CONTENIDO

PARTE I
Publicaciones y trabajos enviados a Congresos y/o Seminarios

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Residuos radiactivos estructurales en el "retubing/refurbishment" de la Central Nuclear Embalse – Perspectiva regulatoria

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RESIDUOS RADIACTIVOS ESTRUCTURALES EN EL "RETUBING/REFURBISHMENT" DE LA CENTRAL NUCLEAR EMBALSE – PERSPECTIVA REGULATORIA

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RESUMEN

A diferencia de la construcción de un nuevo reactor nuclear, el "retubing/refurbishment" de reactores nucleares que han estado en operación por muchos años implica el cambio de componentes, en un ambiente radiactivo. Esto exige un programa de protección radiológica planificado cuidadosamente para asegurar la protección de los trabajadores, el público y el medio ambiente así como también un programa de gestión de los residuos radiactivos generados durante el proceso, los cuales van más allá de los generados durante la operación normal y las tareas de mantenimiento de la planta. La empresa Nucleoeléctrica Argentina Sociedad Anónima (NA-SA) tiene programado llevar a cabo el proceso de Extensión de Vida de la Central Nuclear Embalse (CNE) el cual básicamente consistirá en el "retubing/refurbishment" de la instalación. La Autoridad Regulatoria Nuclear (ARN) tendrá entonces una importante actividad asociada al proceso mencionado. En particular, este trabajo describirá algunos puntos de interés relacionados con la generación y la gestión de residuos radiactivos durante el "retubing/refurbishment" de la CNE, desde el punto de vista regulatorio.

INTRODUCCIÓN

El llamado "retubing/refurbishment" en un reactor nuclear tipo CANDU es el proceso mediante el cual se efectúa básicamente el recambio de todos los tubos de presión y tubos de calandria, los alimentadores y componentes varios del reactor permitiendo extender la vida en operación del mismo por 25/30 años [1]. Dicho proceso es necesario una vez que el reactor nuclear ha cumplido su vida útil nominal y se ha detectado que algunos componentes fundamentales del reactor evidencian el desgaste del paso del tiempo provocando significativas deformaciones en los canales de los combustibles.

Debido a la activación neutrónica de los materiales presentes en el núcleo del reactor durante su operación normal y a la acumulación de depósitos (productos de corrosión) radiactivos en el sistema primario de transporte de calor, la mayoría de los residuos generados durante el "retubing/refurbishment" serán radiactivos. Esto implicará la implementación de un cuidadoso programa de protección radiológica para asegurar la protección de los trabajadores, el público y el medio ambiente.

El operador, deberá prever el cumplimiento de los requerimientos establecidos por la Autoridad Regulatoria, entre los cuales se encuentran el de caracterización radiológica de los residuos radiactivos (RR), con el objetivo primordial de demostrar el cumplimiento de los criterios de aceptación del sitio de disposición final.

El proceso de retubing/refurbishment estará dividido en fases siendo sin duda la gestión de los residuos radiactivos generados, incluyendo su transporte y almacenamiento (temporario) una etapa fundamental en todo el proceso de extensión de vida de la CNE.

La empresa Atomic Energy of Canada Limited (AECL) ha sido encargada de efectuar los trabajos de "retubing/refurbishment" en los reactores nucleares de las centrales de Point Lepreau Generating Station (PLGS), Bruce A, Wolsong 1 y está previsto que se haga cargo también de los de Gentilly-2 y Pickering B. La Empresa NA-SA contaría también con los servicios de AECL para llevar a cabo las tareas en Embalse [1]. Cabe mencionar que AECL fue la constructora de esos reactores y del de Embalse.

El reactor tipo CANDU 6 de la CNE entró en operación en enero de 1984 mientras que el de la planta de Point Lepreau hizo lo propio en el año 1983. Ambos reactores fueron fabricados al mismo tiempo y son muy parecidos, especialmente en lo que hace a la composición de los materiales utilizados, por lo tanto, la experiencia adquirida en Point Lepreau (actualmente en la etapa del montaje de nuevos componentes) [2] será muy valiosa durante el "retubing/refurbishment" en la CNE. Por este motivo, en este trabajo se describirán algunos de los puntos relevantes relacionados con la gestión de los RR en la planta de Point Lepreau.

