EDEN RADIOISOTOPES

Overview of Company

Who We Are

A new healthcare company, leveraging IP licensed from Sandia National Laboratories, with financial investment from the Yates Family

What We Do

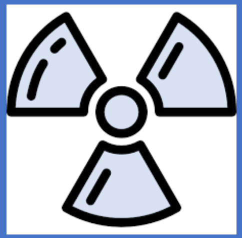
Eden is a healthcare company, producing medical isotopes for the $4.2B radiopharmaceutical molecular imaging industry

Abo Empire

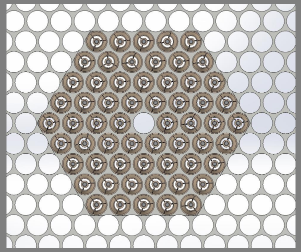
Sandia National Laboratories

EDEN RADIOISOTOPES

Eden Radioisotopes



A new startup company, will build a small scale 2 Megawatt all LEU-target reactor and processing facility, solely dedicated to medical isotope production, with a year-round Moly production capacity to exceed the current entire global demand of 10,000 6-day Ci /wk, along with other medical isotopes.



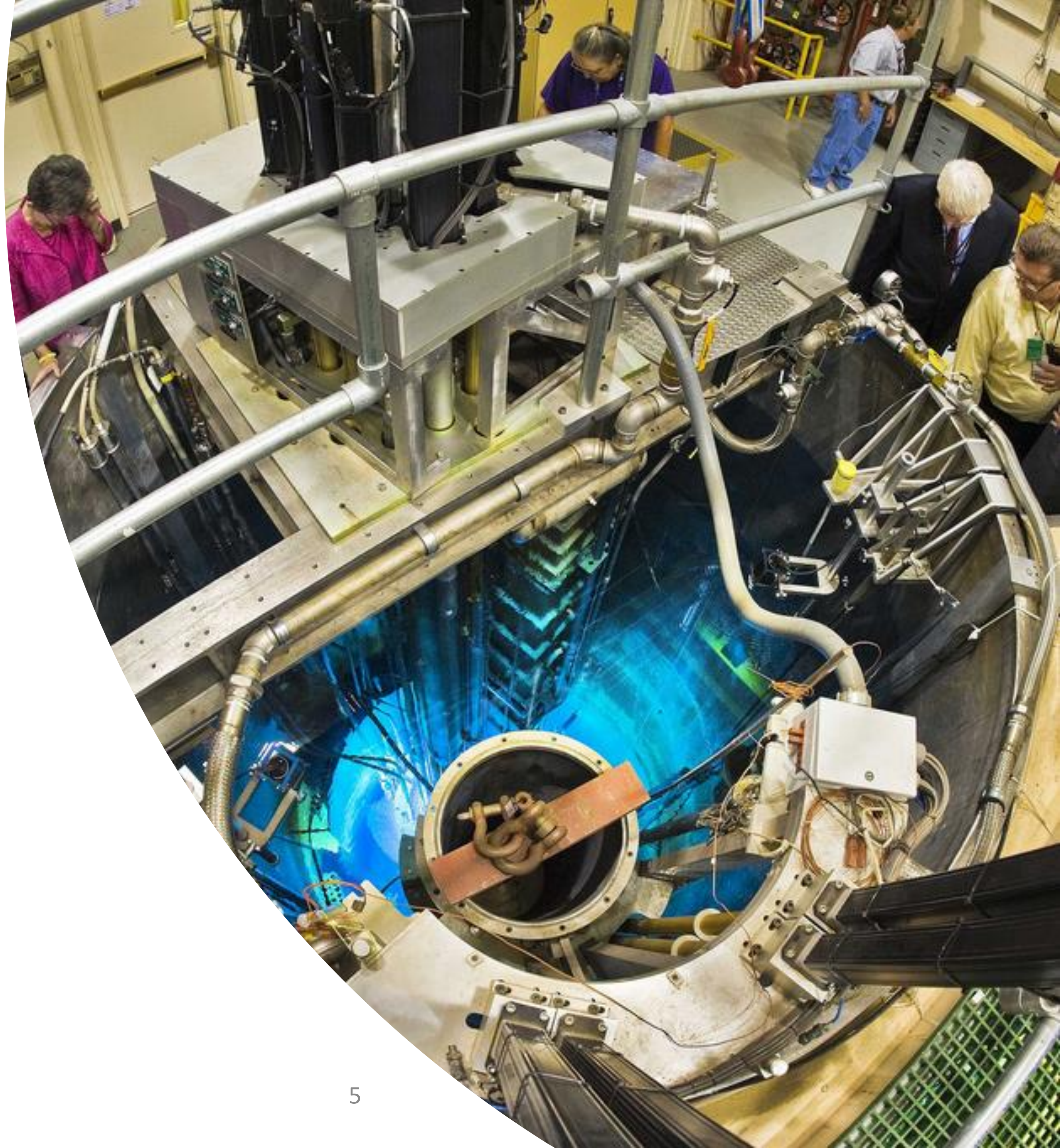
The GENESIS reactor design is a fully dedicated medical isotope reactor, utilizing an ***all-LEU target/core****. This patented all-LEU target reactor technology, exclusively licensed from Sandia National Laboratories, will operate continuously year round, at a fraction of the cost of other reactors.*

1990s DOE Medical Isotopes Program

- $45M program at Sandia National Laboratories in Albuquerque, NM
- Involved modifications to Annular Core Research Reactor as well as construction of Hot Cell Facility for Mo-99 Production
- SNL staff worked with Cintichem engineers to reverse engineer their processing technique. This work was later passed on to ANL and adapted for LEU
- Project was successful and product was created and quality assured by Mallinckrodt

