



Comisión Nacional
de Energía Atómica

THE ROLE OF RADIATION IN TISSUE PRESERVATION/STERILIZATION AND BLOOD IRRADIATION



Celina I. Horak

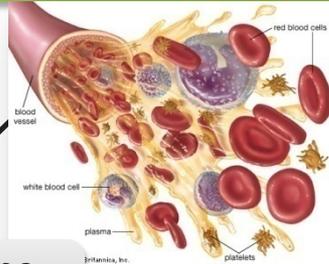
Head, Radiation Processing Application Dept

Comisión Nacional de Energía Atómica

ARGENTINA

Blood banks

Organization responsible for providing **safe & biologically useful human blood and components** to improve life quality or save lives



Intrauterine transfusion

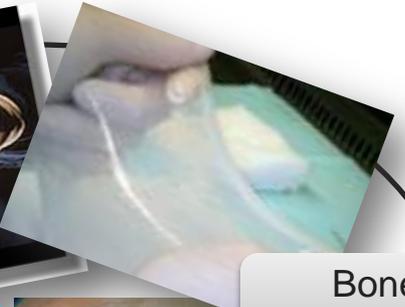
Heart Surgery

Risk patients (cancer, transplanted)

New born infants

Tissue banks

Organization responsible for providing **safe & biologically useful human tissues** to improve life quality



Heart valves replacement

Bone replacement

Eyes pathologies



Skin diseases

Burnt patients



Blood bank and irradiation

TA-GvHD is a potential complication in the transfusion of any blood component containing viable T lymphocytes when there is disparity in the histocompatibility between donor and recipient.

IRRADIATION is the major treatment to inactivate T lymphocytes on blood components (Gamma rays and X-rays) .



Tissue Banks and irradiation



Irradiation is used for Sterilization in order to inactivate or completely kill all types of microorganisms (bacteria, fungi and virus), thus preventing infection and the transmission of diseases.