RESIDUOS RADIACTIVOS GENERADOS DURANTE EL "RETUBING / REFURBISHMENT"

A los fines de clasificar, para su almacenamiento temporario, a los residuos radiactivos sólidos generados durante el proceso de "retubing/refurbishment" en CNE, se los agruparía de la siguiente forma (de acuerdo a lo hecho en Point Lepreau) [3]:

Clase A:

- tubos de presión (TP) y de calandria (TC)
- insertos de los tubos de calandria (ITC)
- "end fittings" y tapones de blindaje
- anillos espaciadores de los canales de combustible
- filtros HEPA utilizados durante la operación de reducción de volumen

Clase B y M:

- Material no compactable
    - tubos alimentadores
    - hardware de los alimentadores
    - tapones de cierre
    - herramientas contaminadas
    - maderas, metales
    - cilindros de gas
- Material compactable
    - papel
    - ropa
    - trapos
    - vidrios
    - plásticos

De acuerdo a esta clasificación basada esencialmente en la tasa de dosis asociada a los materiales, los residuos radiactivos se acondicionarían en dos tipos distintos de bultos y en diferente ubicación, para lo cual se construiría una instalación para el almacenamiento apropiado de los

mismos. Dicha instalación fue diseñada para un almacenamiento transitorio de los RR, durante un período de al menos 50 años, hasta su transferencia a un sitio de disposición final adecuado para ellos.

Los RR clase A se almacenarían en contenedores metálicos, de sección cilíndrica y de dos longitudes diferentes. En los más largos se dispondría a los "end fittings" enteros y en los más cortos se haría lo propio con los TP, TC (sometidos previamente a un proceso de reducción de volumen - aplastado y cortado en pequeñas piezas con máquinas diseñadas para tal fin-) e ITC. Los filtros HEPA usados durante la operación de reducción de volumen serían almacenados con los TP y los TC, aunque se espera que la actividad de dichos filtros sea significativamente menor que la de los TP y los TC. Ambos tipos de contenedores se colocarían en cilindros metálicos que a su vez estarían contenidos en otros cilindros metálicos ubicados simétricamente y a su vez se colocarían dentro de silos de hormigón, de aproximadamente 9 metros de diámetro y 7 metros de altura, denominados "retube canister". Estos silos cuentan con aberturas laterales para permitir la circulación de aire en su interior para un enfriamiento por convección natural.

Los RR clase B y M se almacenarían en contenedores de sección rectangular con tapa abulonada con capacidad de 2300 kg. El mayor volumen de residuos de esta clase correspondería a los tubos alimentadores y se almacenarían con una segregación mínima. Estos contenedores se depositarían a su vez en contenedores de hormigón del tipo "*vaults*" cuyas dimensiones serían aproximadamente de 5x5x10 m.

Se estima que durante los trabajos de la extensión de vida de la CNE se generaría una cantidad de RR tal que se requeriría de la construcción de 7 *"vaults"* y 4 "*retube canisters*".

CARACTERIZACIÓN DE LOS RESIDUOS RADIACTIVOS

Existe un consenso a nivel internacional sobre la necesidad de la caracterización de los RR de manera de optimizar las opciones de los almacenamientos y los sitios de disposición final [4]. El requerimiento de la ARN, RQ-NASA-035 del 25/09/2007 menciona específicamente la necesidad de una caracterización radiológica completa de los RR generados en las Centrales Nucleares. La caracterización radiológica implica un conocimiento de la actividad y la concentración de actividad de todos los radionucleidos significativos contenidos en cada ítem de RR [5]. En el caso de un reactor de potencia, los RR contendrán productos de activación, corrosión (activados) y productos de fisión. En particular, es posible efectuar, por diferentes métodos, estimaciones de la actividad para cada componente de los RR una vez conocida la composición de los materiales.