From Sandia to Eden

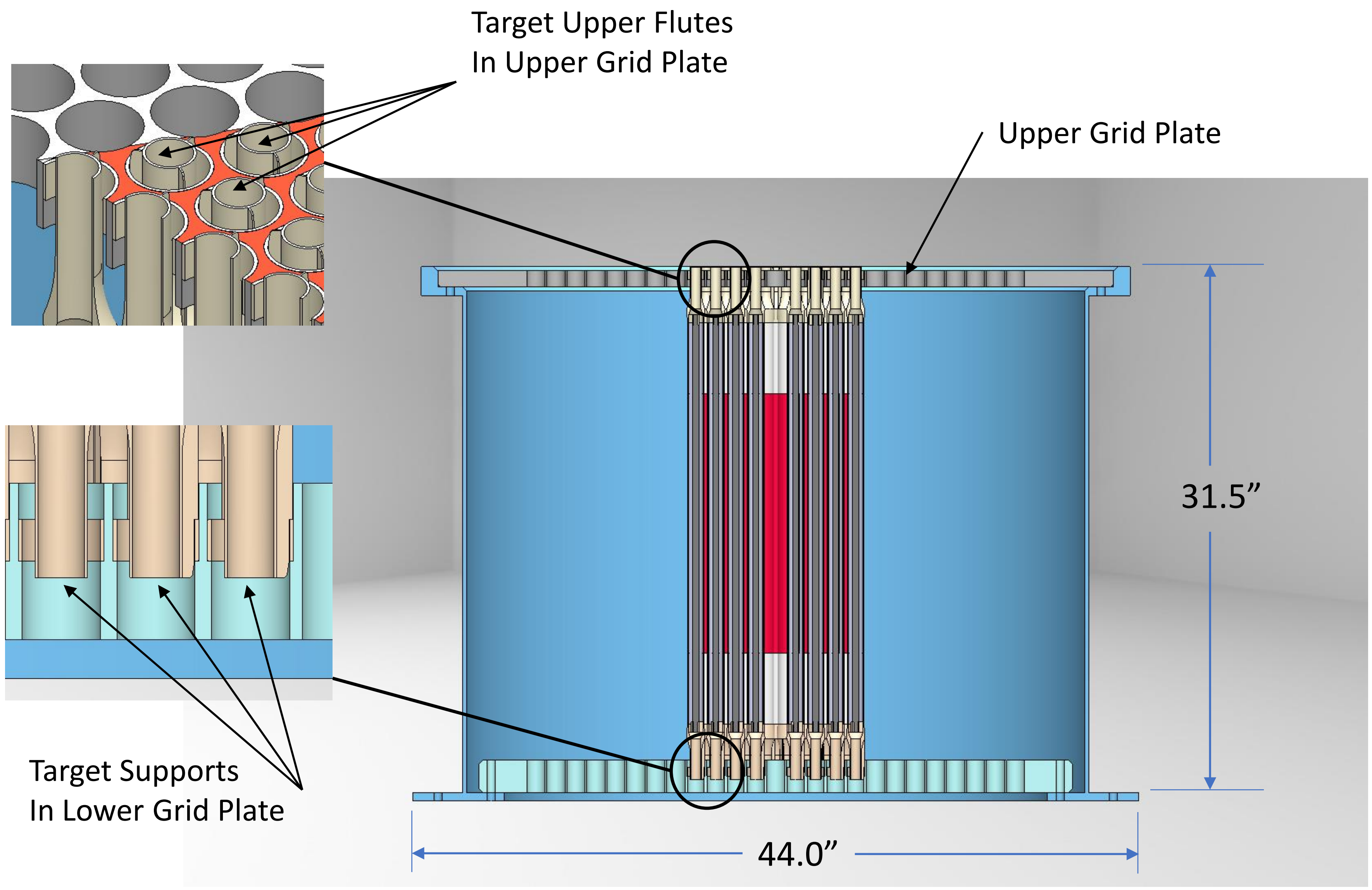
- Eden has privatized the experience from the DOE Medical Isotopes Program at Sandia National Labs
- Eden has a fully exclusive license to the SNL “all-target” reactor technology
- Eden has adapted the SNL program to the modern era:
    - Commercially focused
    - LEU targets
    - New facility to be built near Eunice, NM (by Urenco facility)



Primary Work at Eden’s IPF

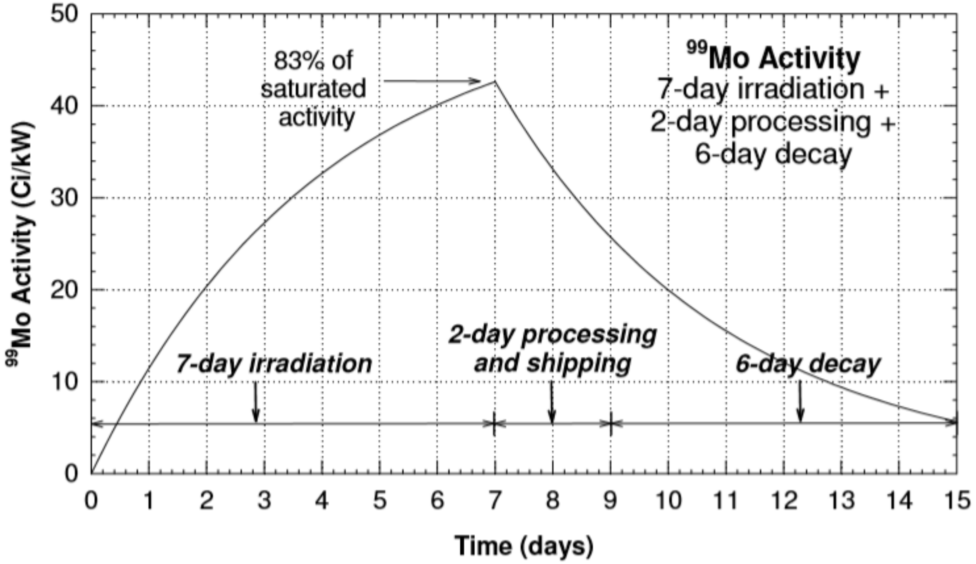
- Target Irradiation
- Target Processing
- Target Fabrication

