MARS MISSION BIOBURDEN REQUIREMENTS

Nelson Labs.
A Sotera Health company

BIOBURDEN CLEANLINESS METRICS FOR SPACE MISSIONS

Martell Winters, Director of Science

Nelson Laboratories, LLC

BACKGROUND

- My expertise:
  - Sterilization science
  - Industrial and manufacturing microbiology
  - Regulatory expectations (e.g., FDA) with respect to both topics
  - Healthcare products
- Not specifically astrophysics or astrobiology
- However seemed to be useful for MSR Sterilization Working Group

Nelson Labs.
A Sotera Health company

CATEGORY IV REQUIREMENTS

- Key words:
  - Contamination control
  - Organics inventory
  - Trajectory biasing (careful selection of location?)
  - Cleanroom
  - Bioload/microbial reduction plan
  - Partial sterilization
  - Bioassay monitoring
- Right up my alley

Nelson Labs.
A Sotera Health company

INITIAL THOUGHTS

- Statement of task for Mars report:
  - *"…determining locations or regions on Mars that are potentially suitable or missions of less-restrictive bioburden than the current requirements for Category IV."*
- No water in any form (frozen or thawed)
- Location not of scientific interest (someplace boring)
- Frequent sunlight

Nelson Labs.
A Sotera Health company

CoPP STATEMENT OF TASK

- Reviewed “Criteria might include”
  - Not surprised to see parity with my main thoughts
  - <-25°C and Aw <0.5 both keep microbial replication essentially nonexistent
  - Addition of frequent sunlight might be helpful
    - Martian UV likely very effective against Earth microbes
    - Andy Schuerger great resource on this
- Not saying my “approval” is necessary, but the criteria are reasonable

Nelson Labs.
A Sotera Health company

EXPERIENCES WITH MSR SWG

- Use meaningful terminology consistently
  - “Inactivate” with or instead of “sterilize”
    - Inactivate covers proteins (e.g., prions)
  - “Passive inactivation”
  - “Active inactivation”
  - “Martian material” rather than microbes or other term
- Focus on fundamental chemistries
  - Nucleic acid-based organisms
  - Heat-resistant protein
    - Prion surrogate

Nelson Labs.
A Sotera Health company

FUNDAMENTAL CHEMISTRY / BOND BREAKAGE

- Previous: select extreme worst-case microorganism and location on product
- Recent: select microorganism with a known, high resistance placed in reasonable location – based on risk
  - Acceptable approach with proper documentation
  - Performed in this manner many times every day in healthcare
  - Many other factors add safety to process – obviates need for extreme approach in sterilization process

Nelson Labs.
A Sotera Health company

RISK AND STERILIZATION

- With sterilization, **not** only “sterile” or “non-sterile”
  - “Sterile” has one definition: free of viable microorganisms
  - Quantity of sterility assurance varies based on risk
  - AAMI ST67 (FDA consensus standard)
    - SAL of 10^{-3} and 10^{-6} both acceptable with risk-based justification
    - Non-compromised vs. compromised tissue
  - Healthcare regulatory bodies accustomed to risk assessments with decisions

Nelson Labs.
A Sotera Health company

RISK AND STERILIZATION

- “More safety” not always better – begin to compromise efficiency, functionality, and fiscal responsibility
- “Just because we can” should be questioned – what is absolutely necessary?
- Cat IV “partial sterilization” in line with healthcare
  - Not required that sterility (microbes) or pyrogenicity (endotoxins) be the same throughout a product or for all product types

Nelson Labs.
A Sotera Health company

BIOLOGICAL CONTAMINATION OF MARS

- Statement of task:
  - *"…how human missions can be carried out without large-scale biological contamination of Mars."*
- Containment
  - Hermetic seals reduce need for internal sterilization
  - Example: pacemakers not internally sterilized
- From MSR SWG report:
  - *"Any form of life on Mars is unlikely to be hazardous to Earth's biosphere or humans; however, without data the risk is not zero."*
  - Same for *vice versa*

Nelson Labs.
A Sotera Health company

BIOLOGICAL CONTAMINATION OF MARS

- Some contamination likely inevitable with increased missions
- What is the real risk?
  - Additional data over time could allow for loosening of requirements
    - Either no extinct/extant life or;
    - Martian extinct/extant life can be distinguished from that of Earth
  - Self-decontamination properties of Martian surface
  - Should be able to distinguish between Martian/Earth life with genetic techniques
  - MSR approach and data likely beneficial for this topic

Nelson Labs.
A Sotera Health company

METHODS FOR MISSION CRITERIA

- What value(s) should be established as minimum requirements?
  - Example: Sterile healthcare products usually at 10^{-6} SAL
    - Previous approach: Just achieve the SAL with a sterilization process – 1 aspect targeted
    - Recent approach: End-to-end sterility assurance – consider all aspects of process
    - Analog for PP: Don't have single aspect or value targeted, but focus on entire process – likely already doing this
  - Example: Sterile products at 10^{-6} not tested after full sterilization process
    - Cannot test 1 million products
    - Test after partial sterilization process and extrapolate based on data
    - Analog for PP: Extrapolate based on data – likely already doing this
  - Establish minimum manufacturing and sampling requirements
    - Likely already doing this

Nelson Labs.
A Sotera Health company

THANK YOU

Martell Winters, B.S., RM/SM(NRCM), AAMI CISS(RAD)

mwinters@nelsonlabs.com

Nelson Labs.
A Sotera Health company

Nelson Labs.
A Sotera Health company