De acuerdo a lo efectuado en la central de Point Lepreau, una vez "apagado" el reactor nuclear, el combustible irradiado se retiró (de acuerdo a los procedimientos de rutina) y el sistema primario de transporte de calor se descontaminó, lavó y secó. Durante las semanas siguientes y hasta algunos meses después se efectuaron tareas de preparación de operaciones como la instalación de plataformas, remoción de paneles aislantes de los gabinetes de los alimentadores, etc., etc. Esto permitió que, durante el tiempo transcurrido, los RR decayeran radiactivamente, hasta el momento de ser removidos para su almacenamiento, obteniendo una importante reducción de la actividad. Para el diseño del blindaje de la facilidad de almacenamiento de los RR es necesario conocer las variaciones temporales de la actividad de los RR. Existen códigos computacionales que resultan ser poderosas herramientas con las que se puede calcular las concentraciones de actividad en función del tiempo para un gran número de isótopos los cuales son generados o depletados por transmutación neutrónica, fisión, decaimiento radiactivo, etc. Para efectuar el cálculo citado es necesario conocer, básicamente, la composición química de los materiales que se hallan dentro del reactor y asumir que los mismos han sido irradiados durante la vida útil de

la central bajo un flujo neutrónico constante pero dependiente de la ubicación de cada componente.

Los RR que contienen las actividades más elevadas son los tubos de presión, tubos de calandria e insertos de los tubos de calandria. En una primera aproximación, considerando que la composición química de los componentes es la misma en CNE que en PLGS y asumiendo que los materiales fueron irradiados durante 25 años bajo un flujo constante de neutrones (rápidos, térmicos y epitérmicos) dependiente de la ubicación de cada componente, la actividad específica inicial estimada sería de $6{,}66 \times 10^{10}$ Bq/g (1,8 Ci/g) para los TP, $4{,}44 \times 10^{10}$ Bq/g (1,2 Ci/g) para los TC y $1{,}48 \times 10^{10}$ Bq/g (0,4 Ci/g) para los ITC. Cabe mencionar que la cantidad de tubos de presión es de 380 al igual que la cantidad de tubos de calandria y el peso aproximado de cada uno de ellos es de 60 y 80 kg, respectivamente. Como la cantidad de radionucleidos generados en estos RR es muy extensa, existirá un rango muy amplio de períodos de semidesintegración que será fundamental tener en cuenta, junto con las actividades correspondientes, en las distintas etapas de la su gestión.

Desde el punto de vista operacional, los radionucleidos que contribuyen en mayor proporción a la activación interna de los tubos de presión (zirconio con 2,5% de niobio en peso) y tubos de calandria (zircaloy-2) son ^{60}Co, ^{59}Fe, ^{94}Nb, ^{95}Nb y ^{95}Zr pero luego de uno a cinco años la actividad debida a ^{59}Fe, ^{95}Nb y ^{95}Zr decaerá sustancialmente. La actividad del ^{60}Co en los TC es mayor que en los TP debido a que los TC tienen mayor contenido de níquel y de hierro y bajo un alto flujo de radiación, el ^{60}Co puede producirse por transmutación a partir del níquel y por decaimiento radiactivo a partir del hierro. En los ITC (acero inoxidable), la actividad del ^{60}Co es significativamente mayor que en los TC y en los TP debido al mayor contenido inicial de cobalto, así como los contenidos elevados de níquel y hierro. Desde el punto de vista del blindaje a la radiación, el ^{60}Co es dominante haciendo que los ITC sean los componentes más radiactivos entre los residuos de “retubing/refurbishment”.

Desde el punto de vista de la caracterización radiológica de los RR, el momento del almacenamiento de los mismos es el oportuno para eventualmente efectuar alguna medición particular para contrastar con las predicciones teóricas realizadas mediante el modelo computacional. Si bien la caracterización radiológica es responsabilidad del generador de RR, la ARN prevé efectuar oportunamente una evaluación independiente de la misma.