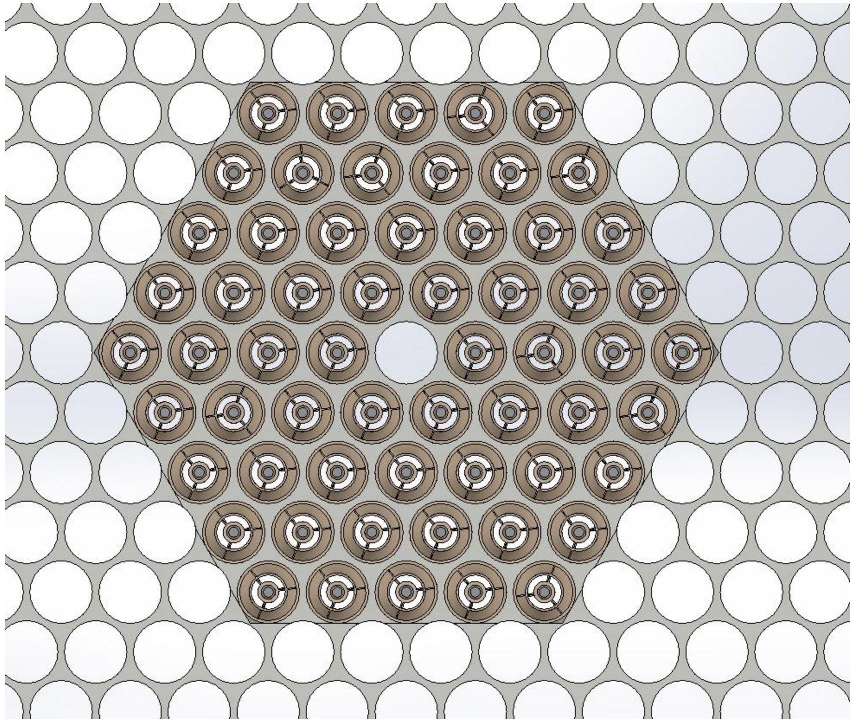
Genesis Reactor Core Cut-Away



“All-target” approach

- Mo-99 reaches saturated activity at about 7 days of irradiation
- By harvesting all uranium in the core, Eden is able maximize Mo-99 production per unit reactor power
- Low burnup times also minimize buildup of long-lived fission products





Genesis Design Features

Simple

- Small, single purpose, medical isotope production
- Flexible core configuration & target irradiation
- All proven technology. Open pool system w/natural circulation cooling

Safe & Readily Licensable

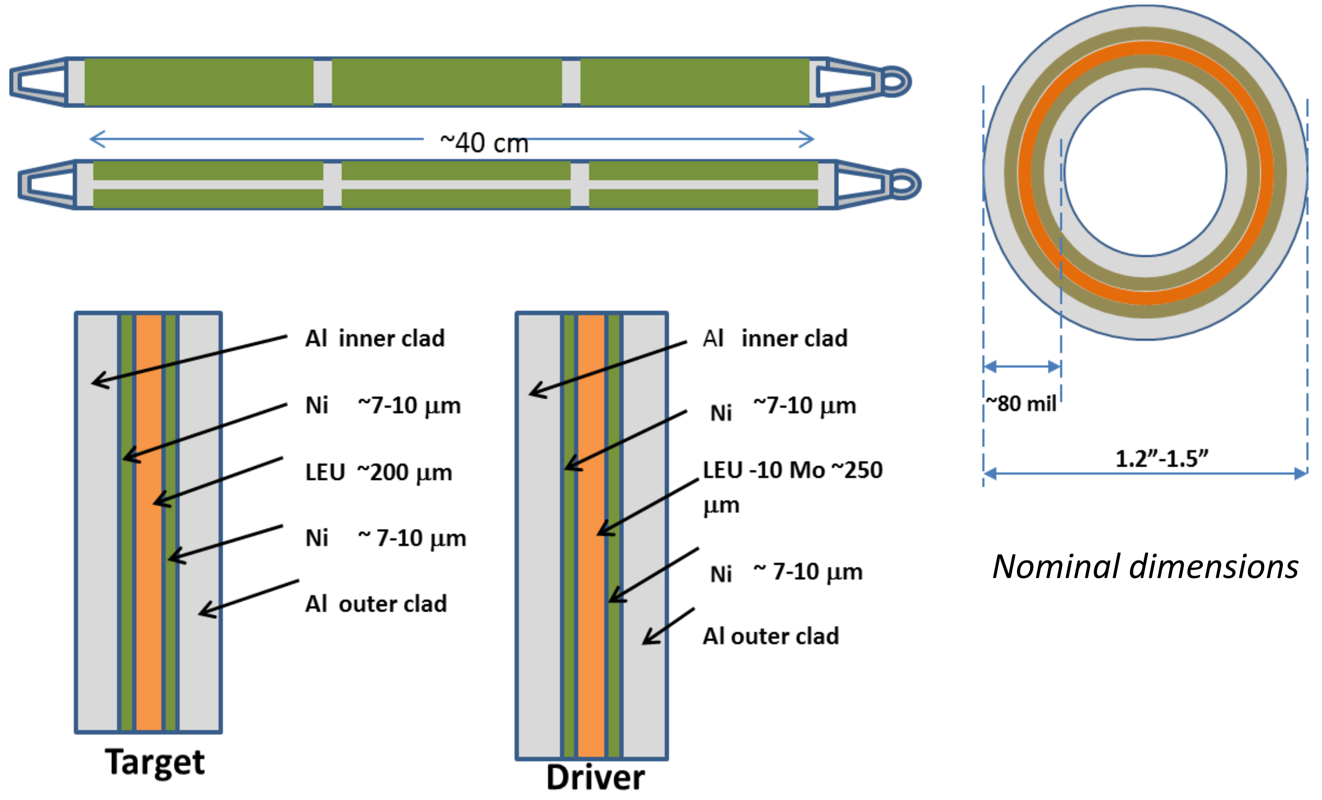
- Annular hexagonal array of targets and drivers
- Targets & Drivers interchangeable (equivalent nuclear & thermal)
- Maintain design within domain of NRC familiarity

