COQUÍ PHARMA

Medical Isotope Production Facility (MIPF) Construction Permit Application & Licensing Strategy

August 12, 2014

Agenda

Topic	Presenter
Project Overview	Carmen Bigles
Licensing Strategy	Hogan Lovells
MIPF Facility, Process, & Design Requirements	INVAP, ENERCON
Questions	NRC Staff, Public
Environmental Report	GS&P, ENERCON
Questions	NRC Staff, Public
Conclusion	Carmen Bigles

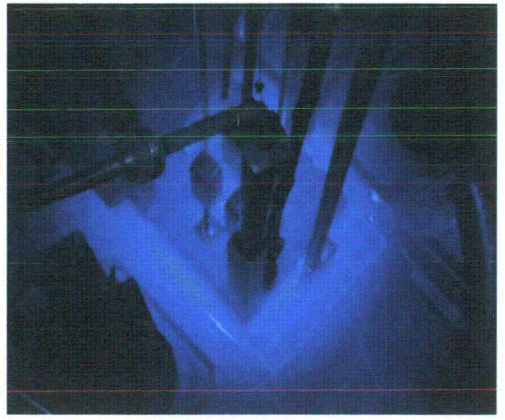
Project Overview

Our Team

- **Coquí**
  - U.S. company, will own and operate the MIPF
- **INVAP**
  - Designer and general contractor for the MIPF
- **Hogan Lovells**
  - Nuclear regulatory and environmental attorneys
- **Gresham, Smith and Partners (GS&P)**
  - Consultant for siting, environmental data collection, and environmental report (ER) preparation
- **ENERCON**
  - Consultant assisting in preparation of the Construction Permit Application

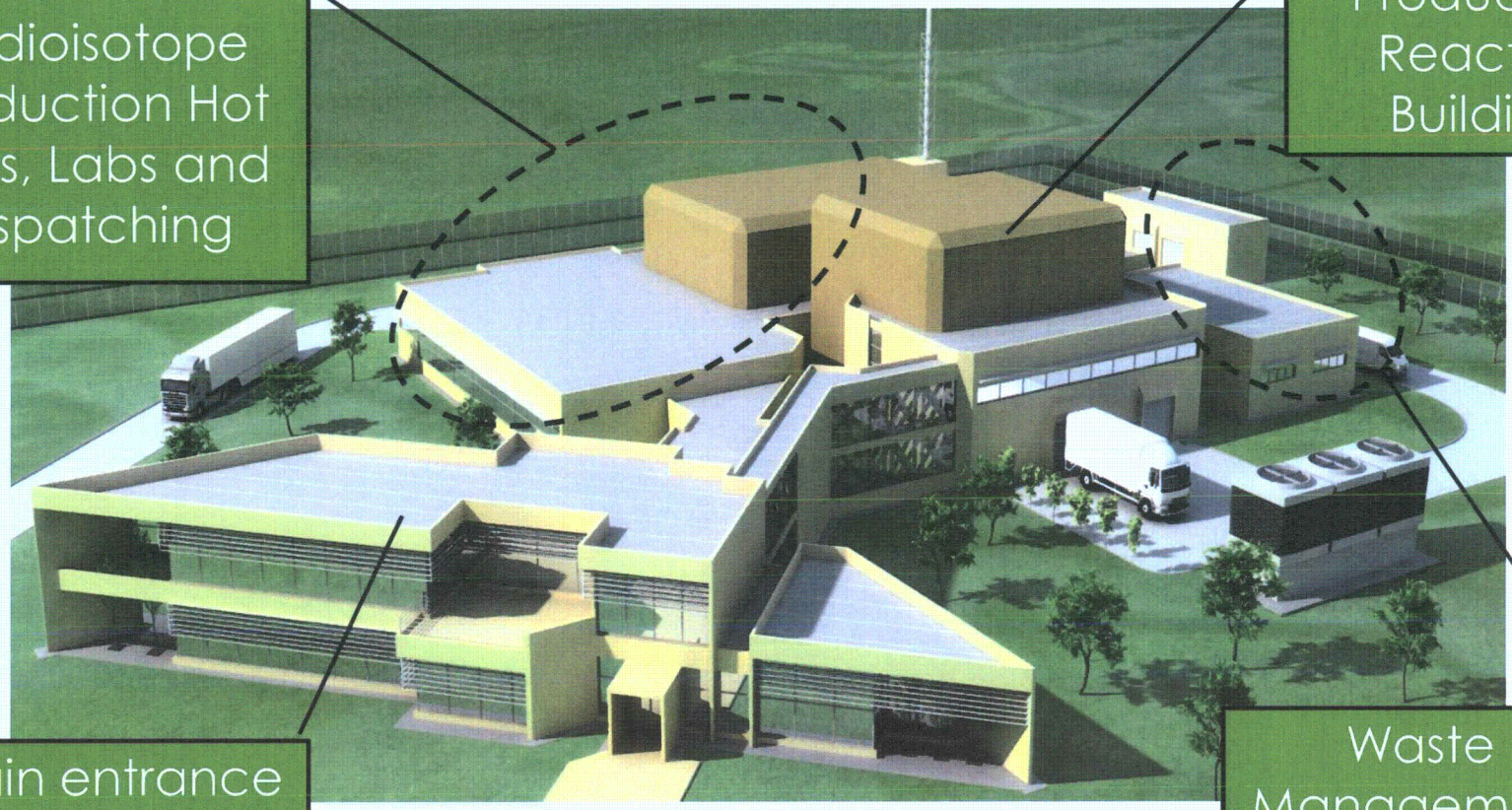
MIPF Description

- MIPF Overview
  - Facilities:
    - Two pool type MTR reactors
    - Radioisotopes processing facility
    - Waste conditioning facility
    - Support services and administrative offices

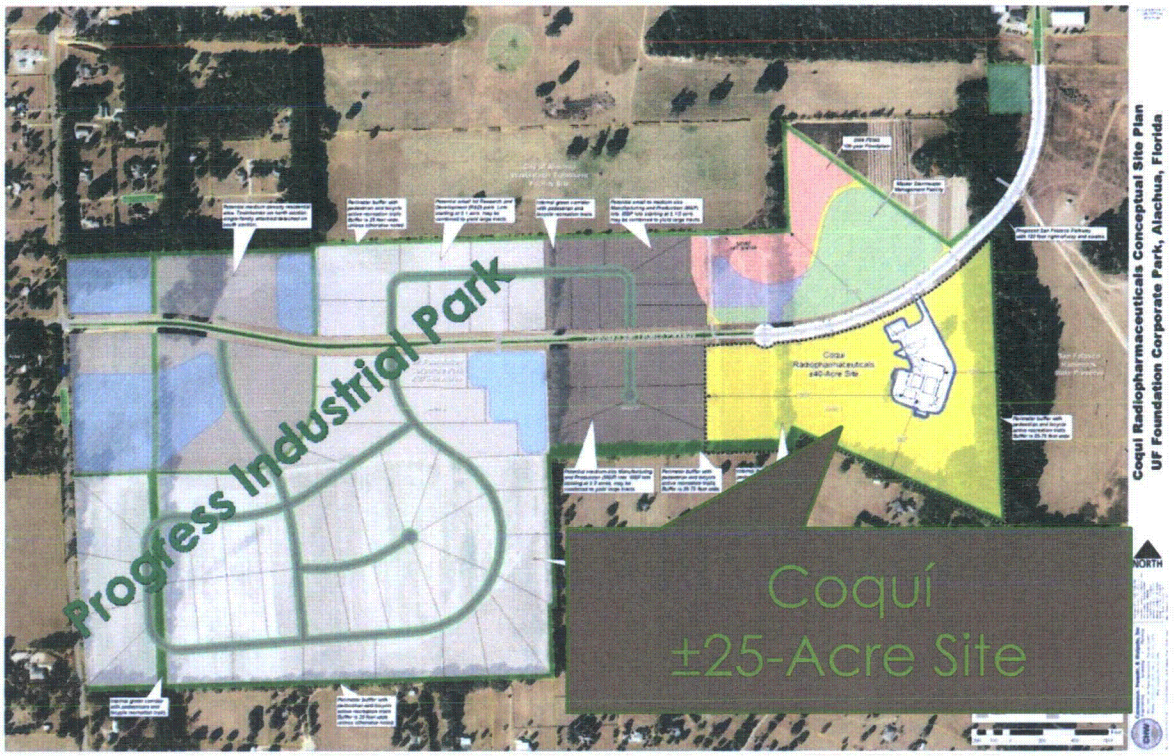


  - Designed and constructed by INVAP with proven technologies tailored to Coquí's specific needs
  - Will use LEU fuel and targets to produce Mo-99
  - The planned capacity for the MIPF will be 7,000 six-day curies per week