The evolution of the Tissue banks

Surgery bank



Tissue bank
GMP
compliance



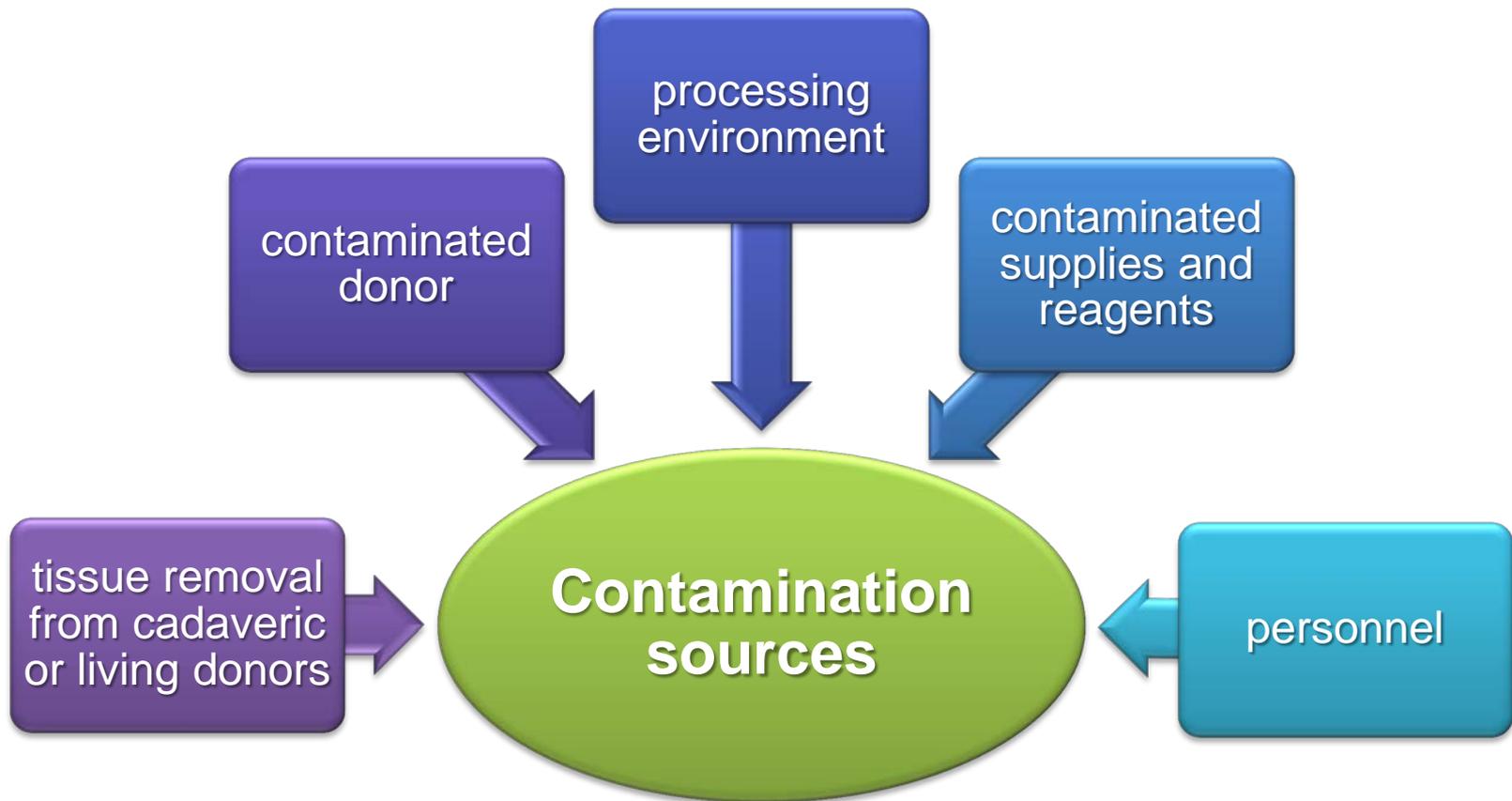
Aseptic
Processing

Clean
processing

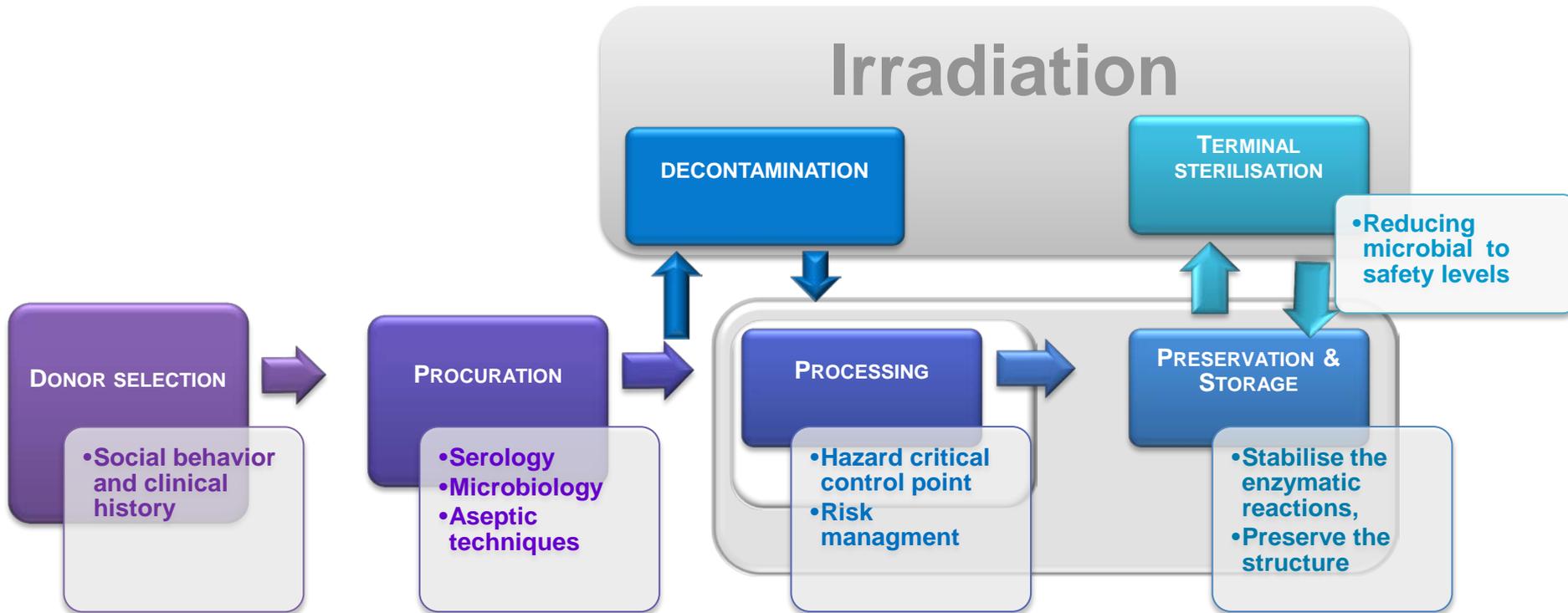


Tissue Banks

- Prevent transmissible diseases (HIV; Hepatitis B, etc)
- Prevent microbial infections (clostridia, *E. coli*, *S. aureus*, etc)
- Reduce chemical residuals



Tissue banking risk management



Which tissues can be irradiated?

YES

Skin: temporary biological dressing

Bone: replace, repair or supplement

Tendon: replace, repair

Amnion: temporary biological dressing eyes pathologies

NO

Heart valves: replace

Cornea: replace

Radiation may induce changes to the tissue grafts, but can be diminished by the election of the proper preservation method

Preservation methods:

- Freeze-dried
- Deep-frozen
- Glicerolized (85 to 90 %)
- Dehydrated





Key variables of irradiation

- Target dose
- Dose range (Min/Max dose)
- Temperature of irradiation
- Tissue treatment prior to irradiation

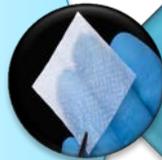
Apply the minimum doses to guarantee sterility