Cost Effective

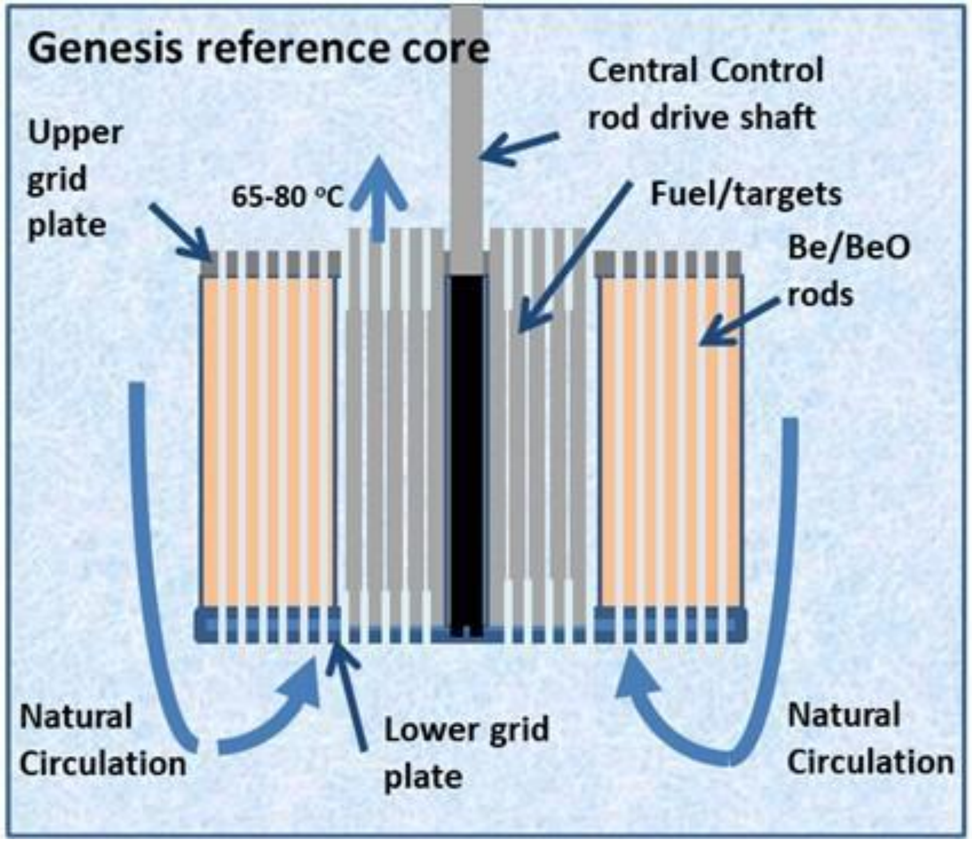
- Operates continuously 22/7/365, with 1-2 hrs/day for target extraction/replacement
- Maximum ^{99}Mo production per unit reactor power
  - Why pay the cost of construction and operation of a 10 to 100 MW system when you only need 1.5-2.0 MW to satisfy WD
- Maximum ^{99}Mo production per unit LEU used

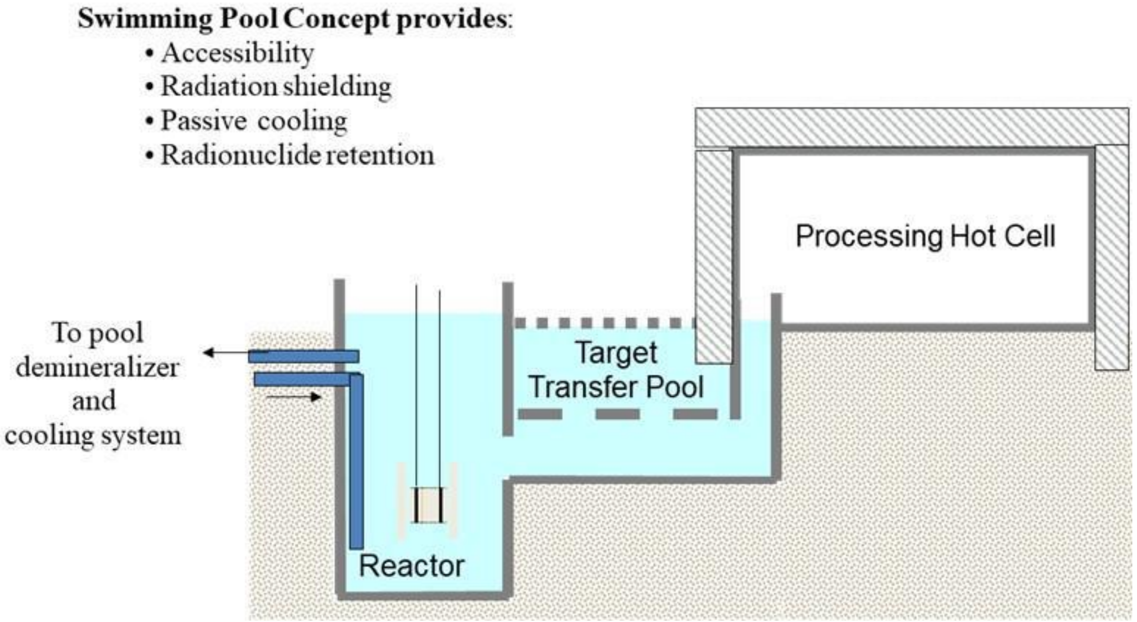
Genesis Reactor Target & Driver Design

- Based upon Argonne Mo-99 targets with a decade of research and proven performance
- Driver targets, with a useful life of 21 days, are used in addition to targets for early low market share to avoid non-productive reduction of target inventory.
- Goal following start of commercial production is to fabricate targets in-house



