



Centralized Radiopharmacy in Brazil: present scenery and challenges

XII ENAN - INAC
2015/ October

Centralized Radiopharmacy

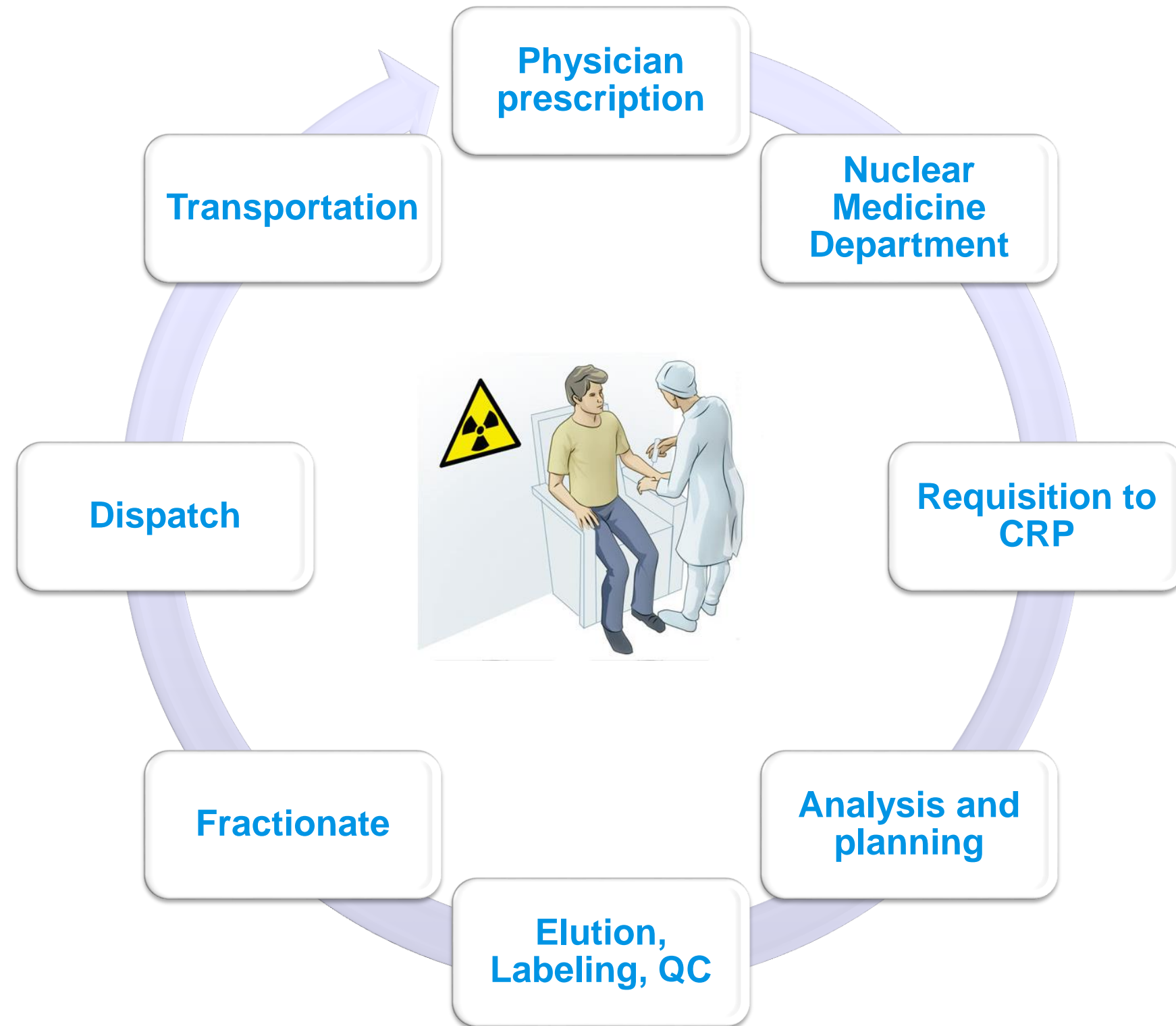
CONCEPT

Radiopharmacy with highly specialized manipulation and distribution processes

KEY FEATURES

- ✓ Precise dose based on a physician prescription
- ✓ Distribution of ready to use radiopharmaceuticals
- ✓ Radiopharmaceuticals available in unit dose form
- ✓ Shared by many nuclear medicine departments
- ✓ Transportation logistics
- ✓ High scale gain

