



NEA International Workshop on Medical Radioisotopes: Production and Supply Chain Disruptions of the COVID-19 Pandemic

Presented by: Mr. Thabo Tselane
Group MD for NTP Radioisotopes SOC Ltd.

AGENDA

-  Introduction to NTP
-  NTP Operations Overview 2009 – 2023
-  Impact of COVID-19 on the Mo-99 Market
-  I-131 Market Situation
-  Future Isotope Supply
-  MPR Project overview
-  Summary of Challenges & Opportunities

Introduction to NTP

Our Vision: *To be a global leader in the supply of nuclear related products and services*

Necsa SOC Ltd

State-owned company responsible for undertaking and promoting R&D in the field of nuclear energy and radiation sciences

necsa
We're in your world



NTP Radioisotopes SOC Ltd

NTP Radioisotopes SOC Ltd is an integrated manufacturer and global supplier of radiochemical, radiopharmaceutical, and irradiation products & services, with a footprint in over 50 countries worldwide

1

NTP Supplies over 20% of global Mo-99 demand

2

NTP was the first large scale LEU Mo-99 supplier

3

Annually over 8 million procedures worldwide are performed using NTP manufactured products

4

NTP's Export sales account for approximately 90% of revenue



1965

First self-sustaining chain reaction at SAFARI-1



1973

Small quantities of medical radioisotopes I-131 and Mo-99 produced at SAFARI-1



1989

Peltek-F Tc-99m generator developed at Pelindaba



1991

South Africa signs the nuclear Non-Proliferation Treaty (NPT). First in the world



2003

NTP Radioisotopes Ltd registered as a wholly owned subsidiary of the South African Nuclear Energy Corporation (Necsa)



2005

NTP pioneers the use of cyclotron-based FDG F-18 in South Africa, which is used for cancer diagnosis



2007

NovaTec-P Tc-99m generator replaces the Peltek-F



2009

Conversion of SAFARI-1 reactor core from highly enriched uranium (HEU) to low-enriched uranium (LEU) fuel



2010

First large-scale commercial FDA-approved batch of LEU Mo-99 produced by NTP and shipped to USA for patient use



2012

NTP pioneers the labelling of beta-emitter lutetium-177 (Lu-177) in South Africa



2015

The first medical procedure using Lu-177 nca PSMA was successfully conducted in South Africa, facilitated by NTP

NTP as a Global Player



A leading **Global Player** in the radiation technology business, with market footprints covering **50 countries**

Worldwide
impact



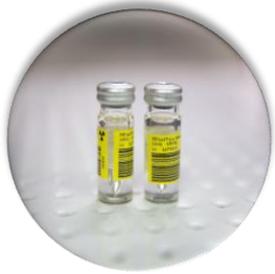
NTP Product Portfolio

NTP produce several diagnostic, therapeutic and irradiation products in our facilities at Pelindaba which are supplied globally



Radiochemicals (Active Pharmaceutical ingredients)

- Molybdenum-99
- Iodine-131
- Lutetium-177



Therapeutic Radiopharmaceuticals

- Iodine-131 Capsules, for thyroid cancer and metastatic disease
- Lutetium-177, indicated for prostate cancer and neuroendocrine cancer