Los radionucleidos de relevancia serán aquellos con períodos de semidesintegración largos para los cuales se estima que al cabo de 50 años mantengan todavía una elevada actividad específica y por lo tanto definirán el tipo de disposición final.

No hay una única forma de distinguir a aquellos radionucleidos de interés; en este trabajo se adoptó como aproximación considerar a aquellos radiosótopos cuya actividad al cabo de 50 años resultase mayor a cien veces los niveles genéricos de dispensa aceptados internacionalmente [6,7]. Esto no es más que un criterio de selección ya que los niveles de dispensa se estiman considerando escenarios donde las vías de incorporación son inhalación, ingestión e irradiación externa y en el caso de los RR generados durante el “retubing/refurbishment” se trata de matrices metálicas donde se debería contemplar solo la irradiación externa. Como una primera aproximación, se consideran a los siguientes RN como los que, como mínimo, deberían caracterizarse en los RR generados durante el “retubing/refurbishment”:

C-14	Sr-90	Cd-113m	Pu-240	Cm-246
Cl-36	Zr-93	Sb-125	Am-241	
Co-60	Nb-93m	Cs-137	Am-243	
Ni-63	Nb-94	Pu-238	Cm-244	

CONCLUSIONES

El volumen de residuos radiactivos generados durante el "retubing/refurbishment" de un reactor nuclear excede a aquel generado durante la operación normal y tareas de mantenimiento de la instalación, generando en la mayoría de los casos la necesidad de construir instalaciones nuevas para el almacenamiento transitorio de los RR hasta el momento de su disposición final.

Establecido el consenso internacional sobre la necesidad de la caracterización radiológica de los RR, la realización temprana de la misma garantizaría una correcta planificación del tipo de instalación de disposición final para los RR generados en el país así como la correcta estimación de la capacidad necesaria para dicha instalación.

Este trabajo presenta una primera estimación de la caracterización de los RR que se generarían durante el "retubing/refurbishment" de la Central Nuclear Embalse, basado en los resultados obtenidos en la Central Nuclear de Point Leprau. Desde el punto de vista regulatorio, la ARN prevé llevar a cabo la investigación de la presencia de radionucleidos relevantes en los RR estructurales, a través de la aplicación de los códigos computacionales, para una evaluación independiente durante el proceso de licenciamiento.

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Analysis of Generic Clearance Levels for Radioactive Materials

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ANALYSIS OF GENERIC CLEARANCE LEVELS FOR RADIOACTIVE MATERIALS

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ABSTRACT:

Clearance values were derived for natural and artificial radionuclides. The radiological basis followed for their derivation was the same for both cases, i.e. practically not to modify the natural radiation background, but the approach to obtain the numerical figures was different. For natural radionuclides the values have been chosen by experts judgments as the optimum boundary between, on the one hand, the ubiquitous unmodified soil concentrations and, on the other hand, activity concentrations in ores, mineral sands, industrial residues and wastes. For artificial radionuclides the clearance levels have been derived from the scenarios postulated in the document “Safety Reports Series N° 44” of the IAEA considering quantitative exemption criterion. A set of 8 scenarios were postulated covering external irradiation, ingestion and inhalation exposure pathways. For each radionuclide, the generic clearance level was derived as the more restrictive value obtained from the scenarios, that is the lowest ratio between the applicable individual dose criterion and the dose per unit activity concentration (Bq/g). It was concluded that the clearance levels are conservative given the fact that the scenarios in which they are based are generic, covering a wide range of possible exposure situations.

KEYWORDS: Clearance, Generic Clearance Levels.

1. INTRODUCTION

Terrestial radionuclides (also called primordial radionulcides) have been present in the environment since the beginning of the Earth. They are mainly the product of four natural radioactive decay series, headed by ^{232}Th, ^{237}Np, ^{238}U and ^{235}U. Radionuclides such as ^{226}Ra and the gas ^{222}Rn are found within the chain of ^{238}U, ^{224}Ra and the gas ^{220}Th are found within the chain of ^{232}Th. ^{40}K is also a primordial radionuclide found in a important proportion in the environment.