Centralized Radiopharmacy - CRP



Centralized Radiopharmacy – Process

The process begins one day before the dose delivery – Planning



- 2 Manipulators
- 1 Dose/Minute
- 110 min.
- 3 Manipulation Batteries
- 660 Doses/Day



1 Laboratory preparation; Elution of the generators

10 min

2 Labeling and incubation: **(Higher margins and added value)**

20 min

3 QC: Simultaneous to fractioning

25 min

4 Fractioning: **(Avoiding waste of raw material)**

110 min

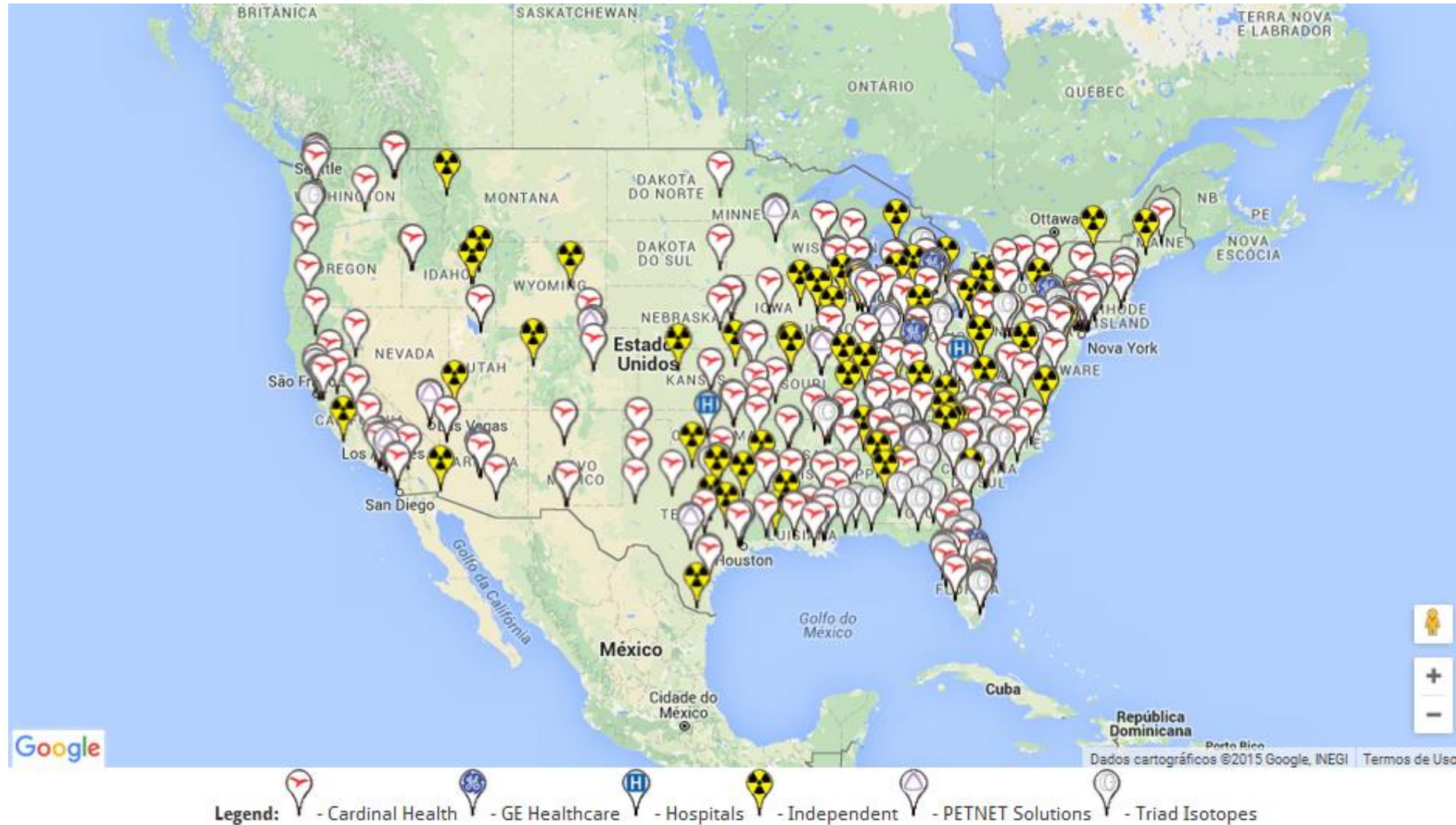
5 Shipping bag assembly

20 min

6 Transportation: **(More efficient logistics)**

60- 90 min

Centralized Radiopharmacy – International Scenery - USA



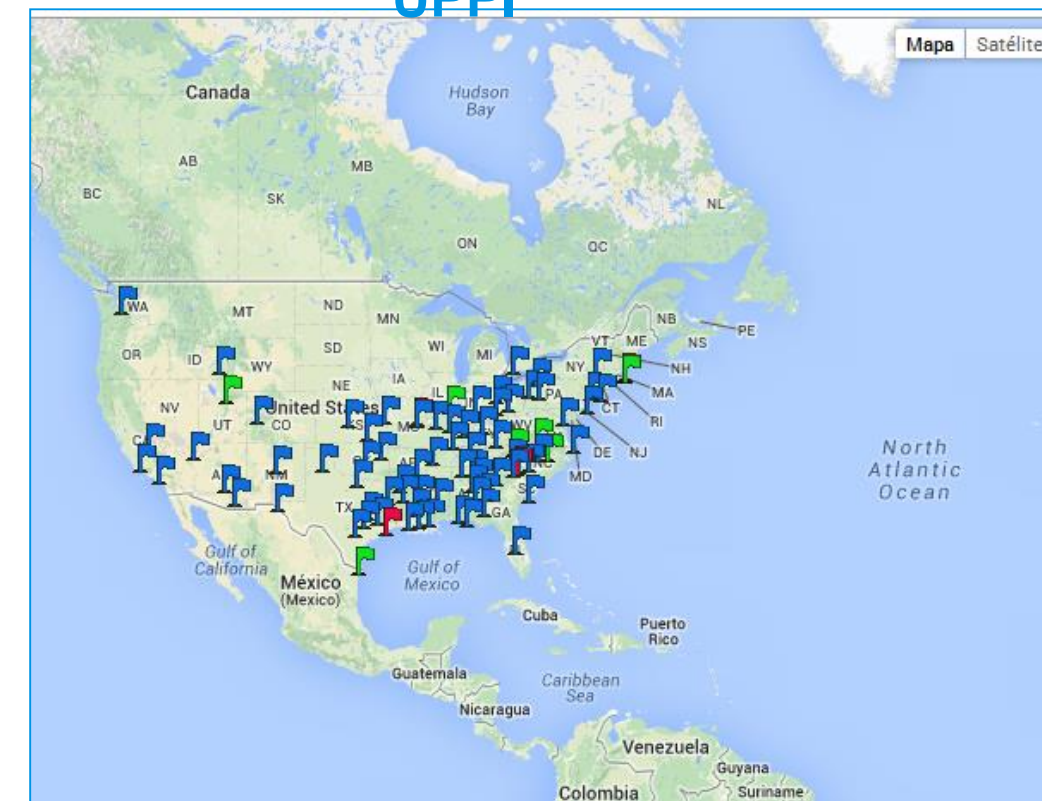
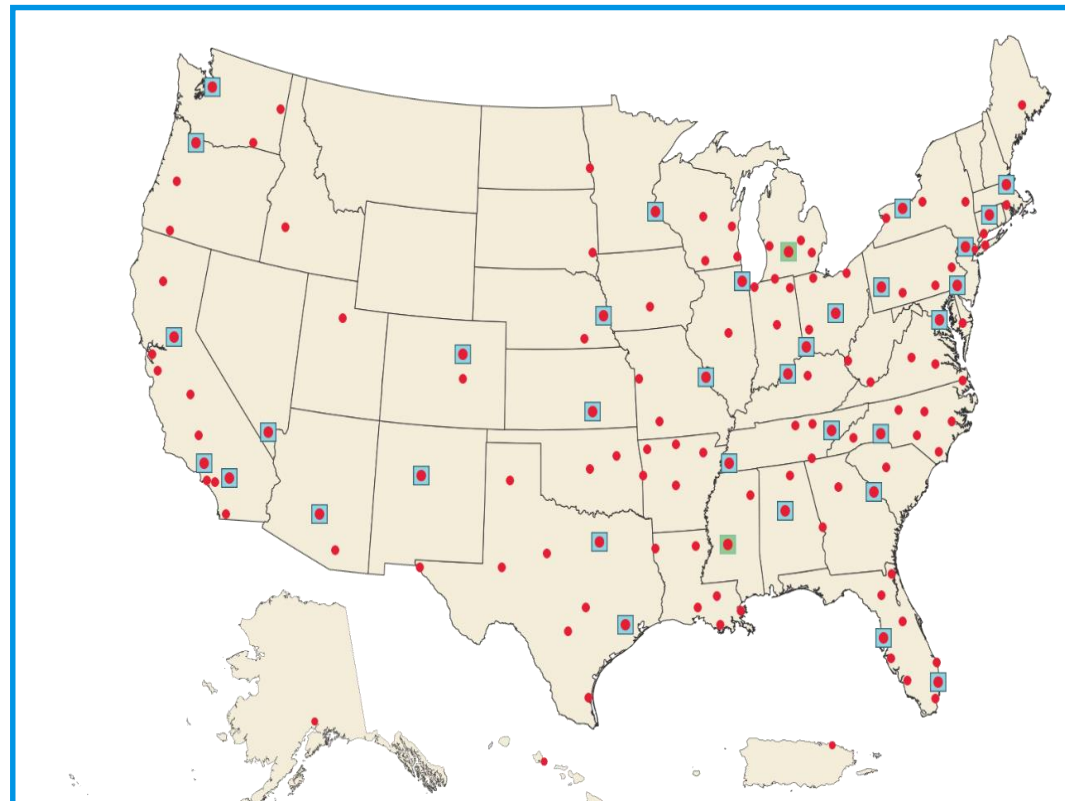
Source: Purdue University. <https://nuclear.pharmacy.purdue.edu/nukeinus/?state=NY>