Radioactive Sealed Sources & Irradiation Services

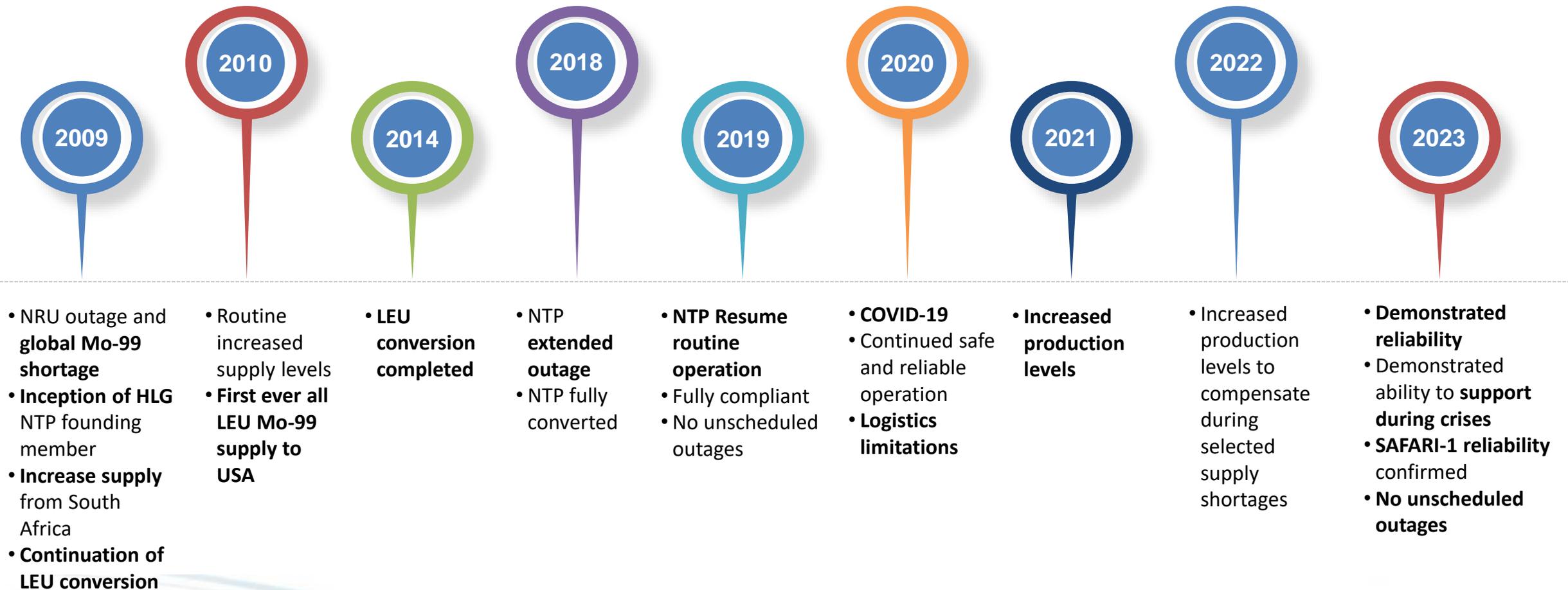
- Selenium-75, Cobalt-60
- Iridium-192, Cesium-137
- Silicon Doping