MINIMUM DOSE

35 kGy



Skin



Amnion



Tendon



Bone

10 kGy

50 kGy

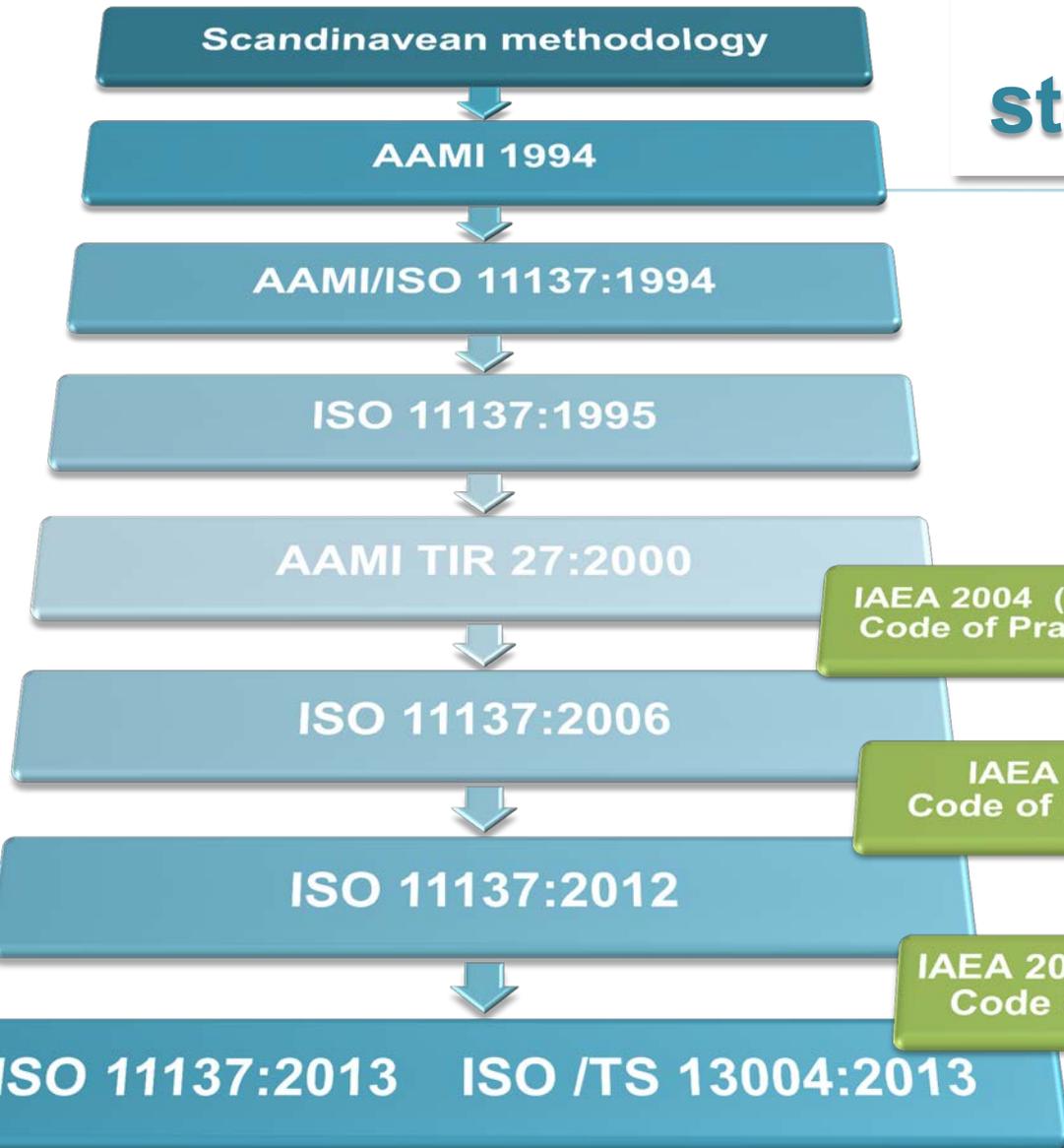
MAXIMUM DOSE

25 kGy

Minimize chemical and physical changes that may affect the biological quality of tissue allografts



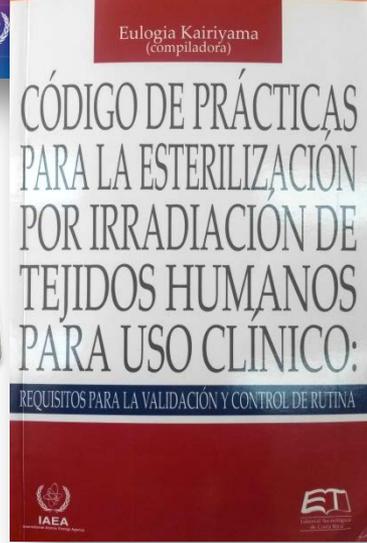
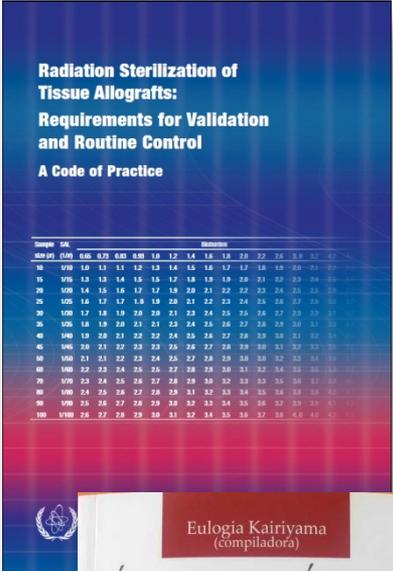
Radiation sterilization process