Conceptual Facility Layout



Conceptual Facility Layout



Licensing Strategy

Licensing Overview

- Production reactors, radioisotope production facility, and waste management facility, including activities regulated by Parts 30 and 70, under a single Class 103 license under 10 CFR § 50.22
- Construction Permit Application
  - Currently on track for mid- to late 2015 application submittal
  - Applicant general information
  - ER
  - PSAR
- Operating License Application
  - FSAR
  - Physical security plan
  - Safeguards contingency plan
  - Protection against unauthorized disclosure

CP Application

- General Information under 10 CFR § 50.33
  - Coquí general information, e.g., name, address, corporate structure, § 50.33(a)–(d)
  - License class, § 50.33(e) (will be Class 103)
  - Assurance of financial resources to complete construction and related fuel cycle costs, § 50.33(f)(1); NUREG-1537, Part 1, § 15.1
  - Earliest and latest dates for completion of construction, § 50.33(h)

CP Application

- Miscellaneous documentation
  - Oath or affirmation, 10 CFR § 50.30(b)
  - Fee information, 10 CFR §§ 50.30(e) & 170.21 (full cost)
  - Classified information agreement, 10 CFR § 50.37 (does not appear that MIPF will involve any)
  - Request to withhold confidential trade secrets and commercial and financial information, and supporting affidavit, 10 CFR § 2.390

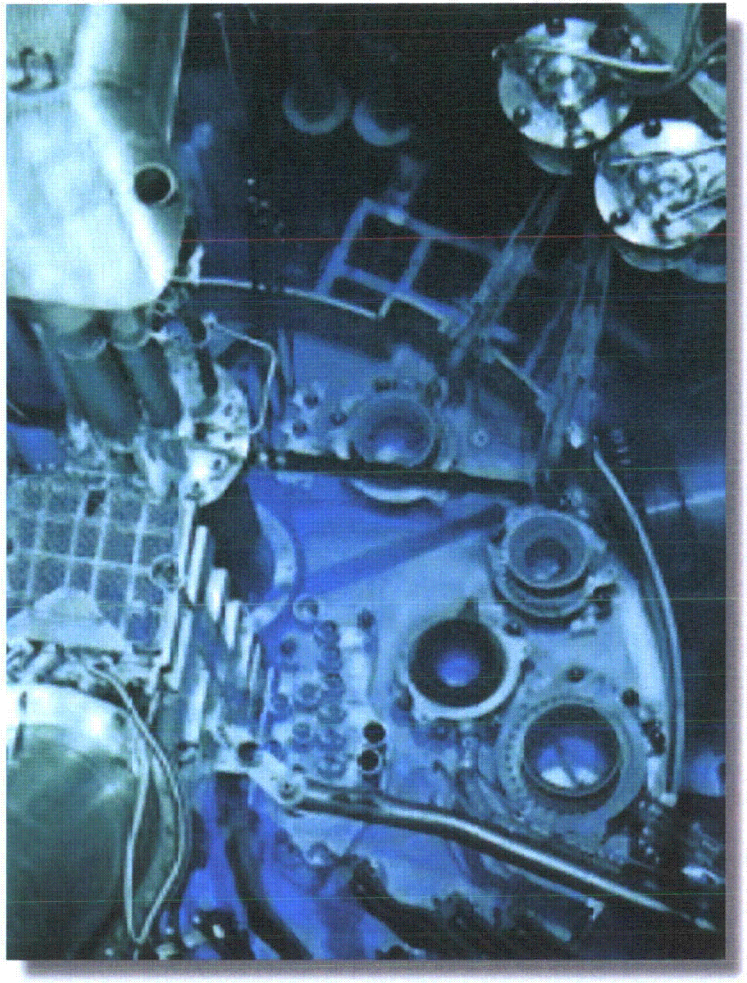
MIPF Facility, Process, & Design Requirements

Technical Presentation Goals

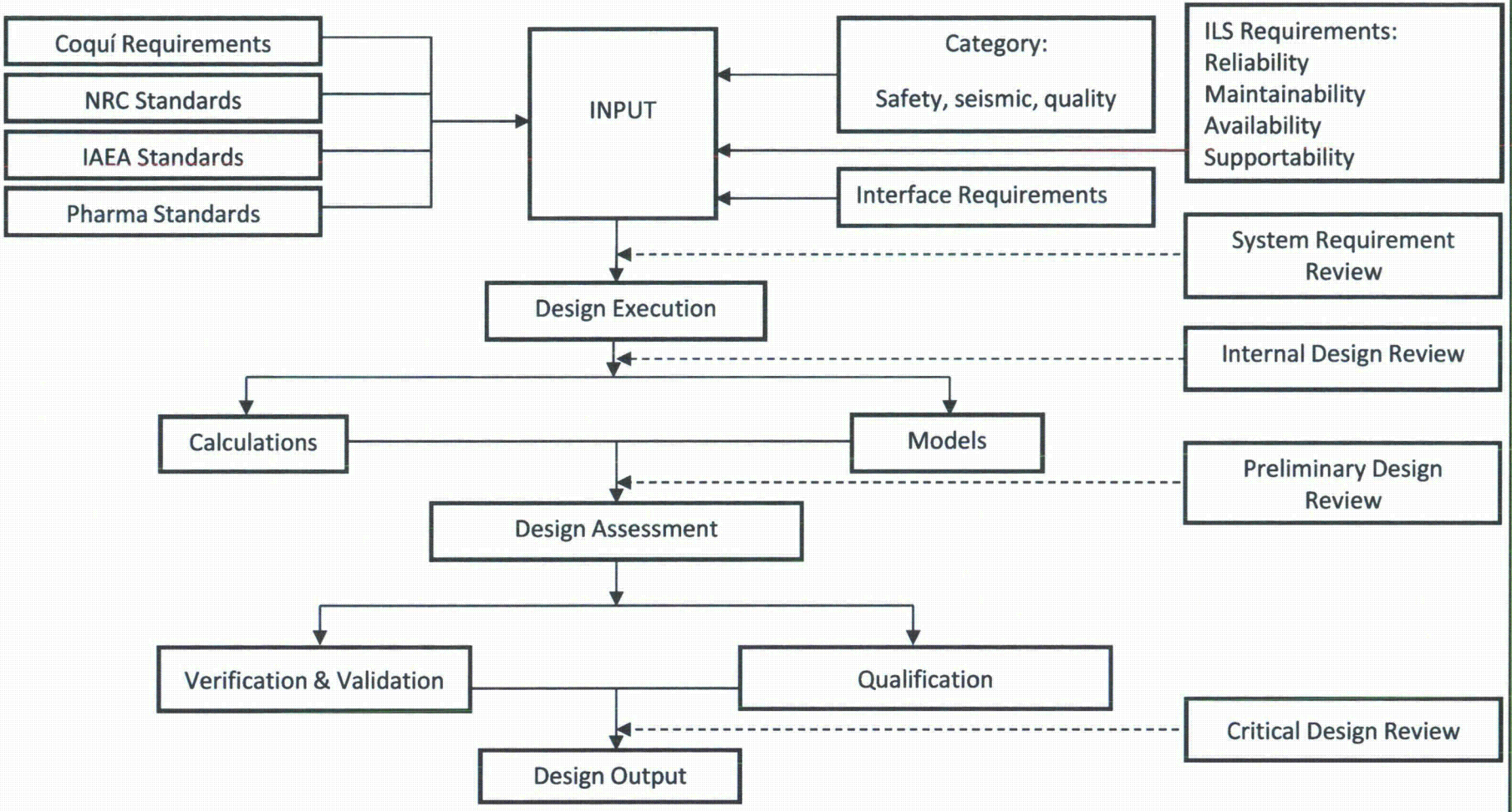
- Demonstrate that Coquí understands NRC requirements and guidance, and is preparing a PSAR that conforms to the NRC's requirements
  - Follow structure of NUREG-1537 (and augmenting ISG) and identify NRC guidance and regulations, and other national and international standards, applicable to each aspect of facility design
- Present positions and ask questions to fill in gaps
- Update the NRC on status of facility design

Facility Description

- Design Objectives:
  - Inherent safety features
  - Passive safety features
  - Defense in Depth approach
  - Safety Systems featuring:
    - Redundancy
    - Diversity
    - Independence
    - Single Failure resistant design



Design Process



Primary Design Criteria

- Design Basis Event:
  - Event caused by a single failure in a system, structure or component
- Design Basis Accident Sequence:
  - Design Basis Event + Single Failure in the most relevant safety system that actuates automatically within 30 minutes

Primary Design Criteria

- Safety Classification:
  - Definition of Safety Functions
  - Identification of Safety Functions that intervene in Design Basis Accident Sequences
  - Safety Function ↔ Defense in Depth Level
  - **Safety Class 1**: SSC with action in DBAS – DID L3
    SSC primary barrier for radioactive material - DID L1
  - **Safety Class 2:** SSC whose single failure causes a DBE – DID L2
  - Other Safety Class 2 SSC: DID L4 systems
  - **Safety Class 3:** No safety function