Other natural radionuclides that are dispersed into the environment are ^{3}H, ^{7}Be and ^{14}C, which are formed as a result of the interaction between cosmic rays and atmospheric gases (called cosmogenic radionuclides) [1][2][3].

All these radionuclides are dispersed in rocks, soils, underground water, atmosphere etc. As consequence, for these radionuclides there is a heterogeneous worldwide distribution of low activity concentrations levels.

In addition to natural origin radionuclides, there are also dispersed in the environment artificial radionuclides, product of human activities. The main activities that contributed to this dispersion were nuclear explosions that liberated or generated various radionuclides, such as ^{14}C, ^{90}Sr,

^{137}Cs, ^{239}Pu, ^{240}Pu and ^{241}Pu. As a result of the Chernobyl accident, ^{90}Sr and ^{137}Cs, as well as isotopes of Pu and ^{241}Am were disperse mainly in Europe.

In a minor proportion, liquid and gaseous discharges from nuclear power plants and reprocessing plants also contribute to the presence in the environment of radionuclides such as ^{3}H, ^{14}C, ^{90}Sr, ^{99}Tc, ^{129}I and ^{137}Cs [4].

Considering that there are cases in which the radioactive materials generated in nuclear activities contain very low activity concentration levels making them not worthy of any further control, there is a regulatory procedure called *"clearance"* that could be applied to enable operators to remove them from the scope of its obligations allowing the cleared material to be recycled, reused or disposed of as non radioactive waste.

A similar situation occurs with radionuclides of natural origin. For those which are not excluded from the scope of the regulatory system, exists the possibility of removing these materials from the regulatory control if they satisfy the clearance criteria.

According to the Safety Guide RS-G-1.7, "Application of the Concepts of Exclusion, Exemption and Clearance" the term "Clearance" is understood as the removal of radioactive materials or radioactive objects under authorized practices from any further control by the regulatory body. Clearance levels were derived for natural and artificial radionuclides, in the document Safety Reports Series N°44 "Derivation of Activity concentration for Exclusion, Exemption and Clearance", (IAEA 2005).

As a result, if within notified or authorized practices, a material containing radionuclides of any origin or mixtures of them, satisfies the clearance levels approved by the regulatory body, they can be automatically cleared from further control. This implies that operators can treat this material as a non radioactive and could be reused, recycle or disposed of as non radioactive waste without any detriment to health and the environment.

It should be bear in mind, that the adoption of generic clearance levels does not preclude the regulatory authority to allow clearance for higher activity concentration levels, in a case by case study if it is proven that this is the best option.

2. METHODOLOGY

Clearance levels were derived for all types of solid materials. The principle followed for their derivation for both natural and artificial radionuclides is the same, but the approach to obtain the numerical values is different. The basis pursuit in both cases seems to be not introducing significant changes on the doses due to the natural radiation background (approximately 2.4 mSv/y, including radon exposures).

In this context, for natural radionuclides, activity concentration levels similar to those existing in the environment are considered acceptable for clearance levels and, for artificial radionuclides activity concentration levels that generate increments of trivial doses are considered acceptable.

An individual radiation dose, regardless of its origin, is likely to be considered as trivial if it is of the order of some tens of microsieverts per year. It was noted that this level of dose corresponds to a few percent of the annual dose limit for members of the public recommended by ICRP and is much smaller than any upper bound set by competent authorities for practices subject to regulatory control. The values of trivial individual doses corresponds to an annual nominal risk of death, which is held to be of no concern to the individual, of 10^{-6} to 10^{-7} [6]. For low probability events that could higher exposure levels, an additional criterion was used: effective doses should not exceed 1mSv per year, and with the purpose of avoiding deterministic effects, 50 mSv per year as equivalent skin dose.