Nominal dimensions



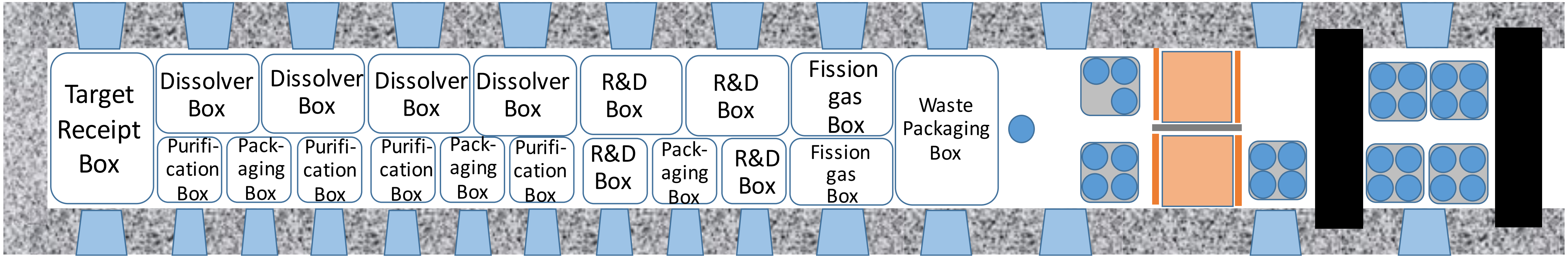


Eden Genesis Reactor & Process Facilities Interface

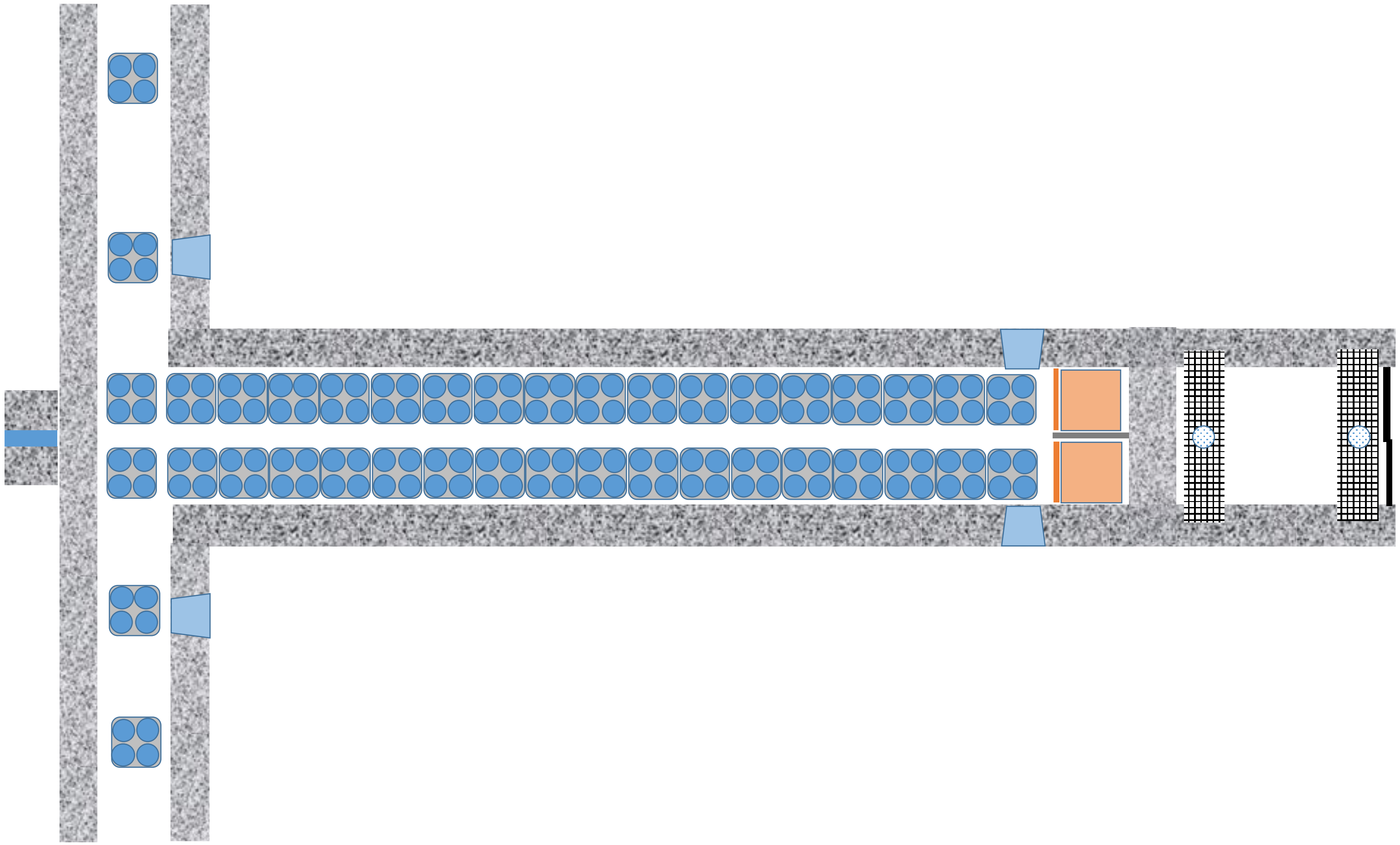
General Facility Layout

The facility will house the reactor facility, hot cell facility and target fabrication facility within a common structure