Primary Design Criteria

Safety Classification: Example

Safety Class	Name	Safety function	DID Level
1	A	To form the primary barrier against the release of fission products from fuel	1
2	B	To store and manipulate new and irradiated fuel	1
1	C	To start protective actions in order to shutdown the reactor, cool and contain radioactive materials, and mitigate accident consequences	3
2	D	To provide Post Accident Monitoring of the reactor in order to: a) Provide information to operators to indicate whether plant safety functions are being accomplished. b) Indicate the successful operation of individual safety systems. c) Alert operators to take safety actions for initiating a system /function that are not automatic. d) Indicate to operators when barriers to fission product release have the potential for being breached. e) Determine the magnitude of release of radioactive materials.	4

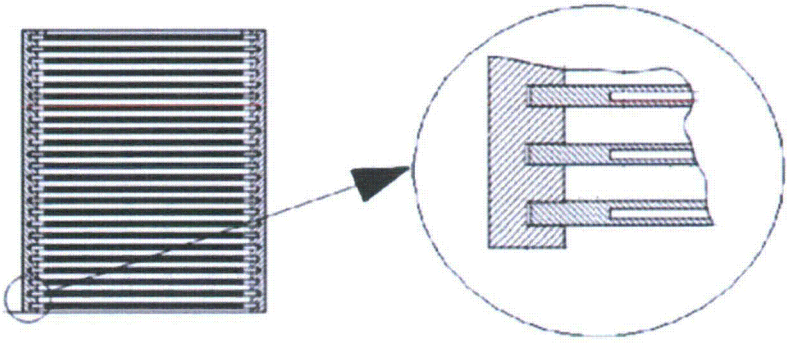
Primary Design Criteria

- Seismic Requirement: maintain safety function following earthquake
- Seismic Classification:
  - Definition of **two** seismic levels, **three** seismic categories
  - Safe Shutdown Earthquake → Seismic Class 1
  - Operating Basis Earthquake → Seismic Class 2
  - Industrial Earthquake → Seismic Class 3
  - All Safety Class 1 Systems belong to Seismic Class 1
  - Some passive structures, e.g. Core Grid, are Safety Class 2 / Seismic Class 1

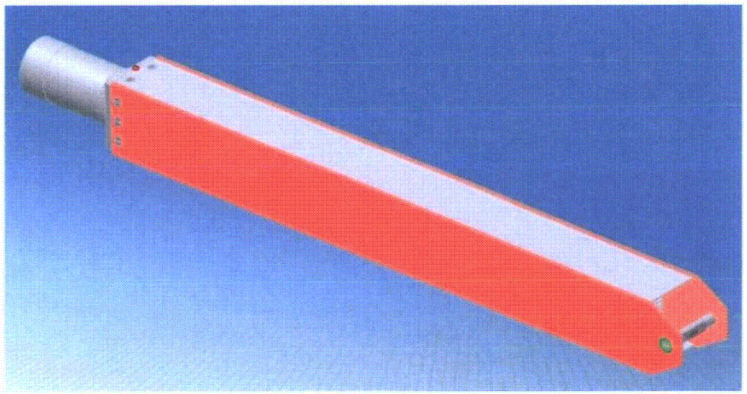
Primary Design Criteria

- Design QA program
  - Previously audited by a U.S. NRC licensee
  - ANSI/ANS 15.8 – NQA 1
  - ENERCON will perform supplier QA audit
- Proprietary design software
  - Developed under INVAP QA program
- Design Codes and Standards
  - U.S. design codes and standards

Fuel Assembly: Preliminary Parameters



MTR - meat U_3Si_2 – Flat Parallel Plates Cladding/Frame: Al 6061
ρ U in meat 4.8 gU/cm^3 LEU 19.8 wt%
U Mass per FA ~2kg



Reactor: Preliminary Parameters

Parameter	Value/description
Power core + Mo-99 targets	~9 MW
Power Mo-99 targets	~3 MW
Fuel Type	MTR
Cooling	Down flow / single loop
Average Fuel Cycle	~30 Full Power Days
Core type	Compact - 6 FA estimated
Core Active Height	~50 cm
Reflector	Beryllium / Others under analysis
Reactor Shutdown System	4 Plates Hf
^{235}U Enrichment for miniplates for Mo-99	< 20% wt
Positions for irradiation of other radioisotopes	10 (Under analysis)
Number of Fuel Assemblies replaced per cycle	1 - 2

Reactor: Preliminary Neutronic Parameters

Parameter	Design Objective
Total Reactor Power (Fuel + Mo-99)	< 10 MW
Shutdown Margin (SDM)	> 3000 pcm for the most reactive core
Shutdown Margin with Single Failure (SDM-1)	> 1000 pcm
End of Cycle Reactivity (Hot w/Xenon)	> 1000 pcm
Reactivity Feedback Coefficients (Coolant T, Fuel T, Coolant Void, Power)	Negative
Core Power Peaking Factor	< 3

Reactor: Preliminary TH Parameters

Parameter	Criterion/Requirement
Flow Redistribution Ratio - RDR	RDR $\geq$ 1.8
Departure from Nucleate Boiling Ratio	DNBR $\geq$ 1.8
Requirement	
Cladding Temperature (operation)	$T_w < 150°C$
Pressure drop in core, Moly and Other Radioisotope Irradiation positions	$\Delta P < 70$ kPa

RPF: Preliminary Parameters

Three levels

- Basement: approx. 1200 m^2 (13,000 ft^2) - gas treatment system, overall waste management system
- Ground: approx. 3600 m^2 (39,000 ft^2) production cells, laboratories, personnel access, material storage
- First floor: approx. 2400 m^2 (26,000 ft^2) ancillary services for production cell, technical and administrative offices

RPF: Preliminary Parameters

Three areas based on handling/storage of radioactive material:

- Conventional: no handling or storage
- Monitored: radioactive material in formats with limited exposure and minimal risk of uptake
- Controlled: maximum protection required because handling involves significant risk of exposure and uptake

RPF: Preliminary Parameters

- A number of production lines to guarantee production and availability
- Flexibility to increase production as needed
- Equipment:
  - Hot cells with enclosure
  - Ventilation system to keep the cells at $P < P_{atm}$
  - Shielded containers to transport the targets, radioactive material, and waste
  - Thermal baths
  - Heat exchangers
  - Hydrogen Recombiner
  - Dissolver
  - Vacuum Pumps
  - Tanks for liquid and gaseous waste collection

Reactor Coolant Systems

- Primary Cooling System:
  - Provide cooling to remove core and targets heat
  - Cope with Loss of Flow Events (redundancy, flywheel)
  - No penetrations to pool below core level
- Secondary Cooling System
  - Closed-Cooling Towers
- Water treatment systems
  - To maintain water conditions
- Long-Term Cooling: No safety function
  - Large pool thermal inertia

Engineered Safety Features

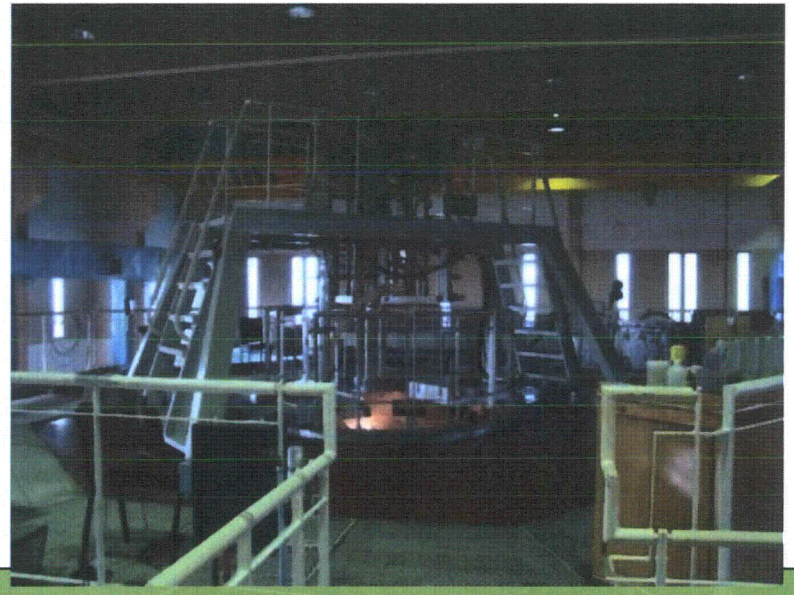
- Final list of ESFs will be derived from the safety assessment
- ESFs: SC1 systems that intervene in accident sequences to ensure that acceptance criteria are met
- Preliminary list:
  - RPS
  - RSS
  - Flap valves
  - PCS piping for natural circulation

Engineered Safety Features

- Design Requirements (examples)
  - Safety Class 1
  - Single-failure tolerant (redundancy, independence, diversity)
  - Fail-safe
  - Reliability
  - Maintainability
  - In-service testing

