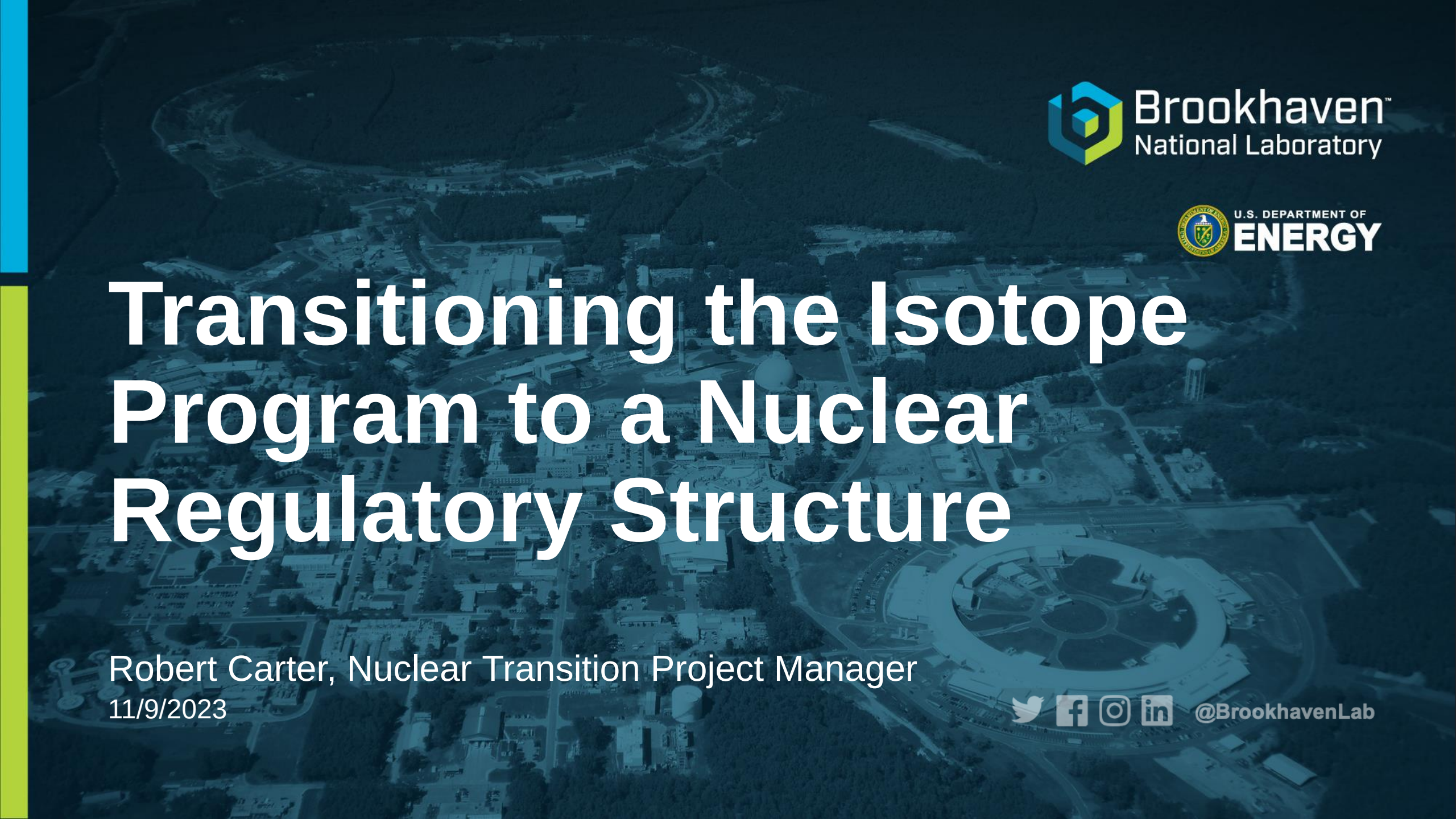

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# Transitioning the Isotope Program to a Nuclear Regulatory Structure