Hot Cell Facility (upper level)



Waste Storage Area (lower level)



Integrated Safety Analysis

- An integrated Safety Analysis is being developed for the Eden Reactor, Isotope Production Facility, and Fuel Fabrication Facility in accordance with the following:
    - 10 CFR Part 70, *Domestic Licensing of Special Nuclear Material* (CFR, 70).
    - NUREG 1513, *Integrated Safety Analysis Guidance Document* (NRC, 2001).
    - NUREG 1520, *Standard Review Plan Nuclear Fuel Cycle Facilities*, Revision 2 (NRC, 2015).
    - Interim Staff Guidance Augmenting NUREG-1537, Part 1, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content, for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors*, October 17, 2012.
    - ANSI/ANS 15.21, *Format and Content of Safety Analysis Reports for Research Reactors* (ANSI, 2006).
    - *Guidelines for Hazard Evaluation Procedures*, Second Edition with Worked Examples, developed by the American Institute of Chemical Engineers (AIChE 1992).

Methodology: What-if & Checklist

- The approach for the ISA consisted two phases. The first phase used the “what-if” & “checklist” methodology to comprehensively evaluate the broad range of potential accidents and to identify accidents of concern. Once accidents of concern were identified, other methodologies were employed to analyze in detail the most significant of those accidents (or any others that are postulated).

Phase I of ISA

The steps for conducting phase I of the ISA consisted of the following:

1. Identify the activities for the reactor and processing facility;
2. Identify the hazards associated with these activities using a checklist;
3. Analyze the hazards using a “what-if” methodology to identify the frequency, consequences, and risk associated with potential accidents,
4. Identify possible mitigative and preventive actions and controls.
5. Identify accidents of concern for further evaluation; and
6. Perform detailed Accident Analysis (AA) (Phase II).

Frequency, Consequence, and Risk

Table 1-2. Consequence Severity Categories

Category[2]	Affected Receptor		
	Facility Workers	**Public**	**Environment**
A	Loss of life, serious injury, or immediate life-threatening radiological doses Greater than or equal to (≥) 100 rem acute **OR** Chemical release that endangers life	Greater than or equal to (≥) 25 rem **OR** Greater than or equal to (≥) Protective Action Criteria (PAC-3)	
B	Significant radiological dose, significant injury or disability Greater than (>) 25 rem acute to less than (<) 100 rem acute OR a chemical exposure with long lasting health effects	Greater than or equal to (≥) 1 rem **OR** Greater than or equal to (≥) PAC-2	Radioactive releases greater than (>) 5,000 times Table 2 of 10 CFR Part 20, Appendix B
C	Radiological and chemical exposures less than (<) those above.	Radiological and chemical exposures less than (<) those above	Releases less than (<) those above

Table 1-2. Frequency categories

Category	Category Descriptor	Frequency (F) Per Year
I	Credible	F greater than or equal to (≥) 10^{-4}
II	Unlikely	F less than (≤) 10^{-4} and greater than 10^{-5}
III	Highly Unlikely	F less than 10^{-5}

Table 1-3. Risk-Ranking Matrix

Consequence Severity Category[a]	Frequency Category		
	III	**II**	**I**
A	Acceptable Risk 3	Unacceptable Risk 6	Unacceptable Risk 9
B	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
C	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

Notes:
a) Rankings based on NUREG 1520, Table A.3.

Unmitigated Analysis - Example

Scenario Description	Material at Risk / Exposure Rate	Unmitigated Frequency, Consequence, and Risk			Controls
Event Category: Reactor Events		**F**	**C**	**R**	
RO-RE-001 – Maximum Insertion of Excessive Reactivity An operator inadvertently or equipment failure causes the control rod bank to withdraw to its fully withdrawn position, adding excess reactivity. Subsequent fuel melting and fuel element cladding breach of all reactor core fuel elements results in a release of MAR to the reactor pool. **Location(s):** Reactor room	Fission products in 19.75% enriched uranium targets or u-10 Mo fuel elements	I	W B P C E D	6 3 3	**Engineered** • Reactor Pool (IC) • Target/Driver design (Cladding) (IC) • Reactor Core Configuration (IC) • CR Bank speed </= 1.0 cm/s Reactor • Reactor power SCRAM (2 independent channels) • Manual SCRAM • Period SCRAM **Administrative (SMPs)** • Conduct of Operations Program • Internal Safety Review Program • Radiation Protection Program • Maintenance Program • Configuration Management Program • Emergency Management Program • Quality Assurance Program • Training Program • Procedures Program **Other Administrative Controls** • Maximum excess reactivity less than or equal to (</=) $12 • Operator Training & Certification • Reactor Operating Procedure
Notes: A control or safety rod bank is inadvertently and continuously withdrawn to its fully withdrawn position resulting in a positive reactivity addition. Scenario caused by Operator error (inattention) or equipment failure (faulty rod position indication and/or reactor power indication) or electrical/mechanical/software fault. Enough excess reactivity is added to cause fuel melting and fuel element cladding breach of all reactor core fuel elements results in a release of MAR to the reactor pool. This scenario is evaluated as the Maximum Hypothetical Accident and assumes that enough reactivity is inserted to affect 50% of core elements. Maximum insertion of reactivity is limited to </= $12.					