Engineered Safety Features

- Reactor Shutdown System
  - Absorbent elements shared with Reactivity Control function
  - Reactivity control function cannot interfere with Reactor Shutdown function
  - Fail-safe on loss of offsite power



Instrumentation & Control System

- Reactor Control and Monitoring System:
  - Safety Class 2 system
  - Visualization of reactor status
  - Operation actions: power control (automatic and manual), control rod withdrawal/insertion, ventilation configuration
  - Actions concentrated in Main Control Room

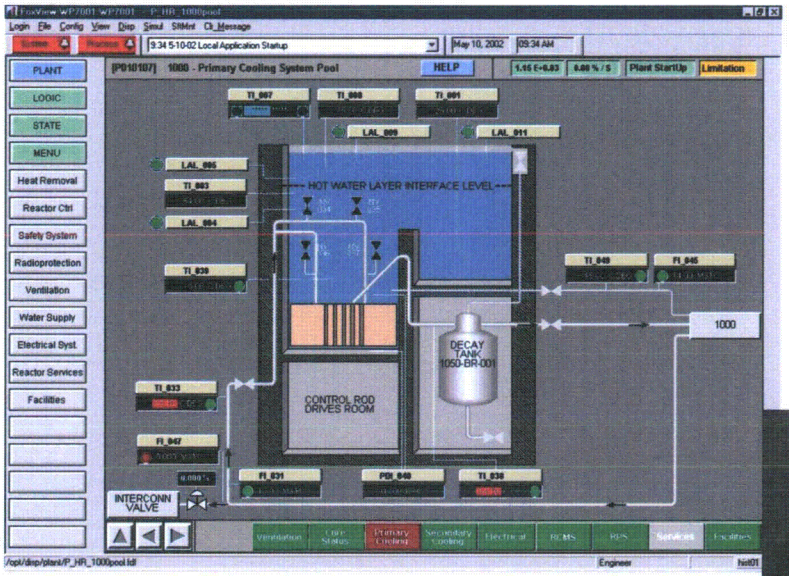
Instrumentation & Control System

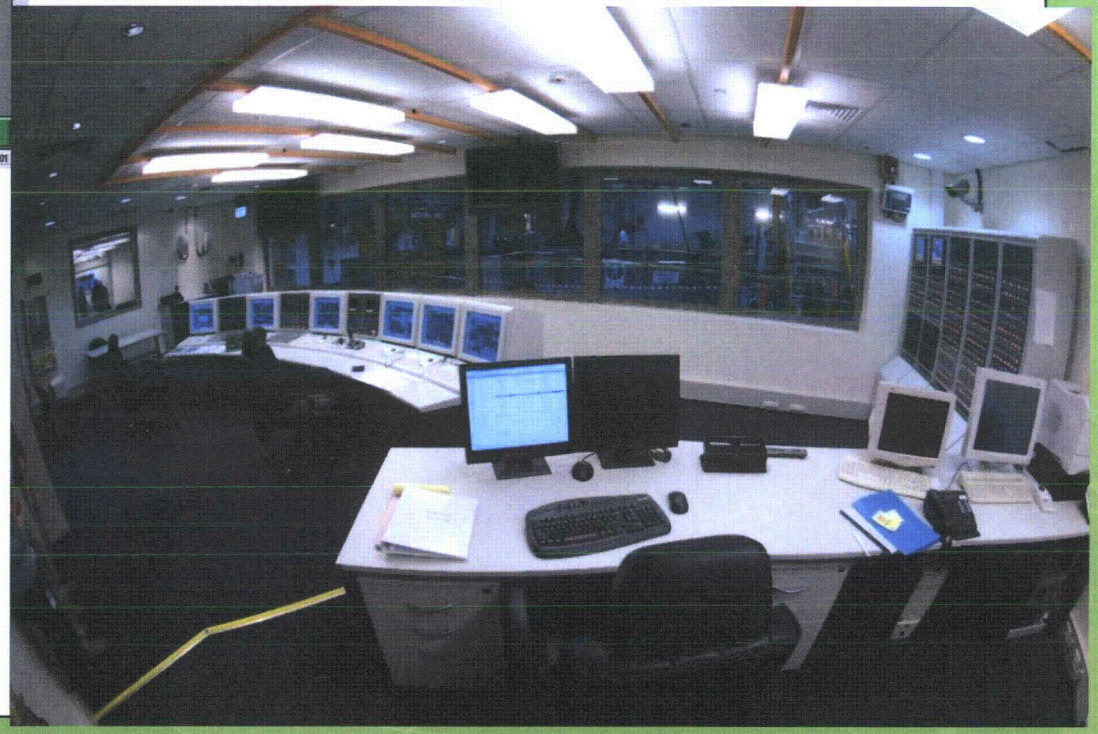
- Reactor Protection System:
  - Safety Class 1 system
  - Protection actions
  - Hardwired, triple redundant, 2oo3 logic
  - Signals based on safety analysis → Coverage matrix
  - Operator cannot interfere with automatic action
  - Signals cannot be bypassed
  - Fail-safe

Instrumentation & Control System

- Facility Control and Monitoring System:
  - Safety Class 2 system
  - Visualization of facility status
  - Operator actions
  - TBD location of control room
- Local actions at the hot cells
- The need for automatic (Safety Class 1) actions at the RPF to be determined by the safety assessment

Instrumentation & Control System





Electrical Power Systems

- Normal
- Emergency

Auxiliary Systems

- Auxiliary systems include:
  - HVAC
  - Compressed air
  - Fire Protection
  - Water control systems
  - Fuel Storage (fresh and irradiated)
- No Safety Class 1 systems

Radiation Protection Program and Waste Management

- Radiation Protection Program
- Waste Management

Waste Conditioning Facility

- Characteristics and waste treatment processes to be determined by requirements from entity that will accept waste for storage
  - Commercial disposal facilities
  - DOE lease and take-back program*
- Temporary storage only
- Frequency of waste transport to be defined
- Minimization of inventory

*The American Medical Isotope Production Act of 2012 requires DOE responsibility for nuclear fuel management and radioactive waste that cannot be accepted in commercial disposal facilities (Type C and Greater Than Type C).

Waste Management

- Radioactive Waste systems, structures and components will be designed and operated to:
  - Minimize waste generation
  - Segregate liquid wastes at the time of collection and processing according to isotopic concentration
  - Minimize radiological releases (i.e. gaseous)
  - Comply with regulatory requirements including NRC, DOE, and waste disposal facility operational requirements
- A Process Control Program will be prepared for operations defining waste practices
- Waste Management practices and approach will be described in the Environmental Report and PSAR consistent with regulatory guidance