Centralized Radiopharmacy – International Scenery - USA

Cardinal Health

Triad Isotop

Independents - UPPI



- Cardinal Health Pharmacy
- Cardinal Health Cyclotron
- Cyclotron Management Agreement

- Cyclotron
- Pharmacy
- Pharmacy/Cyclotron

Centralized Radiopharmacy – International Scenery

USA Market

- 350 Centralized Radiopharmacy in USA, in 2007
- Large private networks and small /independent companies
- Responsible by 81% of the total manipulated and dispatched doses in USA, in 2007

**2007 SALES AND MARKET SHARES OF RADIOPHARMACY COMPANIES
AND INDEPENDENT NUCLEAR PHARMACIES**
(Sales in \$Millions)

Radiopharmacy Company	Annual Sales Per Pharmacy (\$Millions)	Number of Pharmacies	Total Pharmacy Sales	Market Share %
Cardinal Health	\$6.50	150	\$975.0	60.0%
GE Healthcare	4.30	31	133.3	8.2%
Mallinckrodt	4.20	40	168.0	10.3%
Independents	2.70	129	348.3	21.4%
Total		350	\$1,624.6	100%

Centralized Radiopharmacy – International Scenery

2007 SALES OF TECHNETIUM GENERATORS

RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE (Sales in \$Millions)

Company	Generators Shipped	Technetium Doses Utilized	% Market Share (Doses)	Average Price Per Generator (Dollars)	Sales Volume (Millions)	% Market Share (Dollars)
BMS	31,400	11,300,000	52.9%	2,970	\$93.3	56.0%
Mallinckrodt	26,500	10,070,000	47.1%	2,770	73.4	44.0%
Total	57,900	21,370,000	100.0%	\$2,900	\$166.7	100%