2.1) Natural Radionuclides Approach

As it was explained before, the Earth contains natural radionuclides, such as primordial and cosmogenics radionuclides. These are present with an heterogeneous worldwide distribution of

their activity concentrations. For example, the worldwide average activity concentration distribution in soils for K40 is 0.4 Bq/g, for U238 is 0.035 Bq/g and for Th232 is 0.03 Bq/g. According to the report form the UNSCEAR [5] these activity concentration levels generate a doses between 0.3 – 0.6 mSv/year including the one received directly form the soil and the one generated by living in a house constructed with natural materials.

In general, it would not be practicable to implement a control scheme on situations involving natural radionuclides, based on the criterion of an increment to the natural background radiation of 10 μSv, an increment, which is in fact, one or two orders of magnitude below its natural variability. Therefore, clearance values have been chosen by experts judgments as the optimum boundary between, on the one hand, the ubiquitous unmodified soil concentrations and, on the other hand, activity concentrations in ores, mineral sands, industrial residues and wastes. This methodology places greater emphasis on optimization of protection, particularly optimization of regulatory resources rather than just on triviality of individual doses [6] The clearance levels for natural radionuclides are shown in Table 1.

Table 1: Clearance levels for natural origin radionuclides

Radionuclide	Activity Concentration (Bq/g)
^{40}K	10
Rest of radionuclides of natural origin	1

This means, that materials containing natural origin radionuclides could be released from regulatory control if their activity concentration is below the levels established in table 1. Individual doses resulting from the use of these levels are not likely to exceed 1mSv annual, excluding exposure to radon.

The limits of Table 1 are valid for radioactive natural decay series in secular equilibrium, headed by U238, U235 or Th232, applying the established value to the parent. The values can also be applied to each radionuclide product of the decay serie or for those heading subgroups of decay chains.

In the case of mixtures of natural origin radionuclides, the concentration of each radionuclide should be below the correspondent value of activity concentration established in Table 1.

2.2) Artificial Radionuclides Approach

The sequence of calculations for deriving the activity concentration values for all material containing radionuclides of artificial origin, except foodstuffs and drinking water, proceeds as follows:

2.2.1) Selection of radionuclides for which the calculations are carried out;

2.2.2) Definition of suitable scenarios and parameter values;

2.2.3) Calculation of annual doses relating to the unit specific activity (1 Bq/g) for each radionuclide;

2.2.4) Identification of the limiting scenario for each set of calculations (the one that gives the highest dose);

2.2.5) Derivation of the radionuclide specific activity concentration values by dividing the reference dose level (10 μSv/a or 50 mSv/a, as appropriate) by the annual dose calculated for 1 Bq/g for the limiting scenario for that nuclide.

2.2.1) Selection of radionuclides for which the generic clearance levels were derived. Mixture criteria.

The set of radionuclides chosen are those that are most relevant to nuclear installation, such as nuclear power plants or fuel cycle facilities, and the application of radionuclides, including short lived radionuclides, in research, industry and medicine.

To apply the activity concentration values to a material containing a mixture of radionuclides (either artificial or naturally occurring), the concentrations should be determined as follows:

$$\sum_{i=1}^{n} \frac{C_i artificial}{(activity\ concentration)_i} \leq 1$$

Where **Ci** is the concentration (Bq/g) of a radionuclide of artificial origin in the material,

(activity concentration)i is the activity concentration value for the radionuclide of artificial origin in that material and **n** is the number of radionuclides in the mixture.

When dealing with mixtures of natural origin and artificial origin radionuclides both conditions established in points1 and 2 should be met.

It is worth noting that this is a conservative approach since the pathways of exposure of the critical group of exposed individuals are not necessarily the same for each radionuclide.

2.2.2 Definition of suitable scenarios and parameter values.

The scenarios described below were postulated in the safety series report N°44 for the derivation of generic clearance levels for relevant radionuclides. They are divided into those that consider the exposure of a worker in a facility (like a foundry, landfill, etc.) and those that consider the exposure of any other individual (here on, called public) [5].

It is worth pointing out that the worker could also be exposed anywhere i.e., outdoors or at home.

Scenario WL: a worker is exposed from contaminated material dumped on a landfill. Exposure pathways encompass external irradiation from the material, the inhalation of contaminated dust and the inadvertent ingestion of contaminated material.

