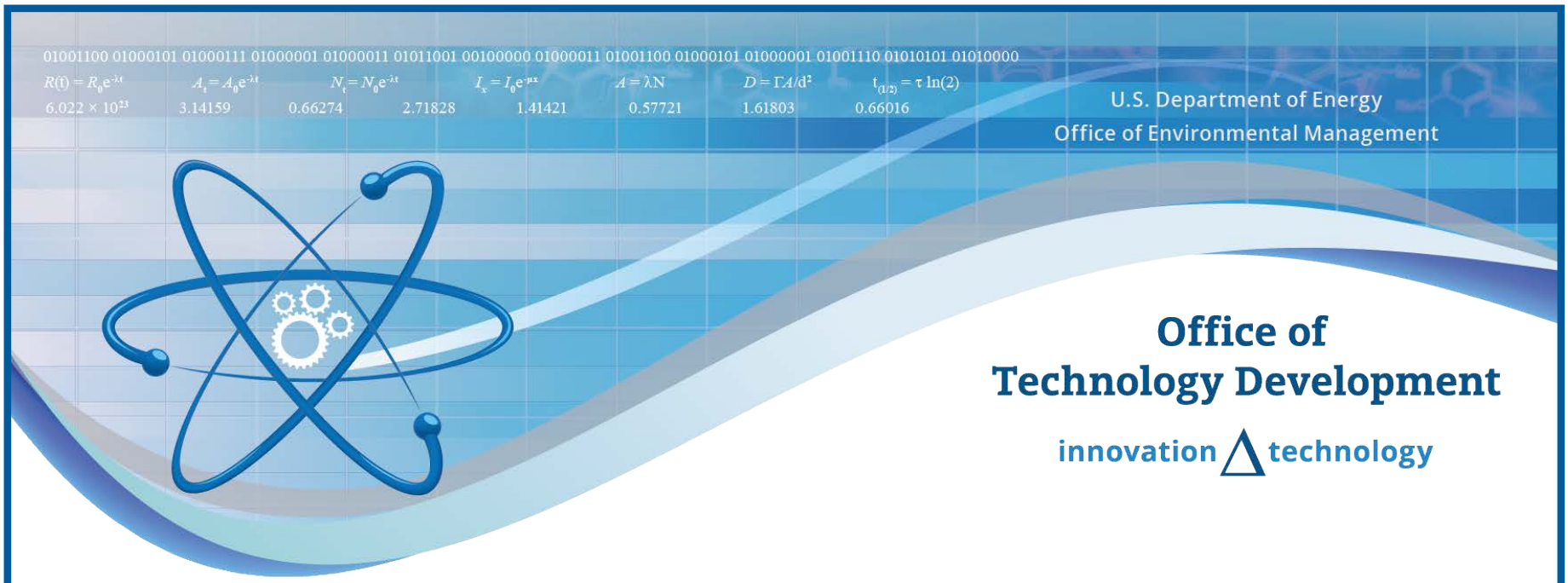


# Risk & Regulatory Working Group

## Exoskeleton - G Meeting

Marriott Gateway

June 28 and 29, 2017

# Where we Started

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- Risks
  - Who is liable for user injuries and equipment failures; manufacturer, user, other?
  - How is fitness-for-service assessed?
  - What are the requirements for basic knowledge, proficiency, and refresher training established?
  - Should the use of exoskeletons be a personal choice?

# Assessment by Group

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- Need Common Terminology
- Concerned with Safety and Insurance
- Existing Standards
  - Robotic Standards
  - ISO 13482 – Robots and Robotic Development - Safety Requirements for Personal Care Robotics
  - ANSI 15066
  - Collaborative Robot Standards
  - UL 227 Electric & Fire standard
  - There are no ergonomic standards
- However, No consensus standards

# Needing Data

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- Exoskeletons are TRL 6 Today, but Need to be TRL 8
- FDA Approves Medical Devices & OSHA will approve Industrial Exoskeleton Devices
- Acceptable Risks a concern, for example at Harley Davidson, a worker requires a hoist to lift a motorcycle frame of 70# , an exoskeleton might be able to eliminate the use of the hoist and change time and money
- However, injury reports from companies are protected and secretive (not accessible)
- We need to understand safety, including PPEs
- For example, is an exoskeleton valued as an automobile or hammer (tool) for liability concerns?

**Today, No compilation of Knowledge on Exoskeletons (No Data)**

# Issues Needing Answers

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- What are the long-term effects to the user?
- What essential muscle groups should we measure with sensors?
- Exoskeletons require the “Human Subject Research Protocol”
- We Do Not Know The Long Term Effects of Exoskeletons
- Need Training Protocols – long term activity
- IRB needs extensive testing and being transparent

# Barriers to Entry

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- Need sharing mechanism to collect data
- Broad-use not regular