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Ensuring Identity and Traceability of Microbiology Proficiency Testing and Reference Material

What's in it….Where did it come from….Why should I care?

Agenda

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- Current Requirements for Microorganism Identity and Traceability under TNI
- Relevant ISO Guide 34 and 17043 Microbiology Identity and Traceability Requirements
- Requirements for Microbiology Laboratories under TNI & ISO 17025
- Intended use of current PT and RM
- Safety Considerations
- Recognized National Collections
- Licensing Programs
  - ATCC Proficiency Standards Program
  - ATCC License Derivatives Program
  - Material Transfer Agreements
- Take Away and Possible Future TNI Considerations

TNI Microbiology Requirements for Identity and Traceability

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- TNI EL-V3-2011, General Requirements for Environmental Proficiency Test Providers
  - Contains only the analytes and footnote information listed on the FoPT (NPW and DW)
    - Total, Fecal, E. coli, Enterococci, Heterotrophic Plate Count
    - Aerogenic strain of Escherichia, Aerogenic strain Enterobacter, Pseudomonas species or other microorganisms which will ensure an appropriate response by approved USEPA methods.
    - Section 5.1.2, Manufacturing system shall meet the requirements of ISO Guide 34
  - Current standard lacks specificity, nothing called out to require the use of strains traceable to or from an international recognized culture collection within volume 3. No verification of identity beyond USEPA approved methods.

ISO Microbiology Requirements for Identity and Traceability

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- ISO Guide 34, General requirements for the competence of reference material producers
  - reference material property needs to be characterized mainly to the level of accuracy required for its intended purpose
  - 5.12.1, The RM producer shall provide documentary evidence on the metrological traceability, of the measurement results to a stated reference

- ISO 17043, General requirements for proficiency testing
  - Current EL-V3-2011 Working Draft Standard harmonize to ISO 17043 and will require PT providers to be accredited to ISO 17043:2010
  - 4.4.5.1 The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose.

ISO Microbiology Requirements for Identity and Traceability

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- Concept of traceability for microorganisms in RM and PT seems to not be fully establish or accepted and therefore somewhat open to interpretation

- Reasonable interpretation of ISO guides and guidance documents (A2LA, P102a) should lead providers to utilize national collections for microbiology sample designs and document appropriately, but is not specifically required.

Requirements for Microbiology Laboratories under TNI and ISO 17025

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- EL-V1-2011, Module 5 (Quality Systems for Microbiological Testing), 1.7.3.6 Selectivity, c. & c.ii)
  - In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body. Microorganisms may be single use preparations or cultures maintained for their intended use by documented procedures that demonstrate the continued purity and viability of the organism.
  - Working stocks shall not be sequentially cultured more than five (5) times and shall not be sub-cultured to replace reference stocks.

Requirements for Microbiology Laboratories under TNI and ISO 17025

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- ISO 17025
  - For Testing Laboratories, Section 5.6.3.2 of ISO 17025:2005 states: "Reference materials shall, where possible, be traceable to SI units of measurements, or to Certified Reference Materials."

- These standards and guides would also lead you to believe that PT providers should be providing products traceable to national collections and be limited to the number of passages (subculture) removed from the original deposit.

Intended use of current Microbiology PT's

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- Intended use of current TNI microbiology PT's is to report identity (P/A) Total, Fecal, E. coli and quantitative determinations of E. coli, Enterococci and HPC's.
- Results are evaluated qualitatively for correct identity (9 of 10 with no false positives) and quantitatively to 2 or 3 standard deviations
- Since the intended use of the PT is organism identity and quantification, PT providers should have more specific guidance to produce their products from national collections and have documented traceability to these sources?
- It also would be appropriate to have analytical procedures that identify organism identity to a higher level than just the USEPA methods alone.

Recognized National Collections of Bacteria

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- ATCC, American Type Culture Collection
- NCTC, National Collection of Type Cultures
- NCIMB, National Collection of Industrial, Food and Marine Bacteria
- Currently 589 culture collections in 68 countries registered with World Federation for Culture Collections (WFCC)

Safety Considerations

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- Biosafety Levels
  - Most laboratories participating in TNI Environmental Proficiency Testing studies have facilities designed and personnel trained to handle BSL 1 or possibly BSL 2. Under current TNI standards organisms selected should fall into BSL 1 or 2. But there are no specific TNI requirements to address this issue.

- PT providers are free to select their own strains and are not necessarily required to report BSL levels to participants. Many "Pseudomonas species" (listed in DW FoPT footnote #9) are BSL 2.

- The agents (analytes tested) listed in Standard Methods that should be handled under BSL 1 practices are Total, Fecal coliform bacteria and E. coli, Enterococci. PT providers selecting a target for these analytes may be forced to select a BSL 2 because no BSL 1 is available.

- Much is left to discretion of PT provider….Just select an appropriate strain….. What could go wrong with that?

ATCC Programs Ensuring Identity, Traceability and Protection of Public Health

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- Proficiency Testing program for registered clinical labs (2005), used raw material supplied by ATCC. Unknown to ATCC a non-circulating H2N2 influenza strain (1957/1958 "Asian Flu") was used in a PT panel. US Dept. of Health and Human Services requested help from ATCC to ensure a similar event does not occur again.

- ATCC Proficiency Standards Program (PSP)
  - Agreed upon material between provider and ATCC
  - Provides dedicated stocks
  - Includes traceable supporting documentation to source material used
  - Gives increased protection to end users
  - Reduces Liability to PT providers and manufacturers
  - Limited Use Label License required

ATCC Programs Ensuring Identity, Traceability and Protection of Public Health

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- ATCC License Derivatives Program (LDP)
  - All manufactures producing reference materials derived from ATCC strains and referencing ATCC are required to have ATCC verify the quality before it reaches the end users. This is accomplished by an audit conducted by ATCC
  - End users purchasing these derivatives are tracked and required to sign and a MTA prior to receiving product under this program

- ATCC Material Transfer Agreement (MTA)
  - Agreement between purchaser and ATCC when the recipient intends to use it for his or her own research purposes. Protects ATCC from claims relating to use or misuse, defines how recipient should use and handle product, provides warranty to recipient and prevents uncontrolled distribution of the Biological Material.

- The SDP & LDP are currently unique to ATCC, but other collections may be following suit in future. MTA's are required by all collections that I've dealt with.

Conclusions and Possible Future TNI Considerations

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- Lack of specificity in TNI Volume 3 relative to microbiology PT's may cause it to fall short of it's intended of scope of producing;
  - PT's that generate technically defensible data on the basis of the type and quality of the samples provided and samples which pose equivalent difficulty
  - and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT provides.
- Lack of specific's can result in a conflict between PT's that are intended to evaluate USEPA methods that are considered a BSL-1 assay with PT's that place additional biosafety requirements on the participants.
- Using recognized national collections should be a requirement clearly stated with the TNI Volume 3 standard. Clear documented traceability to those national collections should be required.

Conclusions and Possible Future TNI Considerations

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- It also would be appropriate to have analytical procedures that identify organism identity in final PT to a higher level than just the USEPA methods alone.
- Acceptable number of Passages removed from the original deposit should also be defined to limit the possibility of natural mutations occurring during sub culturing (3-4).
- ATCC has created programs based on it's experience to help ensure identity, traceability and protect public health. TNI could improve it's standards by adopting aspects of these programs into theirs or requiring participation in similar programs by approved PT providers.

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