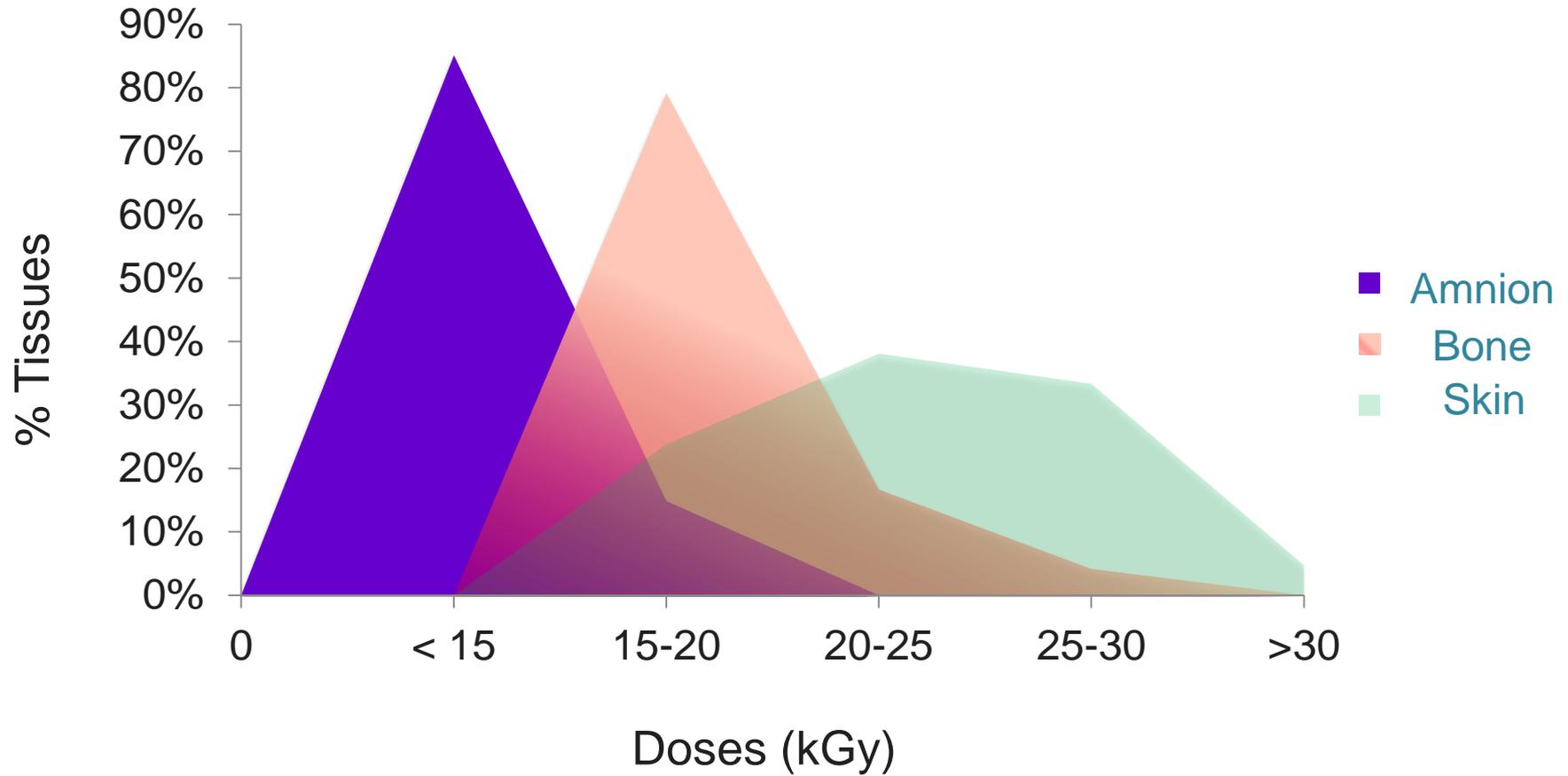
IAEA 2004 (draft)
Code of Practice

IAEA 2007
Code of Practice

IAEA 2013 (spanish)
Code of Practice



Irradiation dose range: Argentine experience