USA Market

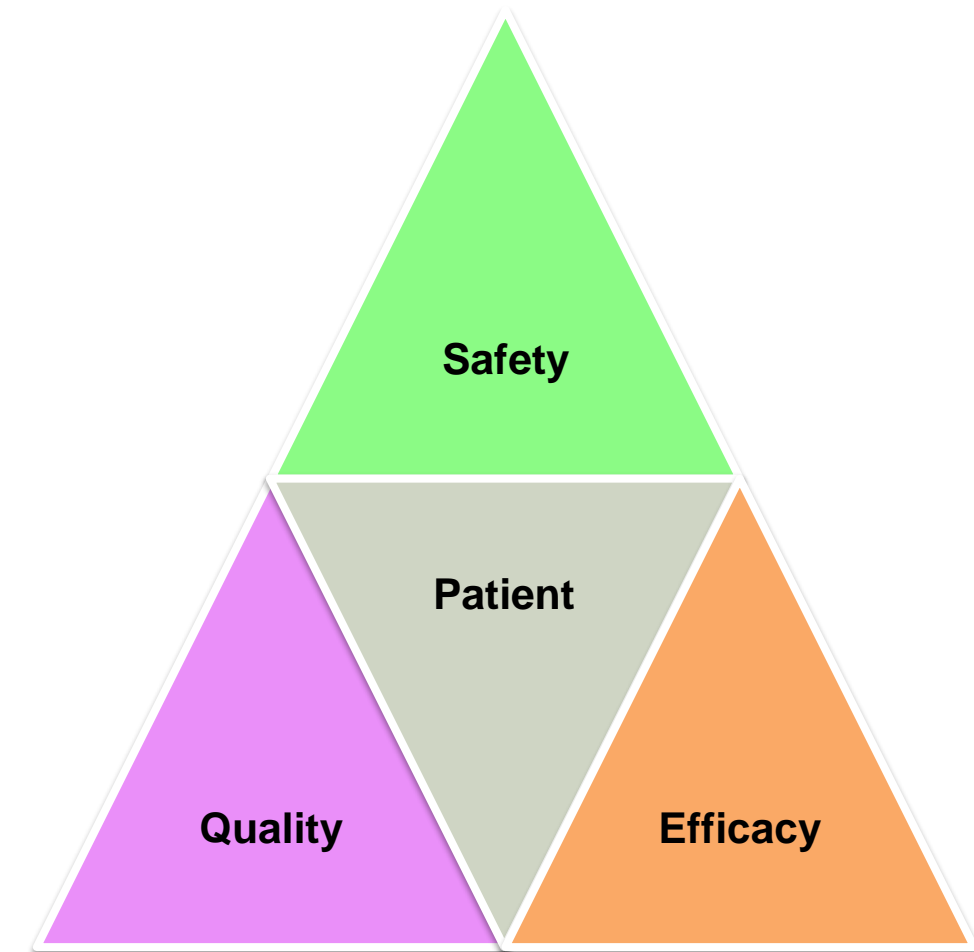
High activity generators
High resources optimization

Distribution of Sales	Average Price Per Dose (Dollars)	Sales Volume (Millions)	Percent Distribution of Sales	Number of Doses Sold	Percent Distribution of Doses
Hospital/Clinic Sales	\$10.08	\$32.4	19.4%	3,210,000	15.0%
Radiopharmacy Sales	\$7.40	\$134.4	80.6%	18,160,000	85.0%
		\$166.7	100%	21,370,000	100%

Centralized Radiopharmacy

Advantages

- Placed in a strategic location
- Qualified team
- Personalized dose to patiente
- Total Traceability → Software
- Decrease risk to patient
- Properly calibrated
- Drug efficacy assurance



Centralized Radiopharmacy

Advantages

- High activity generators
- Resources optimization (Cold kits and radiation)
- Convenience to the user is significant
- Significant savings of personnel time
- Decrease employee radiation exposition and contaminations
- Decrease radioactive waste
- Training center for young professionals



