F1980-16 Revision

ASTM Subcommittee F02.50 Meeting

04/14/2021

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Medtronic
Further, Together

BACKGROUND

- ASTM F1980 is a widely used guide for accelerated aging sterile barrier systems for medical devices
  - It is also a widely used guide for accelerated aging medical devices and materials used in medical devices
  - Medtronic has studied the behavior of polymer materials during aging and shown moisture uptake in polymers is governed by RH not absolute humidity – failures can be masked.

- Current humidity guidance is not optimized for all materials
  - Body of the document – states humidity not a factor in aging calculation without context for inclusion/exclusion
  - Appendix – absolute humidity chart/examples

- Standard used not just for packaging, but for device aging too
  - Goal is to improve the guidance on the use of RH during aging
  - Improve guidance in the body of the document
  - Improve the appendix

UPDATE – APRIL 2021 STATUS

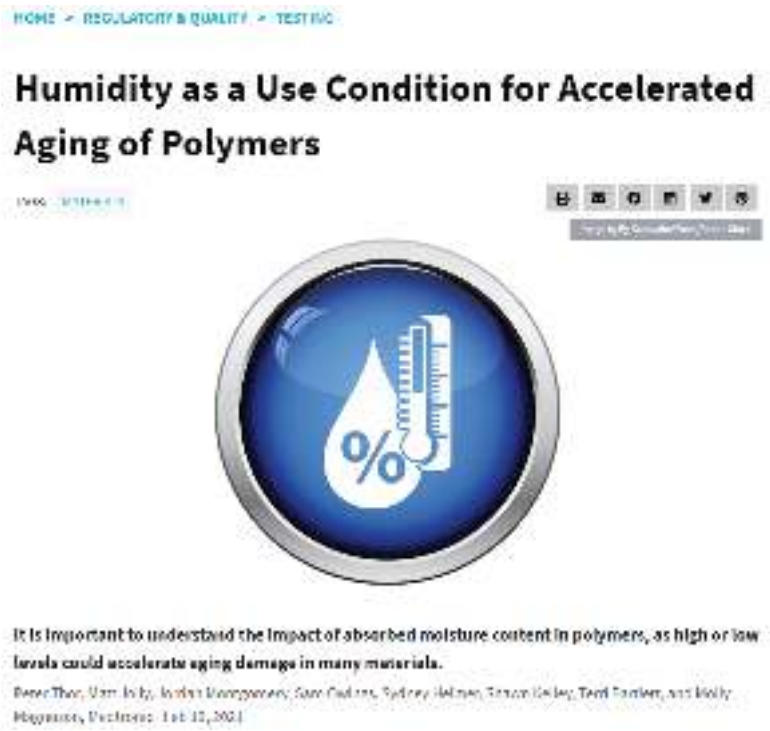
- Subcommittee Ballot 2020
  - Received 35 comments
  - Held a number of meetings over the course of summer 2020 to address comments
  - Redline has evolved

- Publication of Medtronic Data
  - MDDI Online – February 2021

- Latest redline includes the reference.

- Ready to ballot!
  - Subcommittee
    - Or
  - Sub / Main concurrent??

  - Please advise!



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