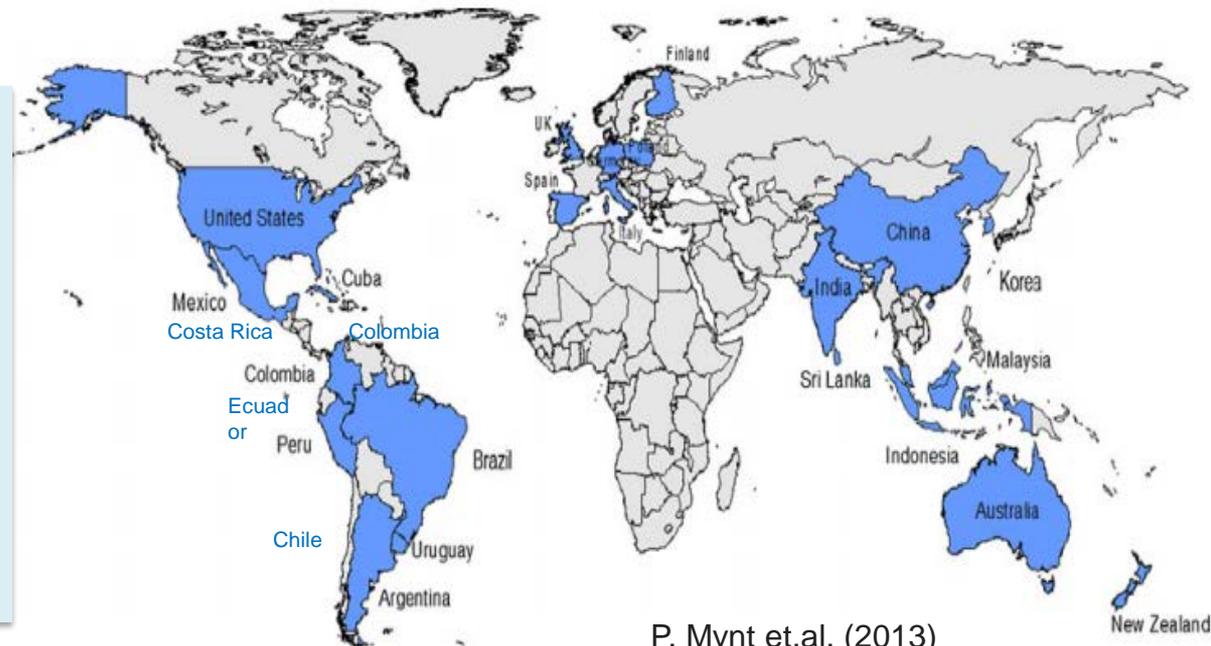
IAEA Role

Countries participating in the IAEA programme
Radiation & tissue banking (starting in the 1980's)