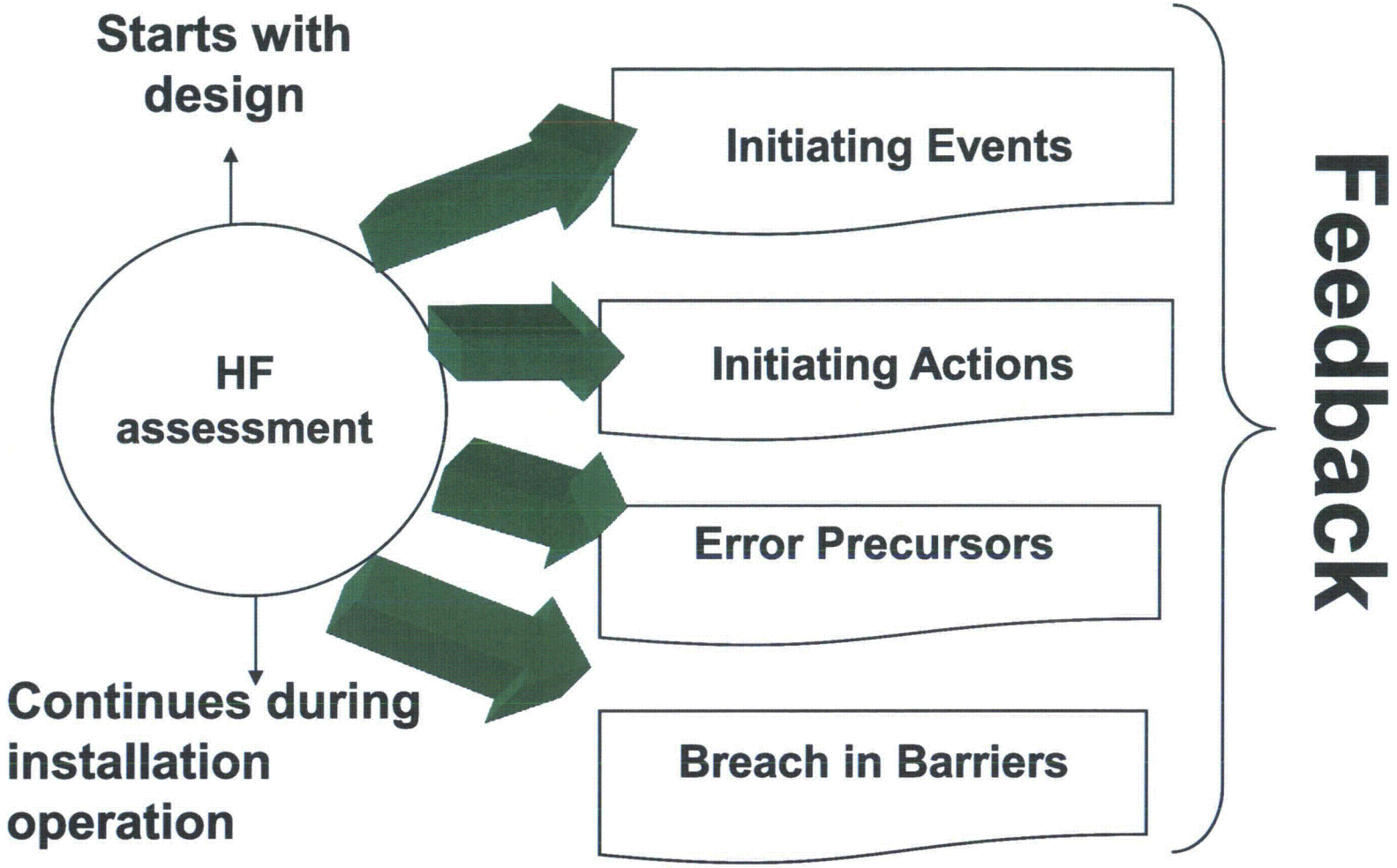
Waste Management

- **Nuclear fuel** will be leased from the DOE and after use returned to the DOE.
  - Temporary onsite storage provisions will be provided to accommodate spent fuel management and DOE pickup practices.
- **Liquid Radioactive Waste** from reactor and moly production facilities will be collected and processed to prepare a waste disposal package that is compliant with 10 CFR Part 61.
- **Solid Radioactive Waste** will be collected, compacted and packaged for disposal compliant with 10 CFR Part 61.
- **Gas Radioactive Waste** predominantly from the moly production facility will be collected in holding tanks to achieve decay prior to release within 10 CFR Part 20.
- **Waste Disposal**
  - Type A&B waste will be disposed in commercial disposal facilities
  - Type C and Greater Than Type C waste will be shipped to DOE for disposal

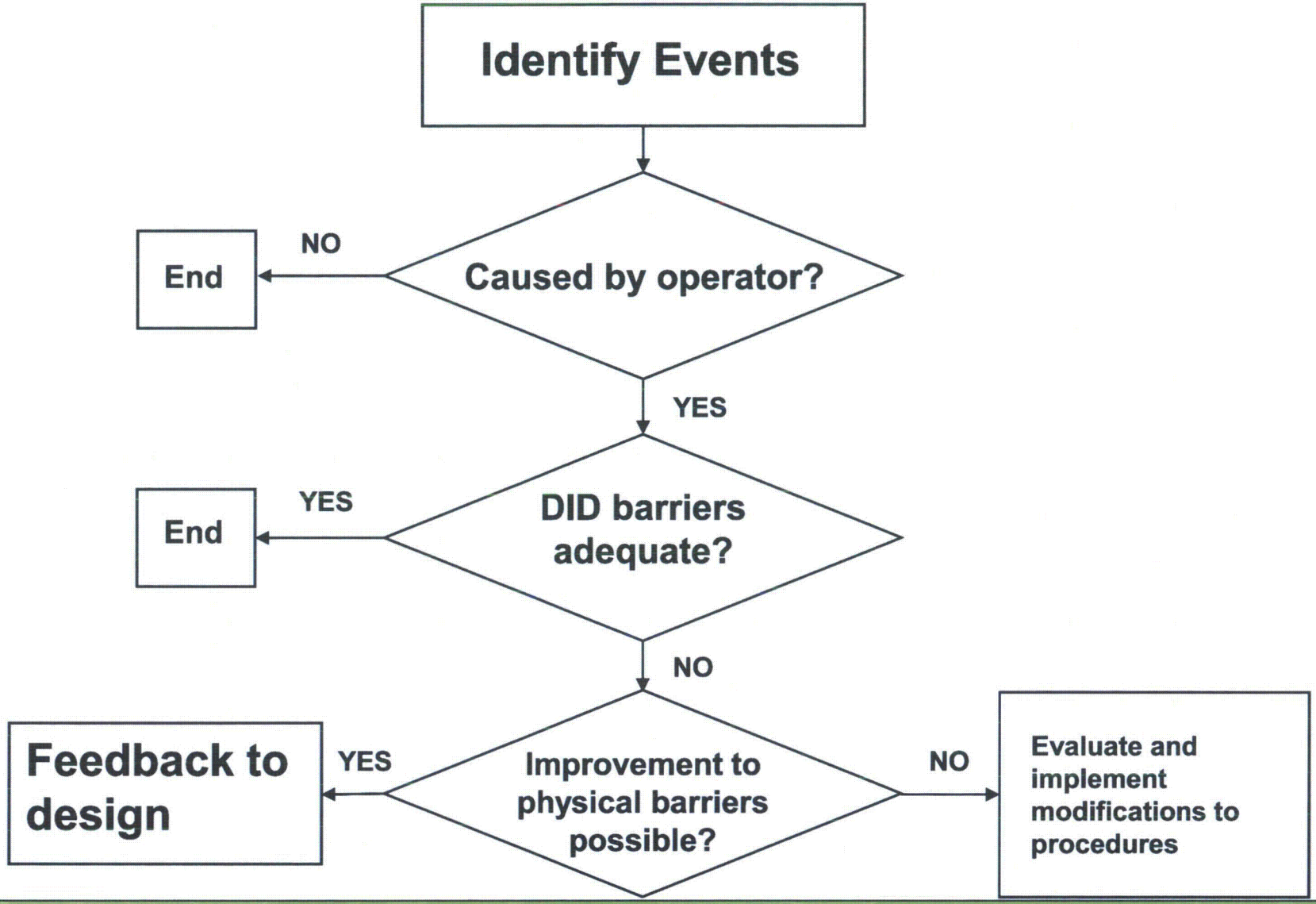
Conduct of Operations: HFE

- At Preliminary Engineering stage: Human Factors Engineering
- INVAP has developed a methodology to integrate HFE in the design process
  - Involves all levels of Defense in Depth
  - Includes identification of latent error causes in design

Conduct of Operations: HFE



Conduct of Operations: HFE



Conduct of Operations: HFE

- Actions with highest potential impact on safety of the facility
  - Operation:
    - Main control room
    - Pool top operations
    - Molybdenum target loading
  - Maintenance:
    - Contributes to latent errors
    - Includes refueling
- Management and mitigation of accidents

Conduct of Operations: HFE

- Design:
  - 30 minutes after initiating events with no action required by operator
  - Procedures design: task analysis
  - Design of tools for pool top operations
  - Hot cell front and telemanipulators
- Operation:
  - Evaluation of information displays (focus groups, checklists)
  - Operation procedures based on previous experience
- Maintenance:
  - Minimize error-forcing context
  - Procedures
  - Determine level of supervision (e.g. for release of equipment for operation)
- Training of operators

Conduct of Operations: HFE

Accident Analyses

- NUREG-1537 + ISG + experience
- Analysis in parallel with design
- Early development of model for analysis to provide feedback to designers
- In initial stage verify for Reactor:
  - Behavior of inherent safety (e.g. feedback coefficients in transients without scram)
  - Actuation time for the RPS/RSS
  - Acceptable delays
- Facility: Integrated Safety Assessment

Accident Analyses: Reactor

- Demonstrate that no DBA leads to release
- Steps:
  - Definition of acceptance criteria
  - Initiating Events
  - Accident Sequence
  - Data collection
  - Development of dynamic model
  - Verification of steady state (initial state for analysis)
  - Analysis of bounding accident sequence in each group
  - Consequence analysis for BDBA

Accident Analyses: Facility

- Demonstrate that there are no events with failure of single barrier that leads to release
- Steps:
  - Definition of acceptance criteria
  - Initiating Events (radiological and chemical consequences)
  - Accident Sequence
  - Data collection
  - Barrier integrity analysis
  - Consequence analysis

Accident Analyses: External Events

- Determined by site characteristics
- Will include all events identified for site
- Possible combination of events (e.g. effects of high winds + missiles on building and other structures)
- Will involve analysis of simultaneous effect on facilities on site

Accident Analyses: Reactor + RPF

- Acceptance Criteria
  - Design Basis Accident Sequences → No damage to core or irradiation targets
  - No release of radioactive material or hazardous chemicals from the hot cell
  - Beyond Design Basis Accident Sequences → Dose-based acceptance criteria (10 CFR Part 20)

Questions?