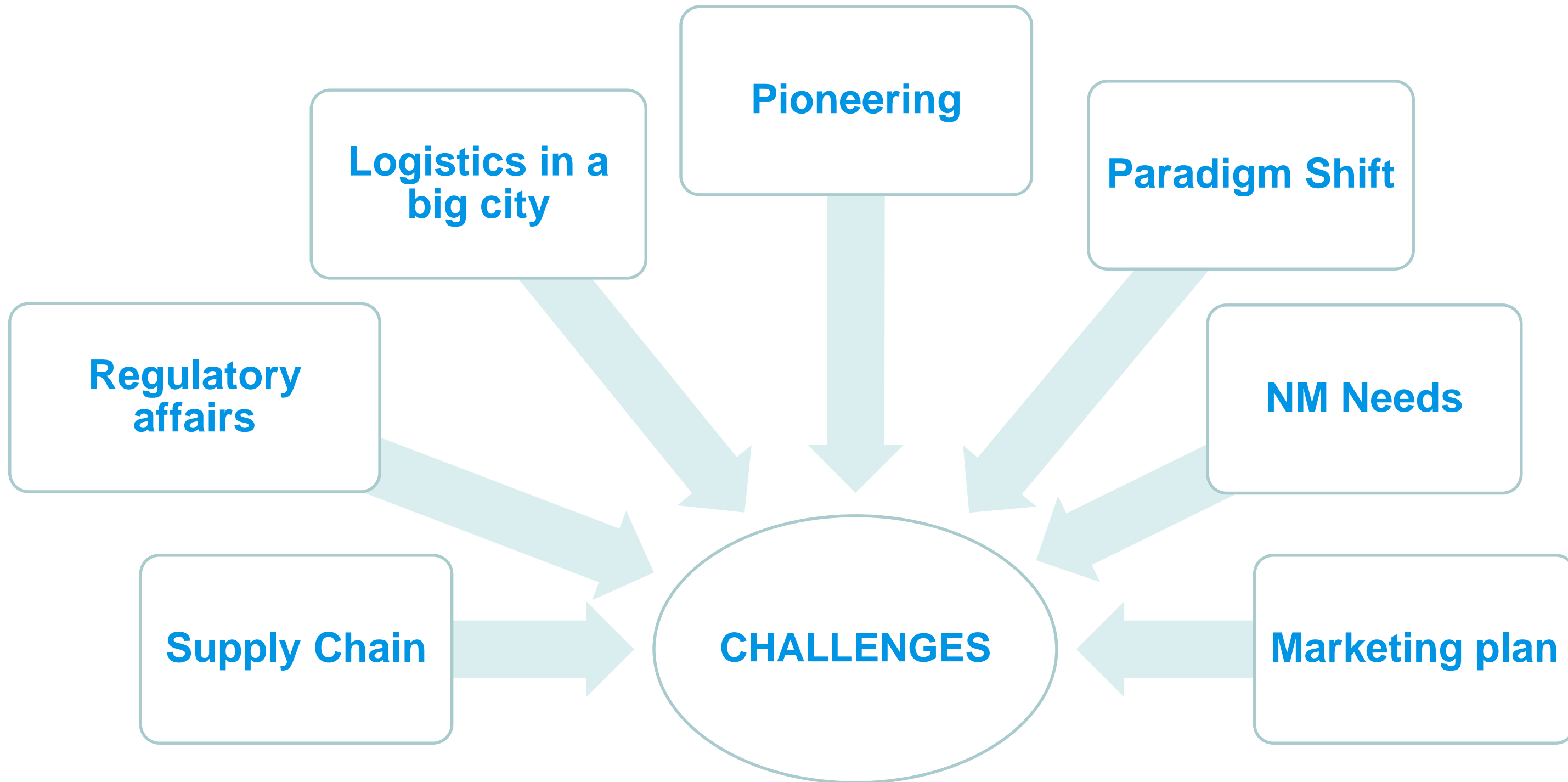
Centralized Radiopharmacy

Advantages

- Standards Compliance
- QC performed
- Introduction of new radiopharmaceuticals
- Infrastructure and equipment
- Qualified suppliers