- Latin-America: 7 to 37 banks
- Asia-Pacific Region: 18 to 66 banks

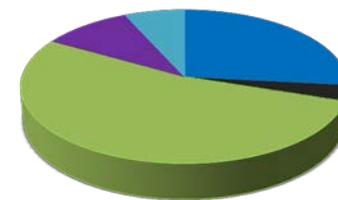
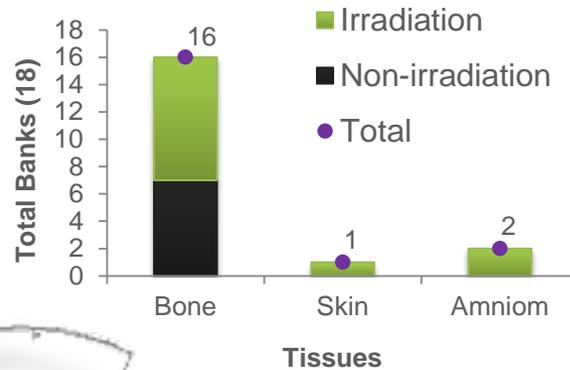
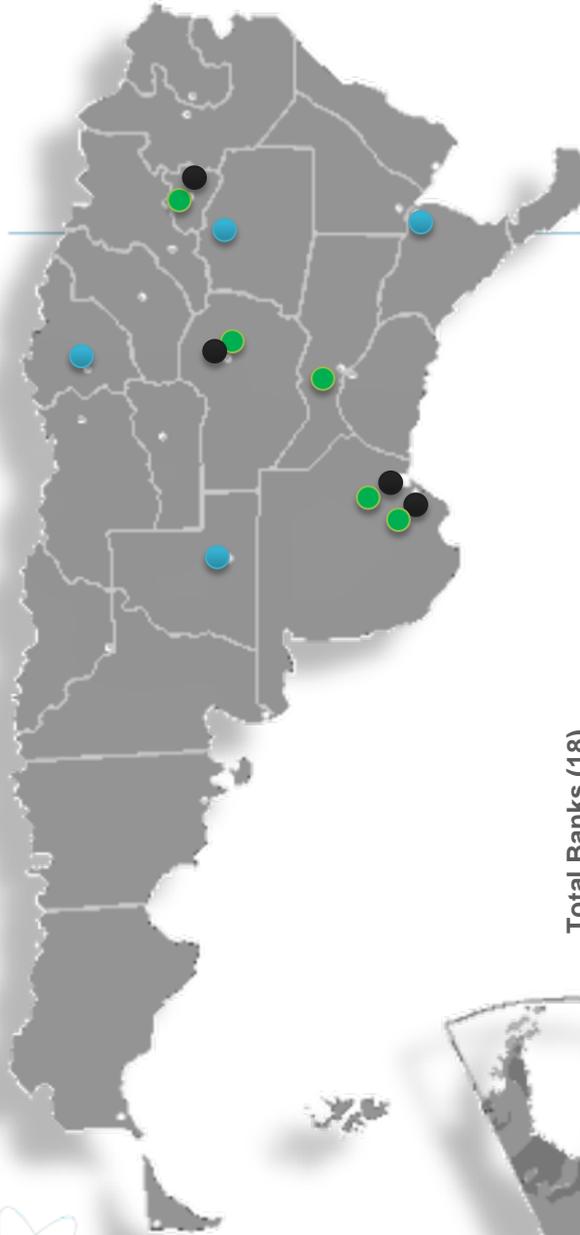
During a Survey, 48 tissue banks have submitted the data:

- 9 from Latin America (13),
- 9 from Asia,
- 19 from Europe,
- 4 from the USA
- 7 from Australia and New Zealand.

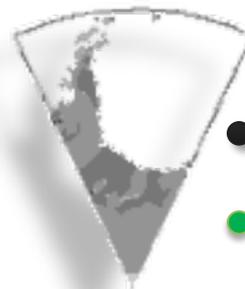


Situation in Argentina

- Tissue banking started in 1948
- In 1993, irradiation as sterilization method
- At present, there are a total of 30 tissue banks, 11 are using irradiation as final sterilization (from 18 that can use it)



- Cornea
- Skin
- Bone
- Heart valves
- amniom



- ● Non-irradiation tissue banks
- Tissue banks that use irradiation as a final sterilization treatment.



Conclusions



TISSUE IRRADIATION

- ✓ The implementation of the IAEA programme on **Radiation & Tissue Banking** improves the procedures and practices for producing **effective** and **sterile** tissue allografts for transplant surgery
 - 7 Training courses were carried out in the RTC of Latin America, 9 Training course in the RTC of Asia-Pacific and 3 in Korea (Morales 2012)
- ✓ The adaptation of medical device dose setting methodology, has helped in the process of tissue irradiation implementation



BLOOD IRRADIATION

- ✓ The major technology for preventing TA-GvHD is **irradiation** of blood components, as far as it gives a secure product for patients at risk
- ✓ It is worldwide implemented, and the use of X ray equipment is being preferred

