



International Conference on Effective Nuclear and Radiation Regulatory Systems: Working Together to Enhance Cooperation

4-7 November 2019, The Hague, Netherlands

Brazil`s experience of radioisotopes production regulation

Samira M. Carvalho
samira.carvalho@cnen.gov.br

Alessandro Facure
facure@cnen.gov.br



CNEN
Comissão Nacional
de Energia Nuclear

Brazilian Commission of Nuclear
Energy (CNEN)



Fact: Radioisotope production is a constantly developing field.

It is great!! New radiopharmaceuticals, new treatments, new production techniques that have made it possible to treat more patients

It is great!!
How to control the radioisotopes commercialization? What are the safety requirements? **How to ensure safe development of the field?**



blog.iclinic.com.br



cbnmaringa.com.br

Brief history of radioisotopes production in Brazil..

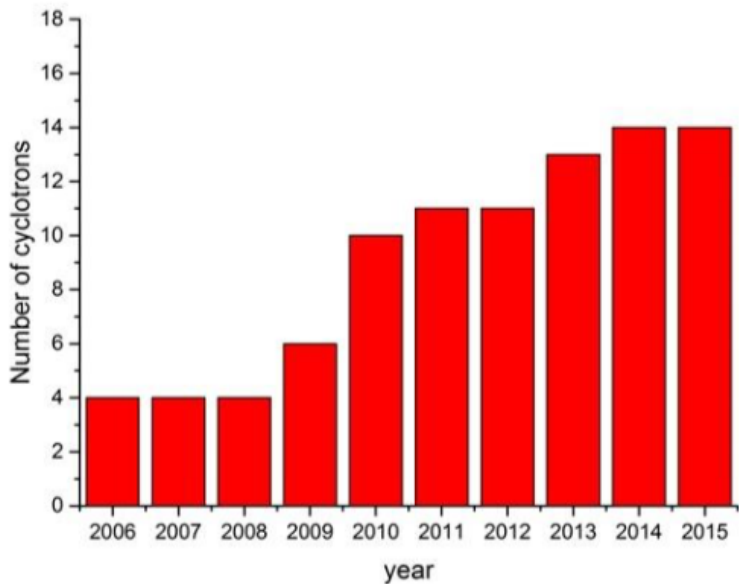
Until 2006 the production and commercialization of radioisotopes was a federal government monopoly (CNEN).

1 Industrial Radiopharmacy in São Paulo (I-131, Mo/Tc generator)

2 Cyclotrons (São Paulo and Rio de Janeiro)

Logistical Problems: Critical point for large countries.
It is very expensive to send radioisotopes that are decaying with the time to distant nuclear medicine services

In 02/2006 (constitutional amendment 49) the monopoly for short half-life radioisotopes (less than 2 hours) ended.



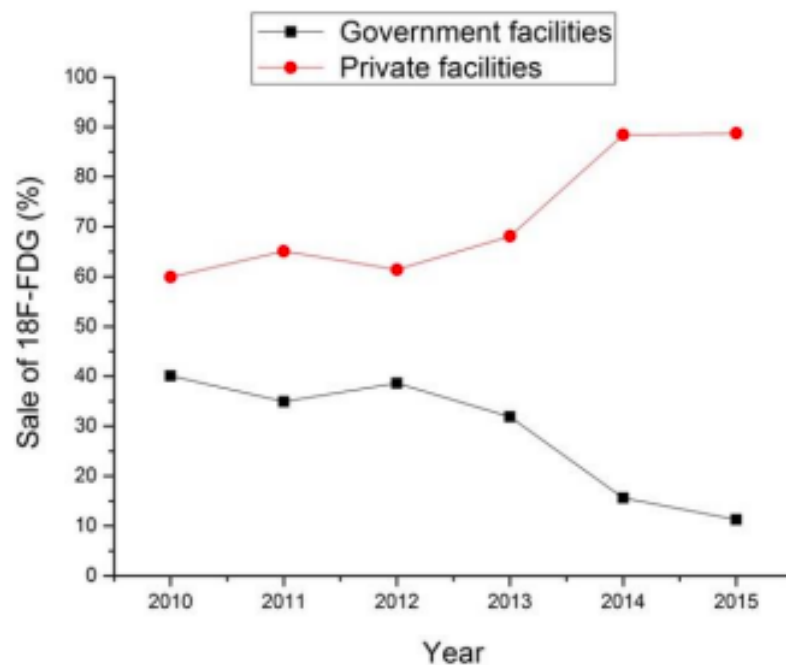
Now there are 14 cyclotrons but a concentration in the southeast region still exists