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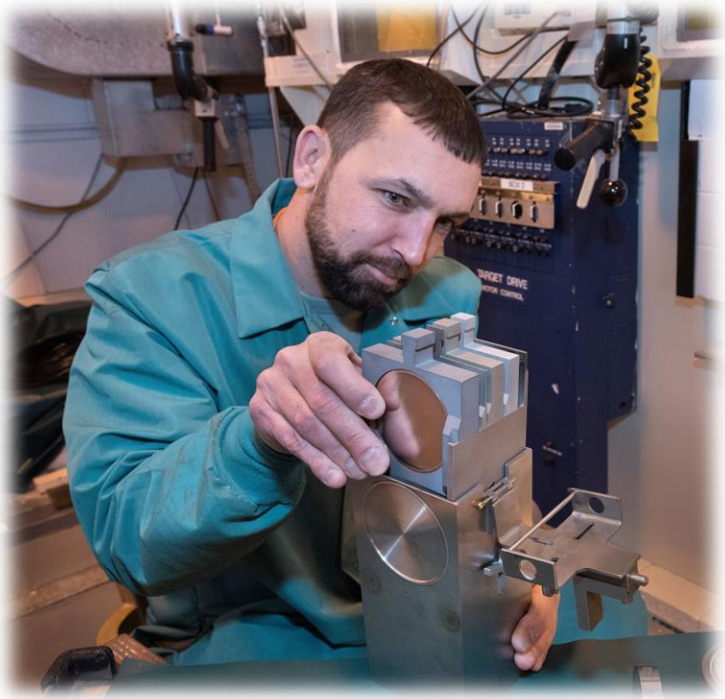
# No Change to Operations

- The isotope laboratory has been safely managed under the DOE Accelerator Safety Order for more than a decade.
- Order content was recently changed:
  - “Accelerator Operations excludes radioisotope processing activities that are not required to operate or maintain the accelerator.”
- The nuclear regulatory structure provides a path for the safe continuation of research.
- Changing the regulatory code only; no change to the actual work

# Nuclear Safety Regulations

- 10 CFR 830 – Nuclear Safety Management.
  - Subpart A – Quality Assurance
  - Subpart B – Safety Basis
- DOE implementation of 10 CFR 830 is accomplished via numerous documents:
  - DOE Nuclear Safety Policy
  - Eight applicable regulatory directives
  - Dozens of technical standards
- Directives require rigorous safety analyses, pervasive quality assurance, and thorough documentation.

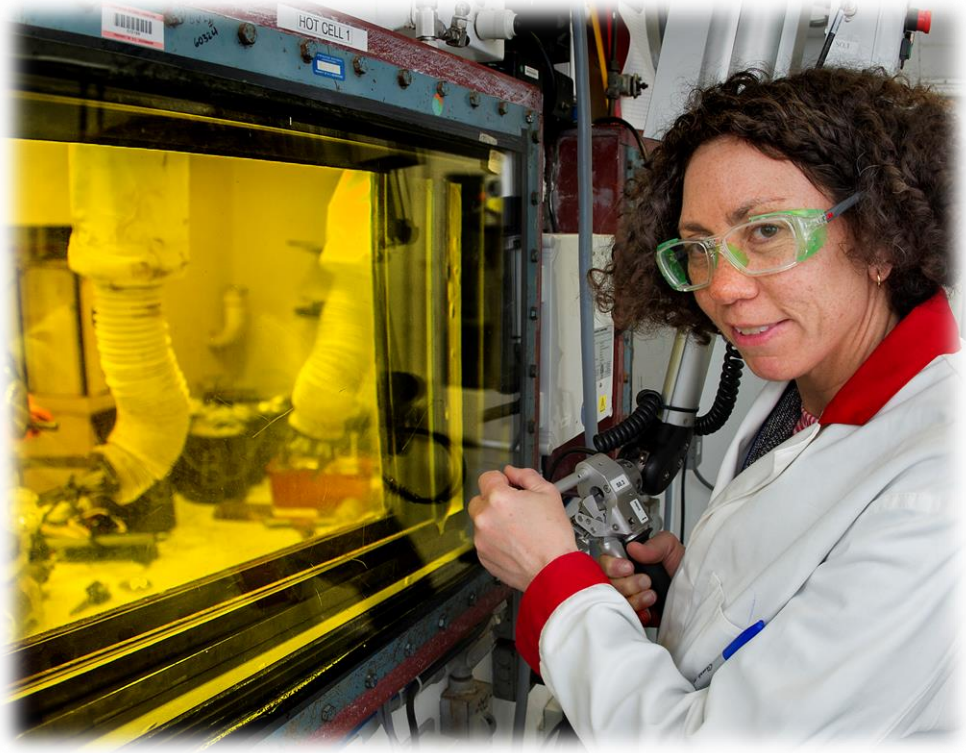
# What is a HazCat 3 Facility?