Environmental Update

Environmental Presentation Goal

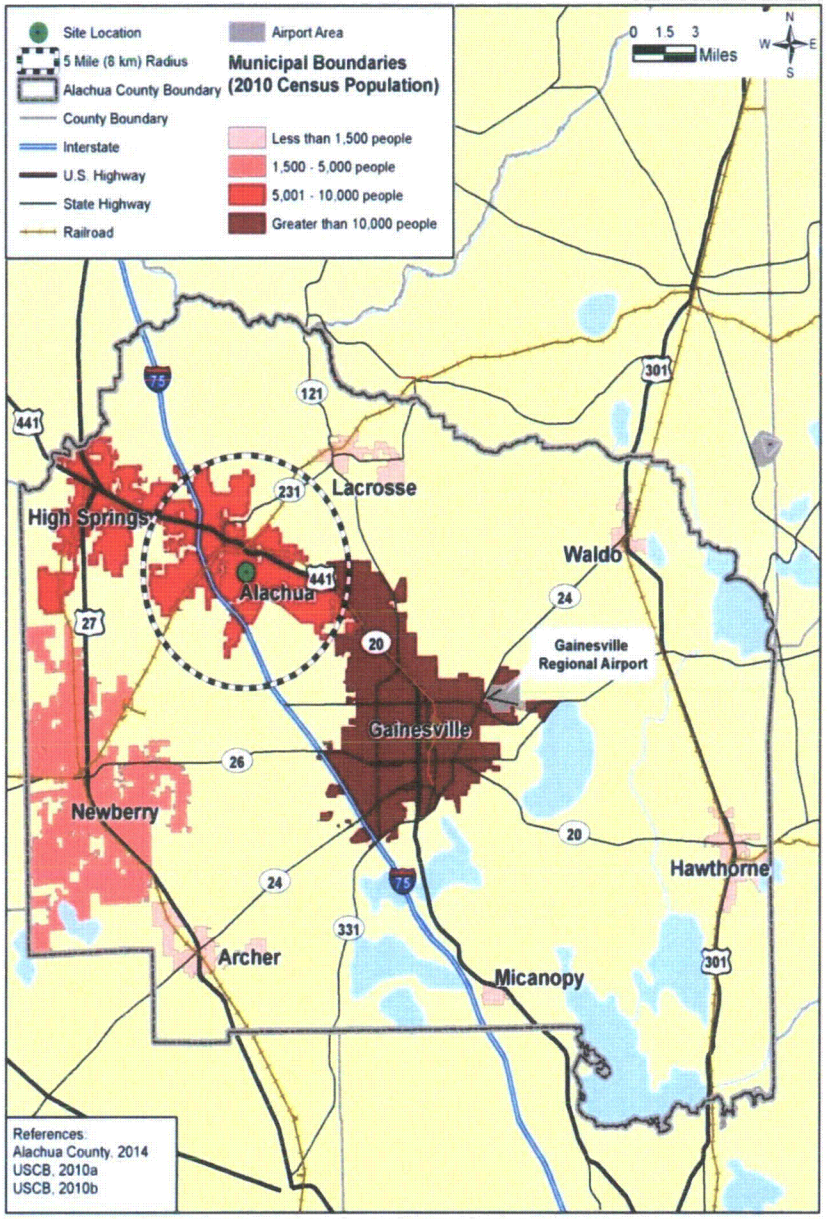
- Provide NRC with an update of environmental work and Environmental Report preparations

Environmental Report

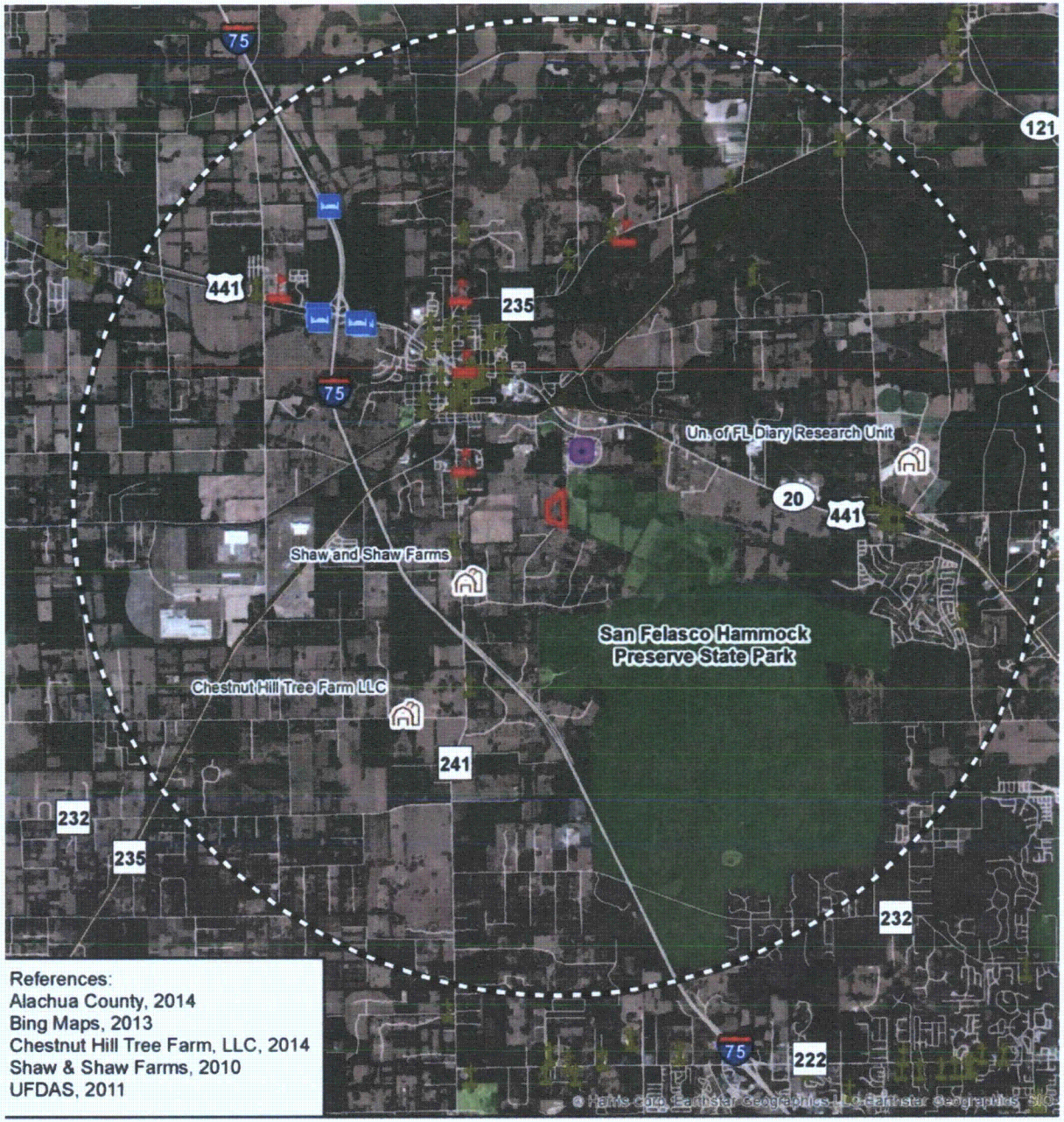
- 10 CFR § 50.33(f) requires an ER in compliance with 10 CFR Part 51
  - Will follow NUREG-1537 and the ISG Augmenting NUREG-1537

Site Location

- Site located in City of Alachua, Florida
- Nearest population center is Gainesville, FL 10 miles SE



Site Location



References:
Alachua County, 2014
Bing Maps, 2013
Chestnut Hill Tree Farm, LLC, 2014
Shaw & Shaw Farms, 2010
UFDAS, 2011

Site Location

Land Use and Visual Resources

- Analysis of existing viewshed has been completed.
- Based upon final exterior building design and site layout, impacts to the viewshed from adjacent properties will be considered

View of COQUI site looking east

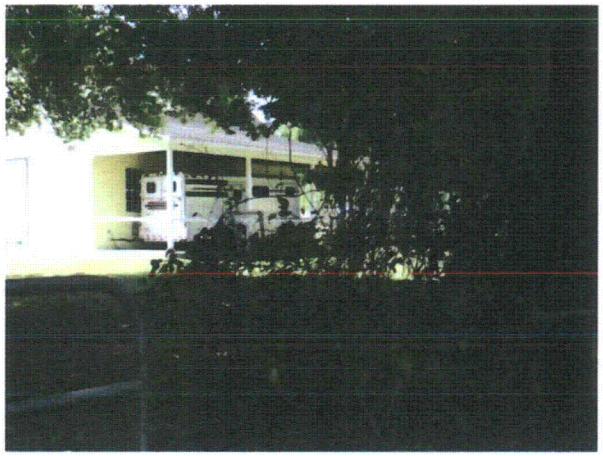
View of COQUI site looking southeast

View of COQUI site looking south

View of COQUI site looking southwest

Affected Environment

View of farm to southwest of the site



View of farm to southwest of site

View of home to the south of site

View of home to the south of the site

Air Quality & Noise

- Regional meteorological data has been collected and analyzed
- Collection of site-specific data is planned
- Site-specific equipment, air emission, and noise sources are being finalized as part of the design process