Centralized Radiopharmacy - Challenges



CHALLENGES - Supply chain

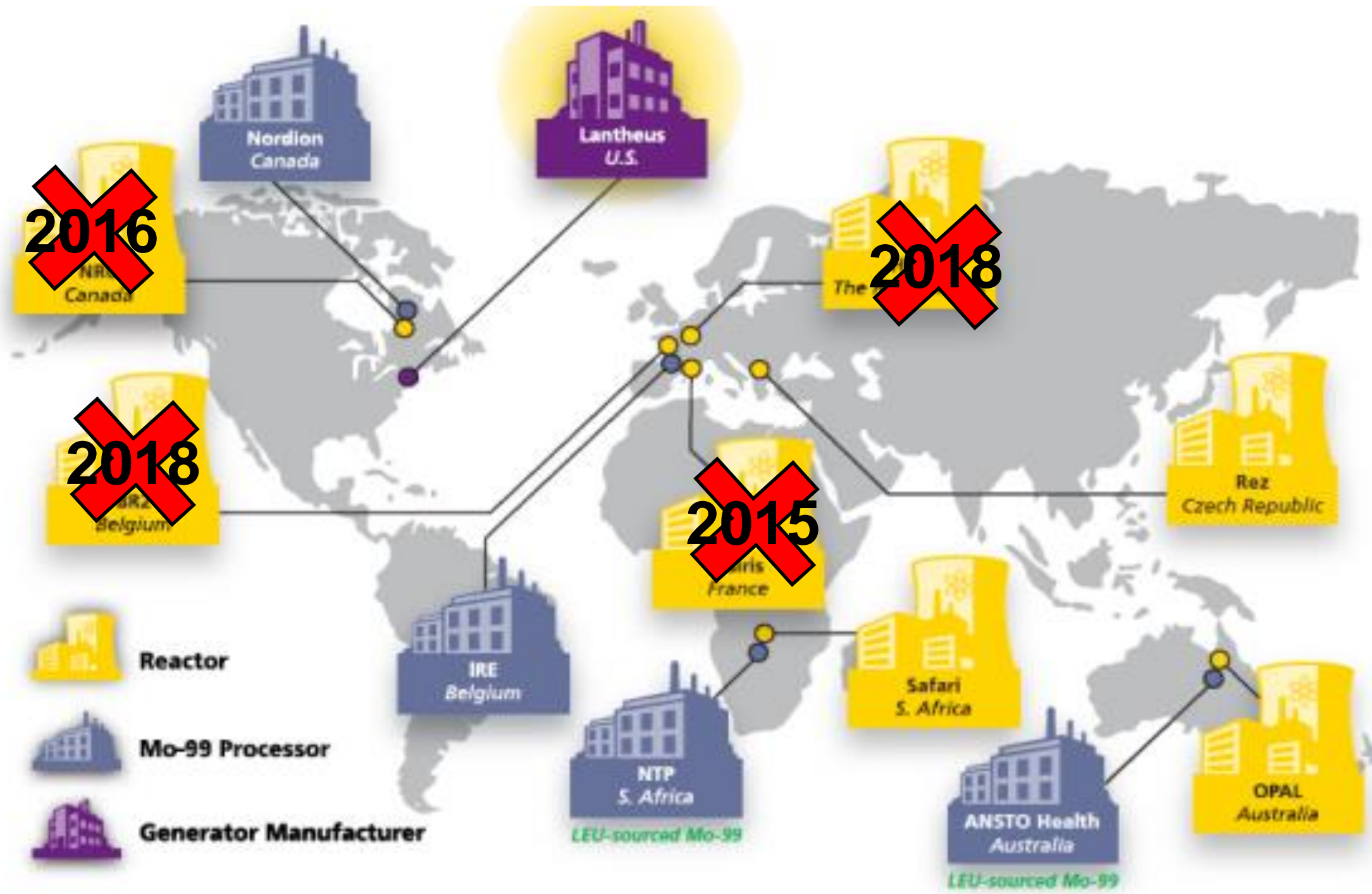
- Technetium-99m crisis in 2009
- Frequent shortage of this radioisotope
- Forecast for an upcoming crisis in 2016
 - Closing major global reactors
 - Risk to society: lack of access
- Solution → CRP
 - Optimizes at least 50% of radiation
 - Sustainable supply chain



CONHEÇA OS SETE REATORES MUNDIAIS QUE PRODUZEM O MOLIBDÊNIO-99 E O TEMPO DE DURAÇÃO DE CADA UM

PAÍS	REATOR	IDADE (ANOS)	PREVISÃO DE DESLIGAMENTO
Canadá	NRU	55	out / 2016
Bélgica	BR2	51	2018
Holanda	HFR	51	2018
França	OSÍRIS	46	2015
África do Sul	SAFÁRI-1	47	-
Austrália	OPAL	05	-
Argentina	RA-3	45	-