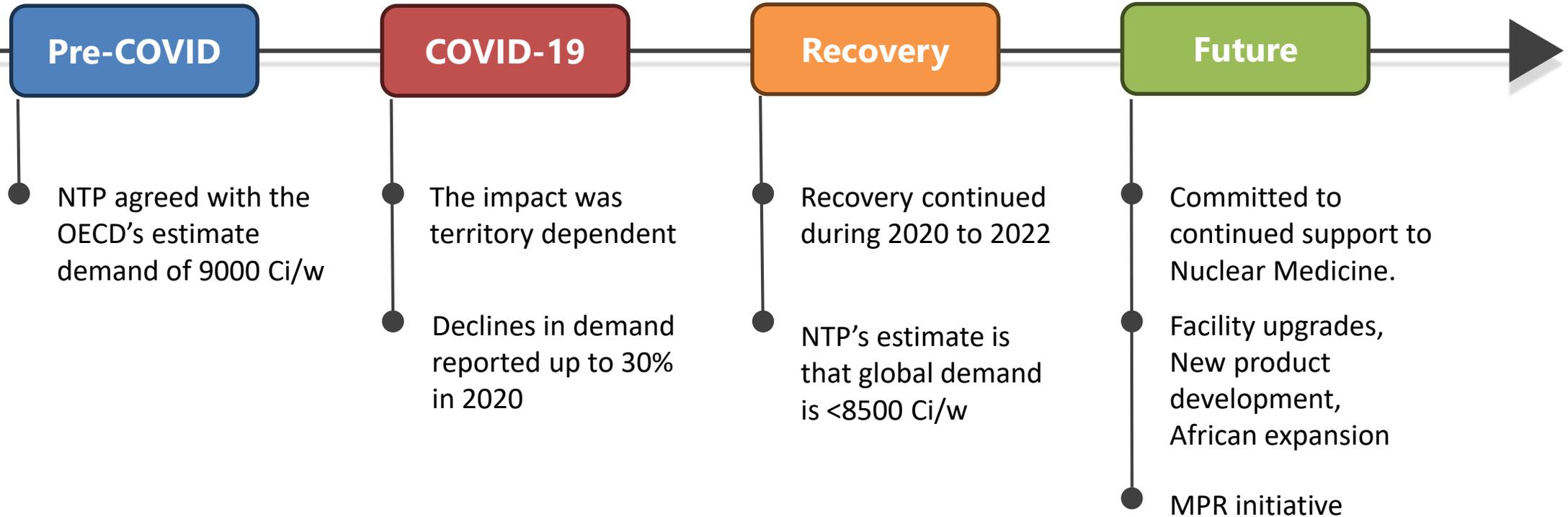
Diagnostic Radiopharmaceuticals

- NovaTec-P® Technetium-99 Generator
- Labelling Cold kits (Registered):
 - MDP, for bone metastasis imaging
 - RBC, for red blood cell imaging
 - DTPA, for kidney imaging
 - DISIDA, for liver function imaging
 - Tin Colloid, for hepatobiliary system imaging
- Gluscan® (F18 FDG), for diagnosis and staging of cancers
- F18-PSMA, for diagnosis and staging of prostate cancer
- Iodine-131 capsules®, for diagnosis of thyroid cancer and hyperthyroidism

NTP Operations Overview 2009 – 2023



Impact of COVID-19 on the Mo-99 Outlook



I-131 Market Situation



Future Isotope Supply

Reactor produced isotopes

- **Re-188:** Beta radiation emitting radioisotope produced from W-186
- **Pt-195:** Gamma and auger radiation emitting radioisotope produced from Pt-194 targets.
- **Tb-161:** Beta and auger radiation emitting radioisotope produced from Gd-160 targets

Cyclotron produced isotopes

- **Cu-64:** Beta radiation emitting radioisotope produced from Ni-64 targets.
- **Cu-67:** Beta⁻ radiation emitting radioisotopes produced from Zn-68 targets.