Mitigated Analysis - Example

Scenario Description	Material at Risk / Exposure Rate	Unmitigated Frequency, Consequence and Risk			TSR Level Controls	Mitigated Frequency, Consequence and Risk			Notes
		F	C	R	Preventive (P) / Mitigative (M) / Initial Condition (IC)	F	C	R	
RO-RE-001 – Maximum Insertion of Excessive Reactivity An operator inadvertently or equipment failure causes the control rod bank to withdraw to its fully withdrawn position, adding excess reactivity. **Location(s):** Reactor room	Fission products in 19.75% enriched uranium targets or u-10 Mo fuel elements	I	W B P B E C	6 6 1	**Engineered** • Reactor Power Scram (2 Independent Channels) - Manual SCRAM and Period SCRAM • CR bank speed </= 1.0 cm/s **Administrative** • Reactor Operator Training and Certification • Reactor Operating Procedures	III	W B P C E C	2 1 1	**Reactor pool (IC):** Reduces the consequences of release scenarios by containing fission products and radioactive particles **Target/driver design (cladding) (IC):** Minimizes the amount of dispersible radioactive materials during a potential release scenario by retaining fission products in the fuel matrix and containing radioactive materials via the fuel cladding. **Reactor core configuration (IC):** Prevents overheating of fuel elements by ensuring that the design and configuration of the core is consistent with the assumed operational parameters. **CR bank speed </= 1.0 cm/s:** Limits how quickly reactivity can be added to the reactor **Reactor power SCRAM (2 independent channels):** Prevents overheating of fuel elements by initiating a power SCRAM. **Reactor Operator Training and Certification**: Reduces the likelihood of operator errors. **Reactor Operating Procedures**: Reduces the likelihood of operator errors by independent verification by reactor supervisor

Choosing the ISA Team

- Mr. Bennett Lee, CEO/Co-founder, M.S., Engineering, ISA Technical and Management Direction
- Mr. Anthony Baca, B.S., Mechanical Engineering, ISA Team Leader
- Dr. Richard Coats, CTO/Co-founder, Ph.D., Nuclear Engineering
- Mr. Milton Vernon, Co-founder, M.S., Nuclear Engineering
- Dr. Edward Parma, Co-founder, Ph.D., Nuclear Engineering.
- Mr. Paul Helmick, B.S., Mechanical Engineering
- Mr. John Garcia, A.S, Mechanical Technology
- Ms. Amber Fosse, Editor
- Ms. Jessica Bridges, Recorder

- The biographies for the team are available. The team members met the criteria established in NUREG 1513.

Scope of ISA

Reactor

- Facility Operations
- Reactor Operations
- Reactor Maintenance
- Target Handling and Storage of Fresh Targets
- Natural Phenomena
- External Events

Processing Facility

- Facility Operations
- Target Transfer
- Target Receipt
- Dissolution Activities
- Purification Activities
- Product Packaging and Shipping
- Quality Assurance and Quality Control
- Waste Operations

Target Fabrication

- Facility Operations
- Uranium Receipt and Prep
- Uranium Processing
- Target and Driver Fabrication
- Target Transfer
- Quality Assurance and Quality Control

Reactor Accident Analysis

MHA: Melt of Target Element

Other accidents are bounded by MHA, but include the following:

- Insertion of Excessive Reactivity
- Loss of Coolant
- Loss of Coolant Flow
- Mishandling or Malfunction of Fuel
- Loss of Normal Electrical Power
- External Events
- Mishandling of Equipment
- Experiment Malfunction

Production Facility Accident Analysis

MHA: Release of Xenon from Long-term Noble Storage System

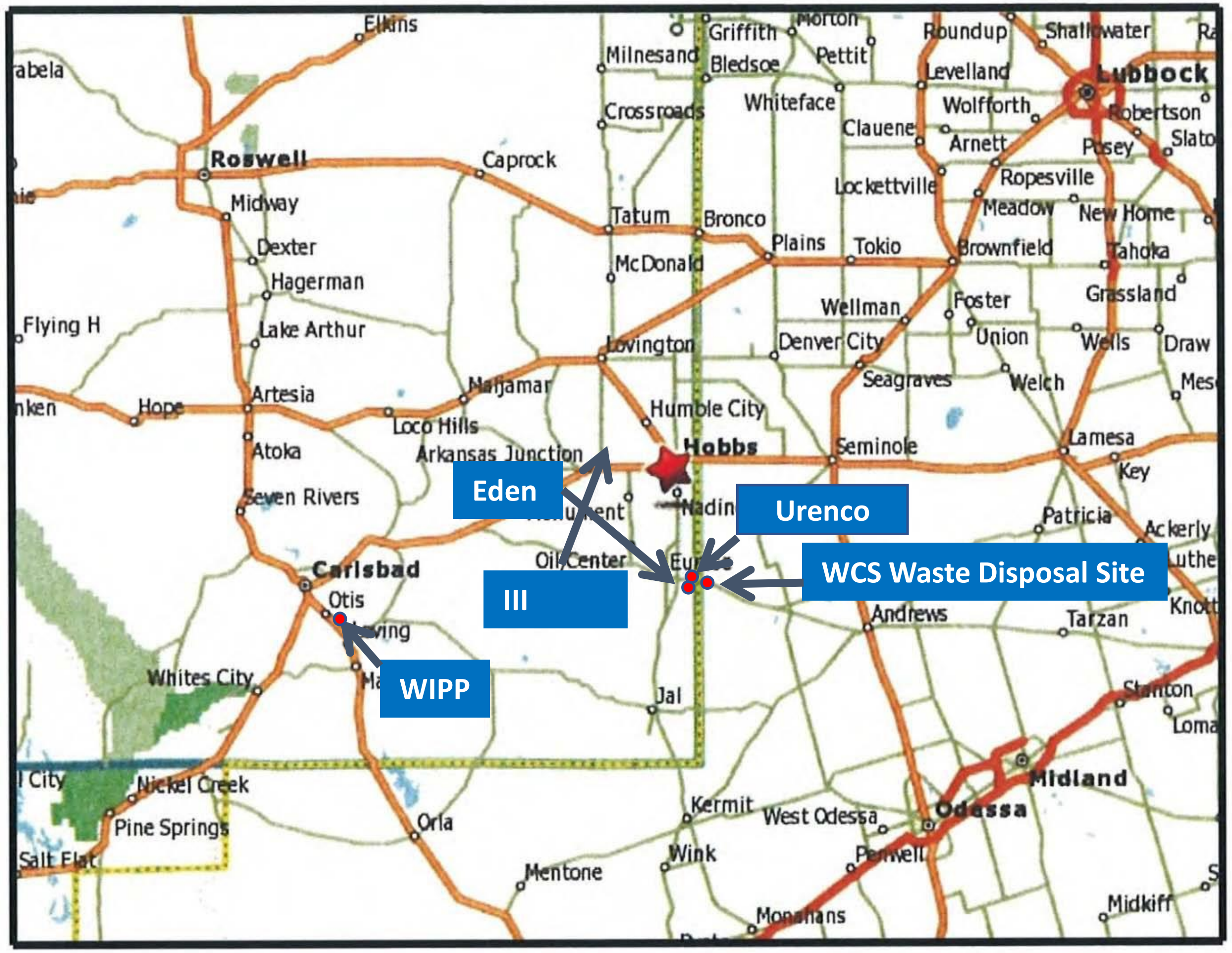
Other accidents are bounded by MHA, but include the following:

- Release of Iodine from Cold Traps
- External Events (Natural Phenomena, Aircraft Crash, etc…)
- Facility Fire
- Inadvertent Criticality
- Chemical Spill
- Loss of Power
- Mishandling or Malfunction of Equipment
- Experiment Malfunction

Why New Mexico

Advantages of New Mexico:

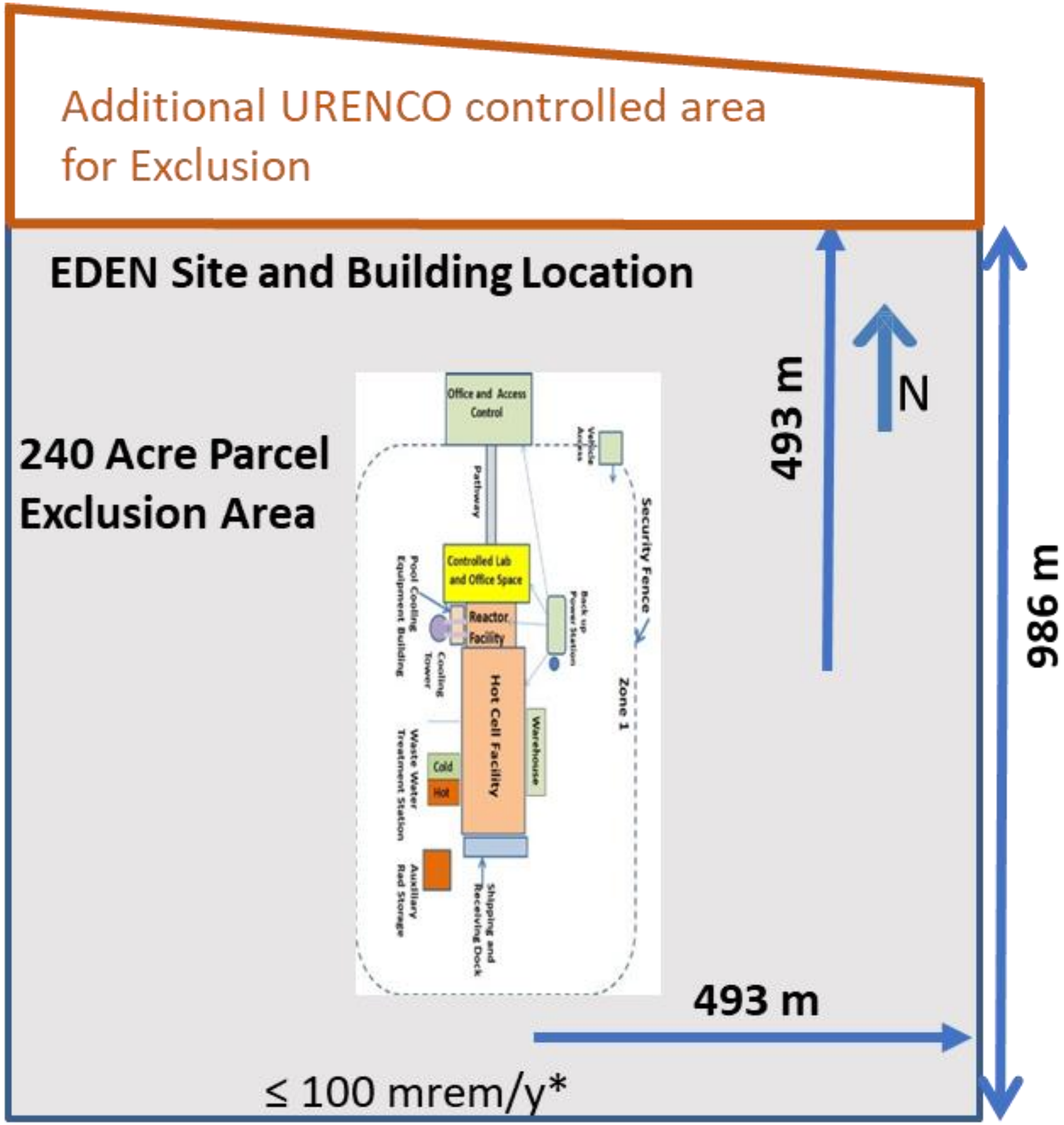
- Transportation logistics
- Nuclear-friendly community
- Ease of waste disposal
- Yates family support of NM
- Ability to contribute to and pull from an educated work force



Proximity to Other Nuclear Facilities

*URENCO granting easement to Eden

Property & Facility Configurations



Current Status of Schedule

Drafts of most chapters have been completed:

- ER is drafted
- ISA is drafted
- PSAR is about 80% complete
- Eden would like to continue communication with NRC to verify assumptions regarding the process
- Expected submittal by mid to late November

Thank You