Centralized Radiopharmacy

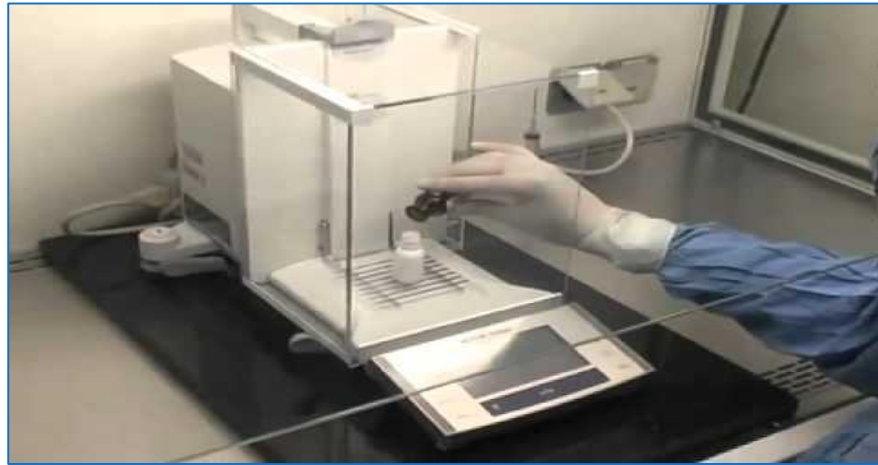


CHALLENGES - Regulatory affairs

- ✓ ANVISA – Agência Nacional de Vigilância Sanitária (health aspects - similar to FDA)
 - Main legislation: RDC 67/07 - Provides on Good Practices for Handling Preparations for Human Use in pharmacies.
 - Use of just registered radiopharmaceuticals according to RDC 70/2014
- ✓ CNEN – Comissão Nacional de Energia Nuclear (radiological aspects - subordinated to IAEA)



Centralized Radiopharmacy – Challenges - Paradigm Shift



Pharmaceutical Industry
Industrial Radiopharmacy



Nuclear Medicine Service
Hospitalar Radiopharmacy



Compounding Pharmacy
Centralized
Radiopharmacy



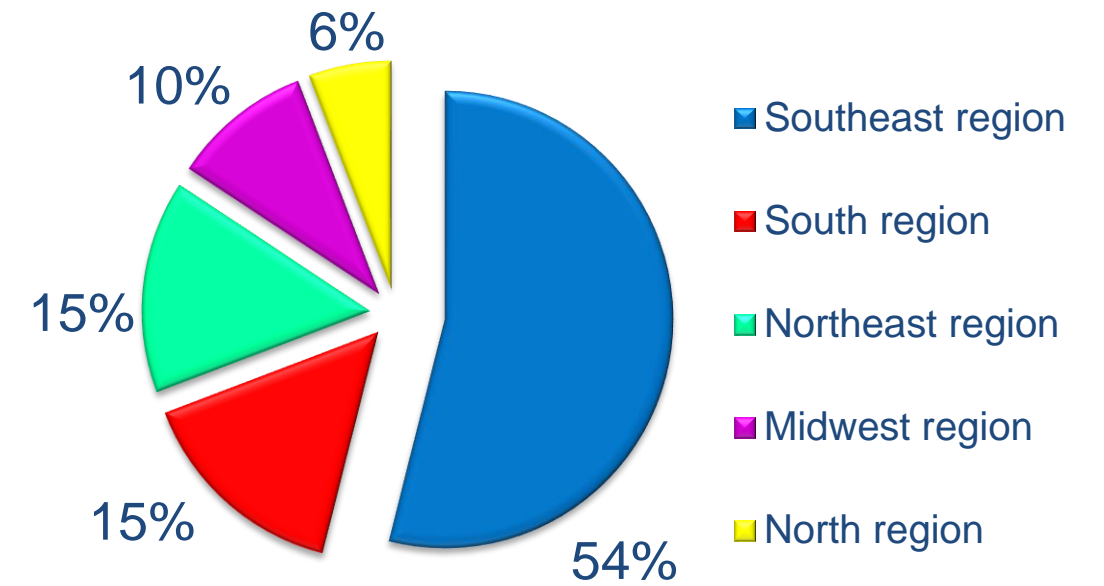
Centralized Radiopharmacy – Nuclear Medicine Departments in Brazil



RPH

2016

1st Centralized Radiopharmacy in Brazil



Southeast region	54%
São Paulo – Capital	52
São Paulo – other cities	61
Minas Gerais	58
Rio de Janeiro	48
Espírito Santo	14

Source: CNEN - 2015/Aug

Centralized Radiopharmacy

RPH GROUP

- ✓ 1st Centralized Radiopharmacy in Brazil will be based in São Paulo's market (the biggest city and economic center in LatAm)
- ✓ Compounding Pharmacy of Sterile Medicines
- ✓ Radiopharmaceuticals
 - Ready for injection
 - Individualized doses
- ✓ Partnership: Beneficência Portuguesa de São Paulo
 - Provided a space area of 157,07 m²

RPH

O amanhã que
o hoje merece.