf-life a “for best results use by” date instead of a drop dead "expiration" date?

- Testing after the shelf life time has elapsed implies that a device or its reagents, by definition, would be out of specification. It may be useful to add wording in Annex O, Section 0.14 that requires unopened bottles of the original lots to be tested within one month of the end of stated shelf life.

- Finally, it may be worth examining whether or not the shelf-life portion of the standard should be retained. Given the issues raised above, would the shelf–life testing portion of the standard consistently provide valid and valuable information for the consumer? Requiring a shelf-life clearly printed on the package with appropriate handling instructions may be the most direct way to protect the end user.
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.

Annex O. section O.14 Shelf Life Testing:
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 +/- 8°F (23 +/- 4°C) for the duration of the shelf life.
For shelf life claims based on closed package studies
After Approximately one month before the shelf life time has elapsed, open/turn on etc. and follow the manufacturer’s instructions to conduct testing with the product WTD or test kit for the appropriate product types or parameters. If the WTD or test kit includes reagents (e.g. liquid, powders, dry-phase chemistry) use reagents from an unopened package of the same lot used during the initial testing phase. If the product does not meet the shelf life claims, the manufacturer shall revise shelf life claims, storage conditions, etc. and/or other pertinent storage information as appropriate. For shelf life claims based on open package studies use the materials from the original testing phase.

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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