“Regulating Radiation Sources and Medical Facilities”

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URUGUAY
In Uruguay uses of ionizing radiation:

Medical Facilities 85% - Industry, Research, Education and Training 15%
ARNR (National Regulatory Authority in Radiation Safety) was created in 2005 by the national budget Law.

Radiation Protection Law 19056/2013 and its national Decree Nº270/2014 confirmed the ARNR competences and the regulatory processes for all facilities and activities using ionizing radiation in Uruguay.

ARNR is the only regulatory authority to control radioactive sources and radiation generators as well as is in charge of regulations for patient protection.

Uruguay is a non-nuclear country.
Regulatory Framework

• ARNR is effectively independent of promotional functions.

• Law 19056 (2013) establishes ARNR responsibilities and main competences as:
  o To establish, approve and issue regulations
  o To carry out licensing process and inspections
  o To enforce regulatory requirements.

• The regulatory framework in place in Uruguay, is in line with the IAEA Safety Standards, in particular with GSR Part 1 (Rev 1) and GSR Part 3.
Regulatory Framework

• Basic Safety Regulation – **NORM UY 100**

• 22 Specific Regulations covering all practices established along the country as well as licencing process - **from NORM UY 101 to NORM UY 123**

• Safety Guides
In Medical Exposure, Uruguay tried to follow the recommendations of the International Conference of 2016 mainly taking into account Regulation in the new medical technologies.
REGULATIONS PACKAGE URUGUAY

as of November 2019

NORMA UY 100 Rev. VIII (Basic Safety Regulation)
NORMA UY 101 GAMMAGRAFIA INDUSTRIAL Rev.I
NORMA UY 102 BRAQUITERAPIA Rev. III (Brachytherapy)
NORMA UY 103 ACELERADORES Rev.I (Lineal Accelerators)
NORMA UY 104 COBALTOTERAPIA Rev.I (Cobaltherapy)
NORMA UY 105 MEDICINA NUCLEAR Rev. II (Nuclear Medicine)
NORMA UY 106 GESTION DE DESECHOS Rev.II
NORMA UY 107 TRANSPORTE DE MATERIALES Rev.II
NORMA UY 108 RX MEDICO-ODONTOLOGICO Rev.II (Radiodiagnostic)
NORMA UY 108 ANEXO I Rev.II (Radiodiagnostic – Annex)
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NORMA UY 110 AUTORIZACIONES INDIVIDUALES GAMMAGRAFIA
NORMA UY 111 OPERACION PLANTAS TIPO IV Rev.I
NORMA UY 112 CRONOGRAMA PLANTAS TIPO IV Rev.I
NORMA UY 113 AUTORIZACION PERSONAL PLANTAS IRRADIACION.
NORMA UY 114 DISEÑO PLANTAS TIPO IV Rev.I
NORMA UY 115 APTITUD PSICOFISICA PLANTAS IRRADIACION Rev.I
NORMA UY 116 MEDIDORES INDUSTRIALES Rev.I
NORMA UY 117 CLASIFICACION DE PRACTICAS Rev.III
NORMA UY 118 SEGURIDAD FISICA
NORMA UY 119 CUALIFICACION PERSONAL DE LA ARNR
NORMA UY 120 SEGURIDAD EQUIPOS CARGA
NORMA UY 121 PERFILAJE POZOS PETROLEROS Rev.III
NORMA UY 122 SERVICIOS DE VIGILANCIA RADIOLÓGICA INDIVIDUAL
NORMA UY 100 Rev. VIII (Basic Safety Regulation)

Contents (chapters):

• GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY
• PLANNED EXPOSURE SITUATIONS
• OCCUPATIONAL EXPOSURE
• MEDICAL EXPOSURE
• PUBLIC EXPOSURE
• EMERGENCY EXPOSURE SITUATIONS
• EXISTING EXPOSURE SITUATIONS
MEDICAL EXPOSURE
in Basic Safety Regulation – Norm UY 100
(Article 165 to 201)

Contents:

• Justification in medical exposure
• Optimization of the Protection and Safety
• Pregnant or breast-feeding female patients
• Release of patients after radionuclide therapy
• Accidental medical exposures
Patient Protection included in Regulations

- Responsibility for Protection and safety for Patients.

**Article 171 of Basic Safety Regulation – Norm UY 100.-**

Registrants and licensees shall ensure that:

The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist.
Patient Protection included in Regulations

• Justification

**Article 172 of Basic Safety Regulation – Norm UY 100.-**

Relevant parties shall ensure that medical exposures to patients are justified. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.
Patient Protection included in Regulations

• Dosimetry of patients

Article 184 of Basic Safety Regulation – Norm UY 100.­

Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following accepted protocols, to determine the following:

• Typical doses to patients for diagnostic radiological procedures included interventional

• Absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy

• Typical absorbed doses to patients for radiological procedures with unsealed sources
Patient Protection included in Regulations

• Use of DRL’s – Dose Reference Level for Diagnostic as optimization strategy.

**Article 185 of Basic Safety Regulation – Norm UY 100.-**

The government shall ensure, a set of diagnostic reference levels is established for medical exposures, including guided interventional procedures.

In setting such diagnostic reference levels, the need for adequate image quality, shall be required. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys that are appropriate for the local circumstances.
Thank you very much!!!