Cyclotron facilities in Brazil: Current status and licensing aspects

A. Facure^a; S. M. Carvalho^a; R. Di Prinzio^a; C. S. Silveira^a; P. B. R. Gasparian^a; W. F. França^a

Private facilities have taken up market demand. Now the public sector is focussed on research and development of new radiopharmaceuticals



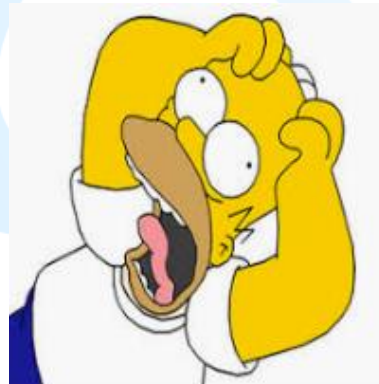
Regulation..

In Brazil we have general standards that are applied to all installations..

- Radioactive Material Transportation (CNEN-5.01)
- Radioactive Waste Management (CNEN-8.01)
- Basic Radiation Protection Guidelines (CNEN-3.01)
- Others..

And specific standards, with requirements for each practice..

- Safety and radiological protection requirements for nuclear medicine services (CNEN-3.05)
- Others..



but the cyclotron and radiopharmacy standards are in the process of publication



Project Aim: To establish licensing and inspection requirements for radioisotope production . *(the focus was cyclotron facilities)*

2010-2012

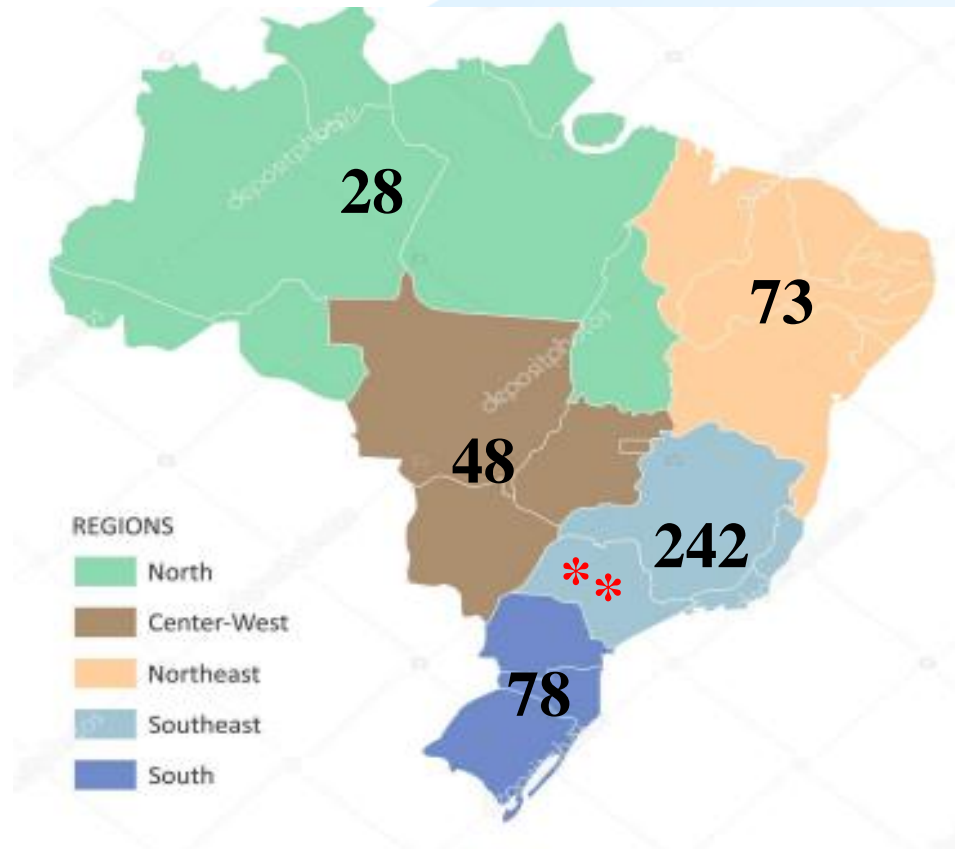
8 countries participated – Coordinator: Brazil (*Facure, A*)

A guideline for licensing and inspection was published in 2013.

After a long bureaucratic process the guideline is being adapted to the official standard

International Cooperation with other regulators is our best tool to improve regulation

New Challenges..



Current Status

**Total: 469 Nuclear
Medicine Centers**

- * **1 centralized
radiopharmacy**
- * **1 industrial
radiopharmacy**

We are changing our distribution model.
The prospect of increasing the number of new centralized
radiopharmacies is our great challenge.