Future Isotope Supply

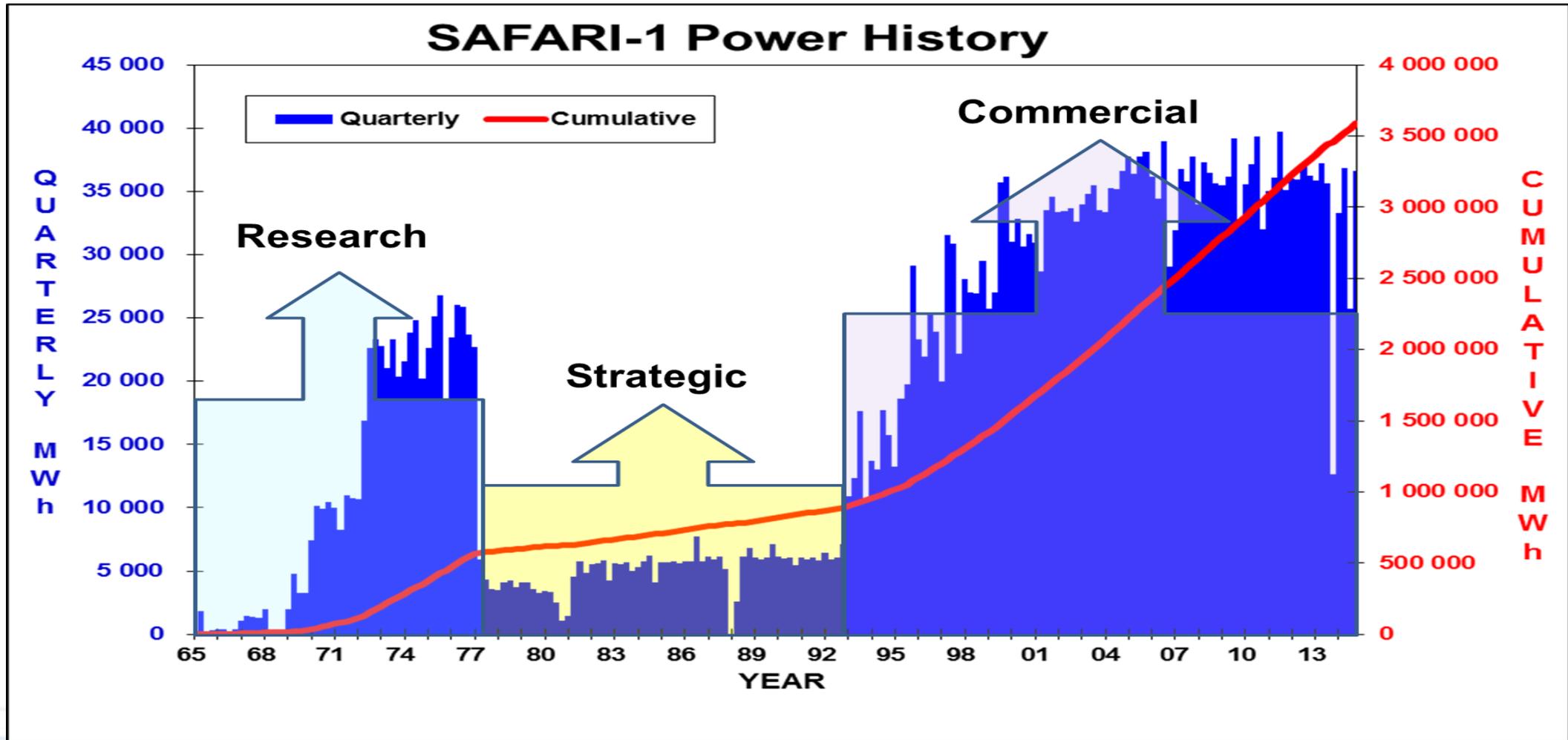
LINAC produced isotopes

- **Mo-99/Tc-99:** Gamma radiation emitting radioisotope produced from Mo-100
- **Ac-225:** Alpha radiation emitting radioisotope produced from Ra-226

Generator based isotopes

- **Mo-99/Tc-99** generator.
- **W-188/Re-188** generator.

Availability and Reliability of SAFARI-1 and Security of Supply for Commercial Isotopes



MPR Project Business Case

The benefit identified with the construction of a MPR includes the following additional facilities



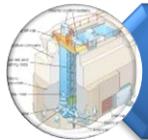
Isotope Production



Fuel Elements, Control Rods and Target plate Fabrication



Cold Neutron Source and Neutron Beamline Centre



Fuel and Material testing



On-site Accommodation

Development of the business case to assess *income opportunities*, *benefits* and *cost analysis* for respective facilities and associated utilizations.

Business case approach:

- Extension of current capacity (Utilisation)
- Benefits
- Estimated cost
- Source of income
- Cost benefit analysis
- Funding model

Project Status

The project is governed by the Framework for Infrastructure Development and Procurement Management (FIDPM) – currently on the concept stage

PROGRESS MADE TO DATE

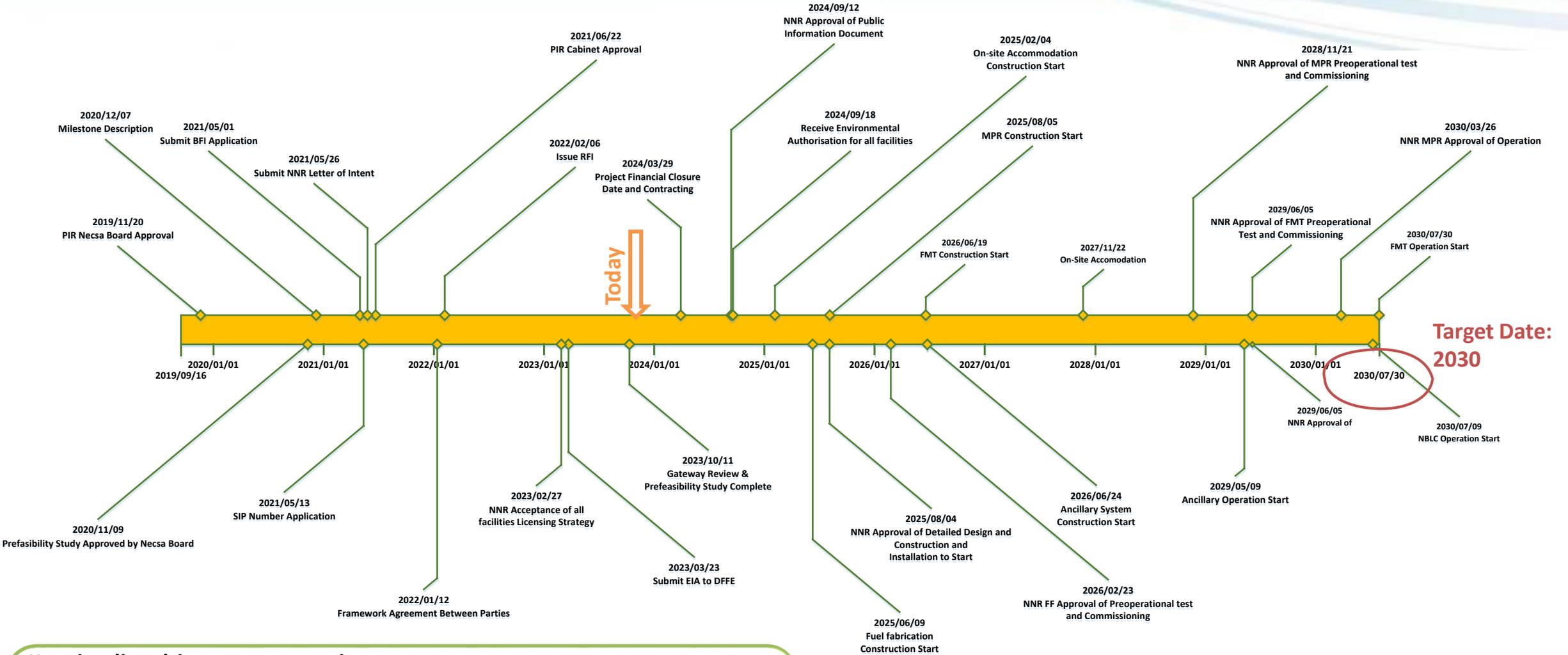
- The project has been registered as a large infrastructure project with SA National Treasury.
- Early Business Case approved by Infrastructure South Africa for Strategic Infrastructure Project (SIP) Registration
- Updated MPR User Requirements Specification based on the market information from RFI
- RFI received from the market
- RFI assessment completed
- First draft of the Feasibility report completed
- First draft of the Procurement Strategy and Plan developed
- Environment Impact Assessment underway
- Siting and licensing activities are on-going
- Complete the Gateway Review of the Feasibility Study Report
- Complete all major Partnerships Agreements
- Prepare a Design Development Plan
- Overarching Licensing Strategy pending approval by the NNR
- Submit the Intermediate Business Case(IBC) to Infrastructure South Africa (ISA)