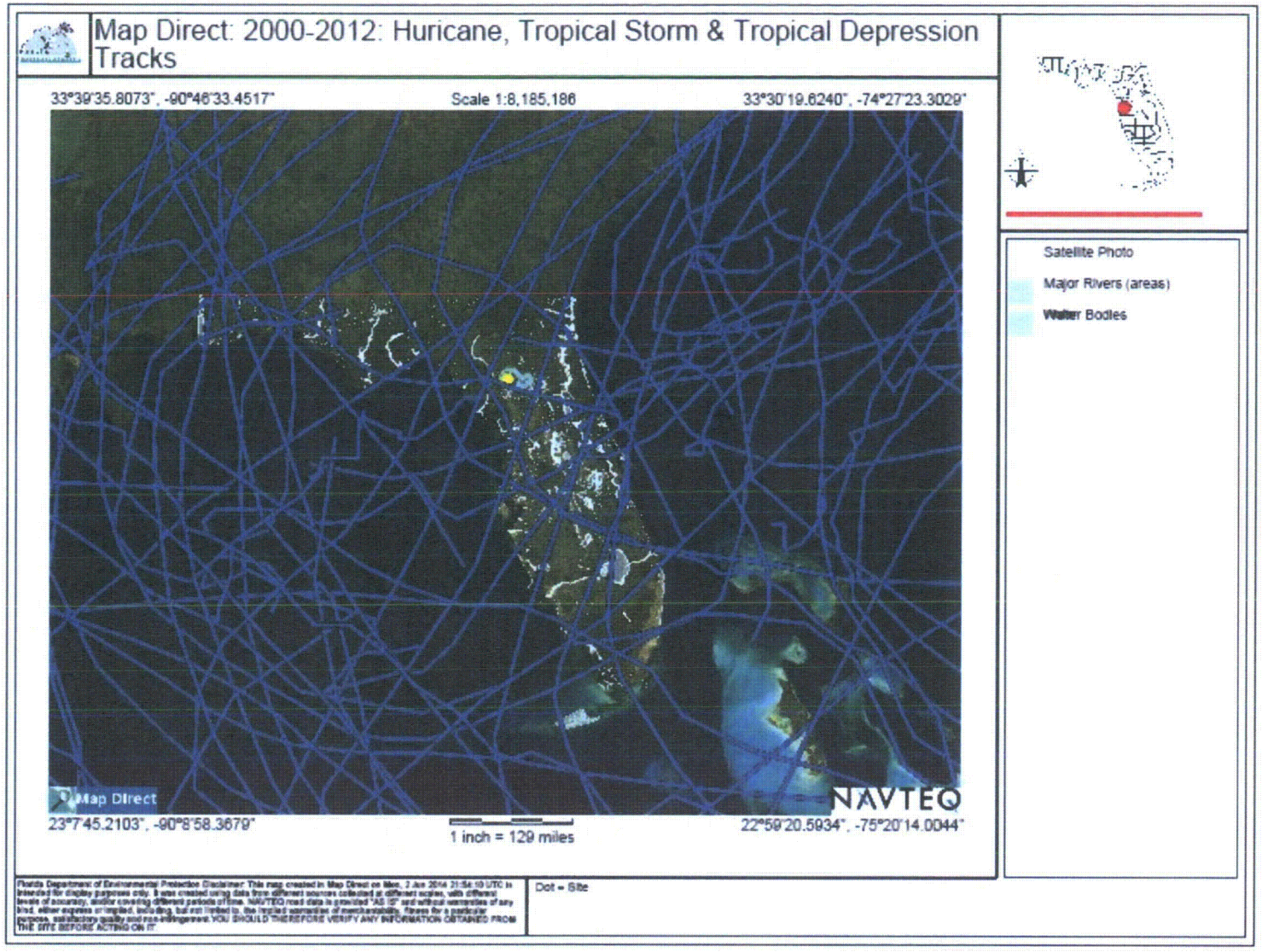
Air Quality

- Nearest nonattainment areas to site are:
  - Hillsborough County , Florida (120 miles south) for lead and SO_2
  - Nassau County, Florida (85 miles northeast) for SO_2
- Not subject to Haze Rule as >100 km (62 miles) from a Class I area
- Nearest Class I Areas to site is Okefenokee National Wildlife Refuge, GA, 105 km (65 miles) north

Severe Weather

- Thirteen hurricanes since 1950 that either made landfall on Florida or brought winds of Category 3 or above (sustained winds >111 mph)
- Frequency of summer thunderstorm activity in Central FL is high
- Design is addressing hurricane missile, tornado protection, lightning and flooding

Affected Environment

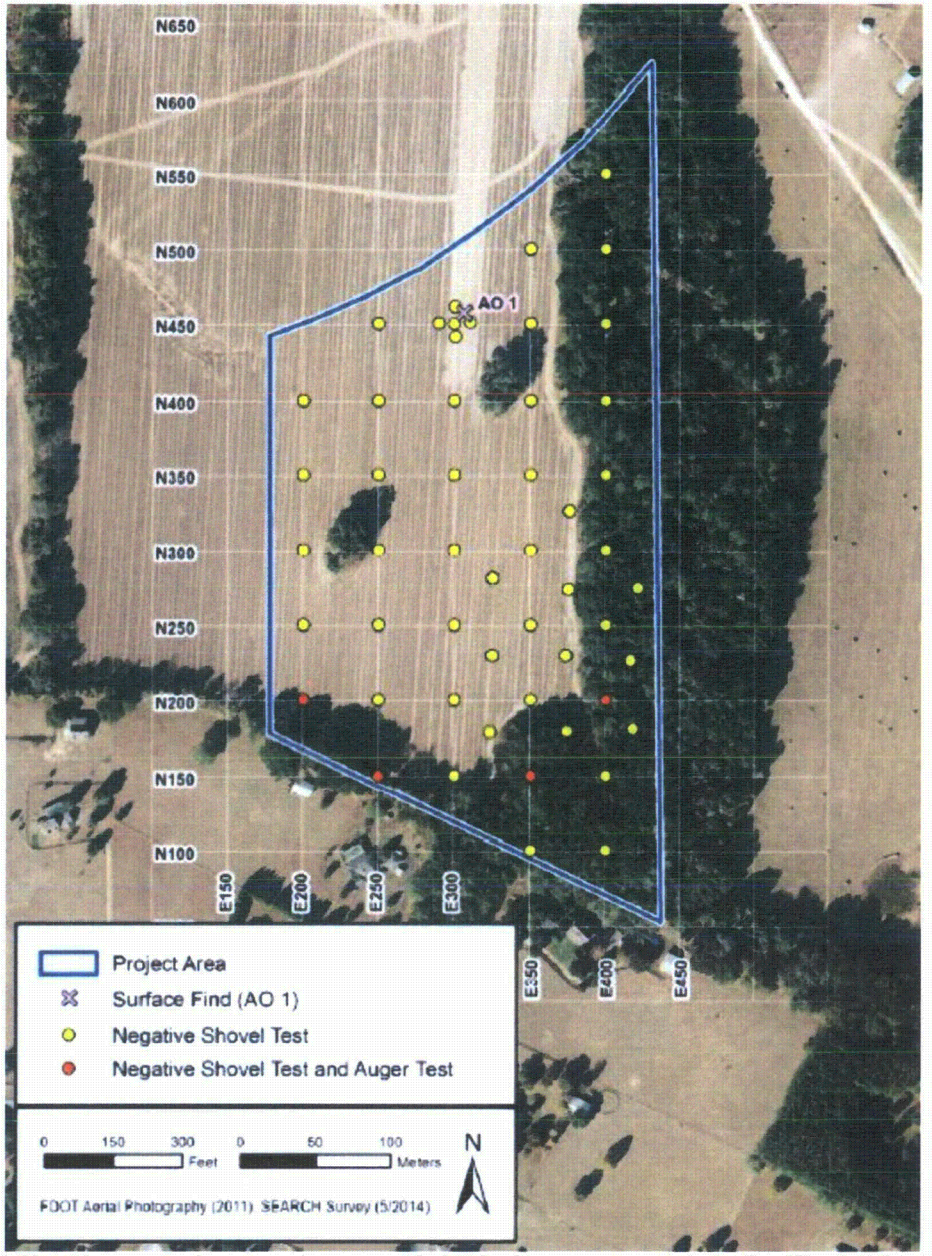


Water Resources

- No surface water on-site
- City of Alachua's available water capacity exceeds facility water needs
- 5 groundwater monitoring wells were installed and are being monitored for potentiometric changes
- Regional groundwater flow paths through primary conduits in limestone bedrock may yield groundwater velocities up to approximately 2,300 feet per day