A new Project approved in FORO IBEROAMERICANO

Project: To establish licensing and Inspection Requirements for Centralized Radiopharmacies

2019-2020

7 countries



Coordinator – Brazil (*Carvalho, S*)

Some expected results:

- To publish a guideline for licensing and inspections in centralized radiopharmacies
- To establish a network of experts in this field
- To development a system to control the radiopharmaceuticals comercialization



International Conference on Effective Nuclear Regulatory Systems

11–15 April 2016 Vienna, Austria

Brazil's presentation: Main Activities to Improve the Control of Radioactive Sources in Brazil (*Maria Helena*)

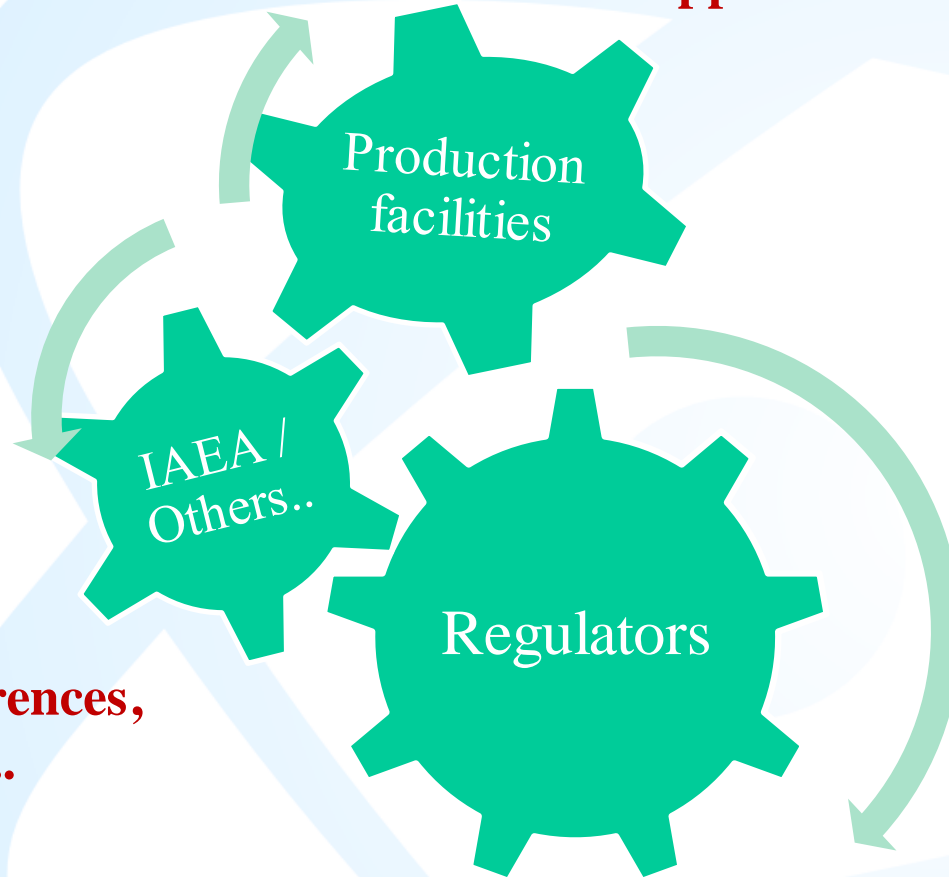
In Brazil there is an online system to control the commercialization of cyclotron facilities (basically ^{18}F and ^{11}C)

The screenshot shows the CNEN website interface. At the top, there is a navigation bar with links for accessibility and high contrast. Below this is the CNEN logo and the text 'Comissão Nacional de Energia Nuclear' and 'MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES'. A search bar is also present. The main content area displays the 'Controle de Venda de Radioisótopo - Ciclotron' form. The form includes fields for 'Fabricante', 'Matrícula', and 'Senha'. Below these is a CAPTCHA image with the text '037K5' and a prompt to 'Digite os caracteres existentes na imagem:'. There are 'Enviar' and 'Limpar' buttons at the bottom of the form. On the left side of the page, there is a sidebar with the CNEN logo and a list of links: 'Quem Somos', 'Emergência Radiológica', 'Normas', 'Certificação de Supervisores', and 'Instalações'.

Now we are
evaluating how to
upgrade the system for
the new model with
centralized
radiopharmacies

Conclusion

New radiopharmaceuticals, new approaches.. It is great!



Meetings, conferences, guidelines..

Our goal is to develop regulations at the same speed!!



**Thanks for your
attention !!**

samira.carvalho@cnen.gov.br