Completed

In-progress

FIDPM	
Project Processes	
Stage	Control Stage Deliverable
1. Initiation	Initiation Report/ Prefeasibility Report
2. Concept	Concept Report / Feasibility Report
3. Design Development	Design Development Report
4. Design Documentation	Design Documentation
5. Works	Completed Works capable of being used or occupied
6. Handover	Works which have been taken over by user or owner
7. Close-Out	Final Completion; Final Account

Key Milestone Timeline



Key timeline driver to construction:

- Regulatory requirements: approval of **Licensing Strategy** and **Siting Safety Assessment Report**.
- Securing of all necessary **funding** and financing agreements.
- Register the project as a **strategic infrastructure** - benefit on reduced timelines of key activities and funding prioritisation.

Challenges and Opportunities

In order to facilitate both the exchange of experience and the ease of cooperation, it is critical to appreciate the challenges as well as the areas of complementary capabilities.

Regulatory

Harmonization of normative regulation required to simplify multi-country access and registration of products.



Shared Vision and Goals

Developing of a shared vision and corresponding goals and objectives across HLG countries to improve the quality of life of patients required.

Production & Logistics

To ensure sustainable supply of NM products, the procurement processes in each country, free-trade agreements as well as optimization of logistical routes are required.



Business

Improvement in the facilitation of collaboration in terms of financial restriction required to ease the flow of business between countries.

Future Focus for NTP Radioisotopes

- ✓ **Safe and Reliable Operations:** Ensuring the highest safety and reliability standards in our operations.
- ✓ **Global Market Leadership:** Sustaining our demonstrated leadership position in the global market.
- ✓ **Lu-177 Market Opportunity:** Capitalizing on the growing Lu-177 market.
- ✓ **Product Portfolio Expansion:** Expanding our product offerings to meet evolving market demands.
- ✓ **Supporting South African Nuclear Medicine Industry:** Offering strong support to our local industry.
- ✓ **Business Growth in Africa:** Developing and expanding NTP's presence and impact in Africa.
- ✓ **Radiopharmaceutical Exports:** Leveraging our expertise for international radiopharmaceutical

exports

Conclusion

South Africa is proud to play a leading role in the global nuclear medicine industry through its scientific medicine participation, reactor operations and radioisotope production. We commit to assume this responsibility and will support nuclear medicine globally with safe, reliable and sustainable radioisotope production.