Historic &Cultural Resources

- On-site archeological survey consisted of 52 shovel tests and surface inspection
- Single lithic waste flake observed on surface of fallow ground
- Survey results indicated that no eligible or potentially eligible resources will be affected

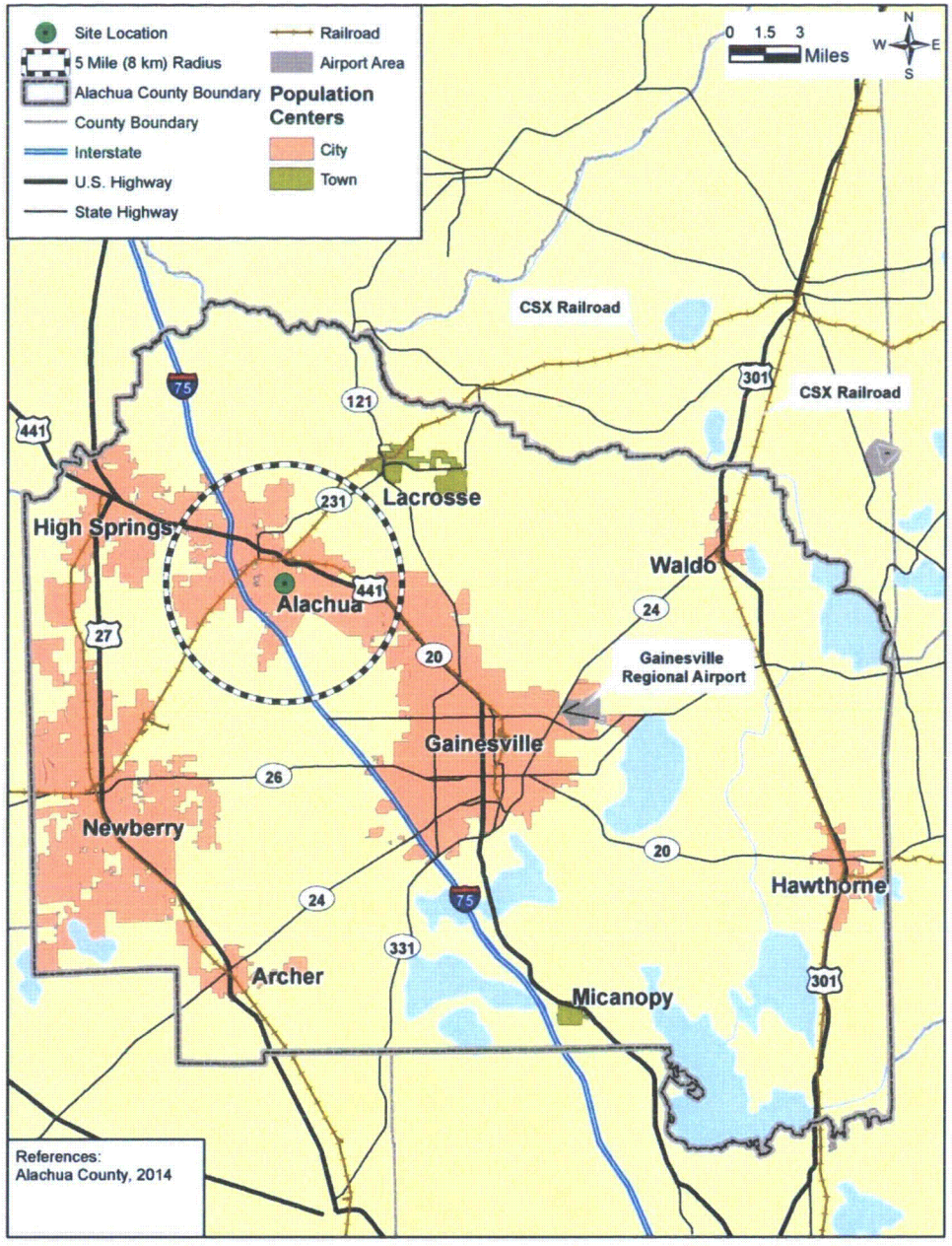


Historic & Cultural Resources

- Outreach to 4 Native American Tribes was conducted
  - One response received
- Cultural resource assessment survey performed and submitted to SHPO

Socioeconomic

- Data has been compiled on:
  - Population and demographics
  - Labor
  - Housing
  - Public water systems
  - Local school systems
  - Local road networks

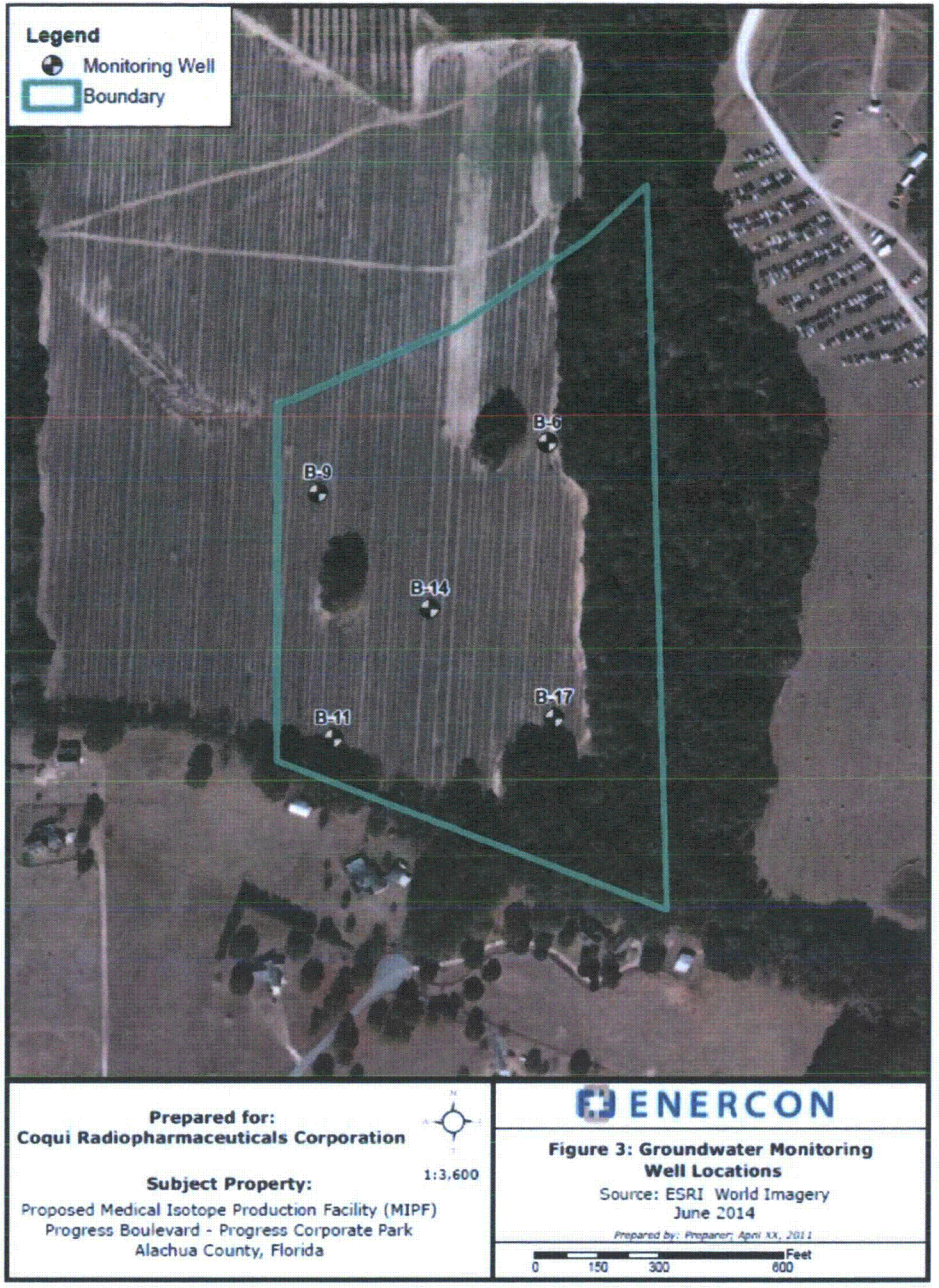


Human Health

- On-site background radiation samples
  - Soil: 20
  - Air: 2

Human Health

- On-site background radiation samples
  - Groundwater: 5



Environmental Justice

- Resources:
  - Council on Environmental Quality's *Environmental Justice Guidance under the National Environmental Policy Act;*
  - NRC *Policy Statement on the Treatment of Environmental Justice Matters in NRC Licensing Actions;* and,
  - NRC Office Instruction No. LIC 203, Revision 2, *Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues*
- Have analyzed local area for potential impact on minority and low-income communities

Questions?

Closing

Coquí looks forward to continue working with the NRC on this important project.

Contact:
Carmen Irene Bigles Raldiris
President & CEO
Coquí RadioPharmaceuticals Corp.

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