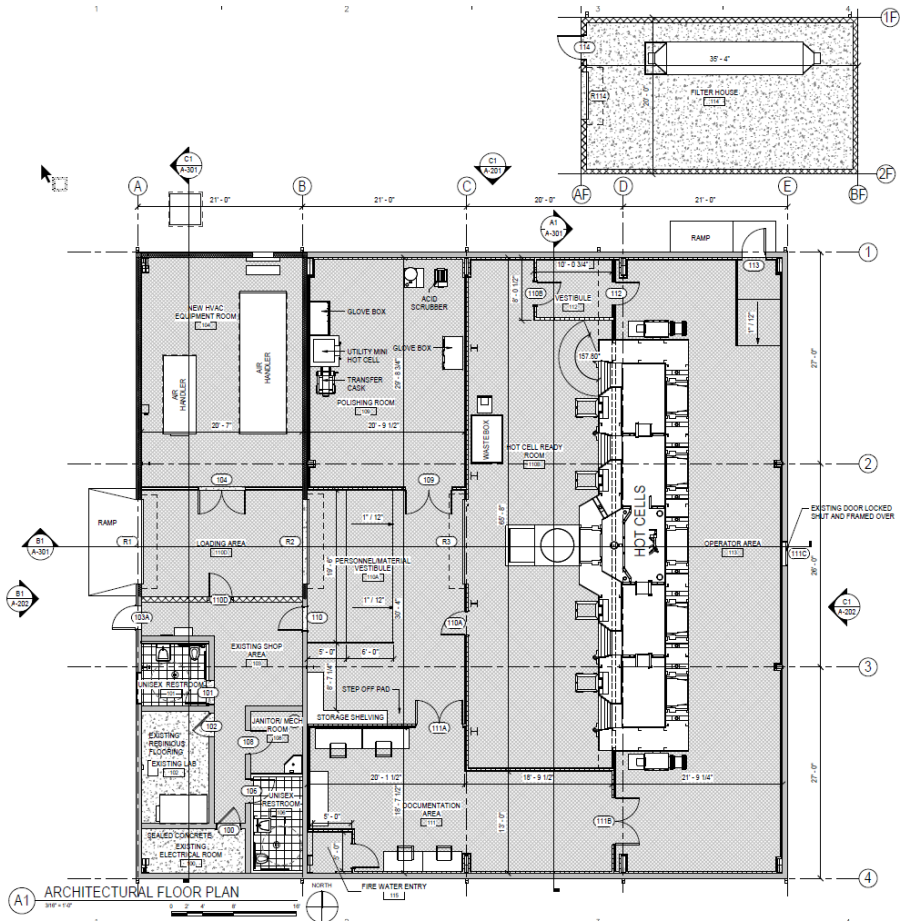
- Hazard Categorization is based on potential consequence:
  - HC1 - Significant off-site consequences
  - HC2 - Significant on-site consequences
  - HC3 - Only local significant consequences
- Analysis confirmed that the Radionuclide Research & Production Laboratory (RRPL) contains HC3 quantities of material.
  - Analysis assumes a completely unmitigated release.
  - Radioisotope inventory is above the HC3 threshold, but below the HC2 threshold.
  - Insufficient inventory to produce significant consequences beyond the local vicinity

# Transition Overview

- Required documentation for many processes is handled differently:
  - Quality Assurance (NQA-1)
  - Safety Basis analyses
  - Configuration Control / Change Management
  - Operational Readiness
  - Facility Safety Management programs
  - Training & Qualifications
  - Conduct of Operations
  - Nuclear Maintenance Management
- The full transition of RRPL is expected to take two years.



# Clinical Alpha Radionuclide Producer




- CARP facility adds capacity but introduces no new risks
  - Same fundamental science as RRPL
  - Very near the waste facility; reduced waste movement
- The CARP facility will not need to undergo a “transition” to nuclear status.
  - Managed as a nuclear project from start to finish
  - Nuclear safety expectations incorporated directly into system design
  - Safety Design Strategy per regulatory standards and approved by DOE
  - Support programs will already be in place

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# Regulatory Activities

- Nuclear Safety regulations contain no provision for “close enough.”
- 10 CFR 830 Exemption Request submitted to DOE.
  - Exemption process via 10 CFR 820.
  - Pending approval by Dr. Berhe (SC-1).
  - 25-month duration anticipated.
- Risk management strategies unchanged during the exemption period.
  - No change to operations.
  - No inherent risk increase.


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