Scenario WF: a worker is employed in a foundry where contaminated metal is smelted. External exposures arise if the worker stays within the vicinity of piles of contaminated material. In addition, the worker is exposed to dust released from the material during the transport and melting process. This dust can be inhaled and inadvertently ingested.

Scenario WO: a worker comes into contact with contaminated material on a regular basis (e.g. a truck driver). The worker is exposed externally from the material (e.g. from the load on the truck). This scenario also covers the exposure from a large piece of equipment that has been cleared from regulatory control and is reused in other workplace.

Scenarios RL-C and RL-A: scenario RL considers individuals living near a landfill or other facility (C indicates a child, A an adult) who are exposed through contaminated dust harvested foodstuffs in a private garden on the site that has become contaminated through the deposition of contaminated material.

Scenario RF: this scenario considers a child being exposed to a contaminated dust released by a foundry. Unlike scenario RL, no food consumption is considered here, because the presence of contaminated material off –site is already covered by scenario RL.

Scenario RH: contaminated material (building rubble, slag, fly ash) may be used in the construction of buildings as concrete aggregate or cement substitute. This will lead to an external exposure of the building residents, which is addressed in this scenario. Other possible

uses in private homes of materials cleared from nuclear facilities are also covered by this scenario (e.g. the use of steel plates for the cladding of walls).

Scenario RP: if contaminated material is used for covering public places. Residents will be subject to external exposure as well as to the inhalation and ingestion of contaminated dust, for example by playing children. This exposure situation is covered in this scenario.

Scenario RW: this scenario emphases in the possible migration to downstream wells of the radionuclides present in cleared material that may lead to the ingestion of contaminated drinking water or of contaminated foodstuff produced in private gardens if the well water is used for irrigation. If the contaminated groundwater discharges into a river, the additional pathway of fish consumption is considered.

Table 2: Exposure Scenarios Considered and Relevant Pathways

SCENARIO	DESCRIPTION	EXPOSED INDIVIDUAL	RELEVANT EXPOSURE PATHWAY
WL	Worker on landfill or in other facility (other than foundry)	Worker	External exposure on landfill
			Inhalation on landfill
			Direct ingestion of contaminated material
WF	Worker in foundry	Worker	External exposure in foundry from equipment or scrap pile
			Inhalation in foundry
			Direct ingestion of contaminated material
WO	Other worker (e.g. truck driver)	Worker	External exposure from equipment or the load on the truck
RL- C	Resident near landfill or other facility	Child (1-2 a)	Inhalation near landfill or other facility
			Ingestion of contaminated foodstuffs grown on contaminated land
RL- A		Adult (>17 a)	Inhalation near landfill or other facility
			Ingestion of contaminated foodstuffs grown on contaminated land
RF	Resident near foundry	Child (1-2 a)	Inhalation near foundry
RH	Resident in house constructed of contaminated material	Adult (>17 a)	External exposure in house
RP	Resident near public place constructed with contaminated material	Child (1-2 a)	External exposure
			Inhalation of contaminated dust
			Direct ingestion of contaminated material
RW- C	Residents using water from private well or consuming fish from contaminated river	Child (1-2 a)	Ingestion of contaminated drinking water, fish and other foodstuffs
RW- A		Adult (>17 a)	

The specific parameters of each scenario (dosimetric factors, inhalation rate, ingestion rate, dust concentration, etc.) have been assessed in order to determine if they lead to representative doses and if they allow the adoption of activity concentration values as clearance levels.

Description of the main parameters.

The differences between the same parameter are due to the consideration of, in one hand realistic assumptions, and on the other hand, more conservative assumptions.

a) Exposure times: exposure times, decay time allowed before the scenario starts and decay time during the scenario have been considered.

- The exposition times varies between 1 whole year of work (conservative assumption) to half or a quarter of the year (realistic assumption).
- The decay time allowed before the scenario starts varies between 30 to 100 days (realistic assumption) and for certain situations from 1 to 365 days.

The decay time during the scenario can last the whole year (realistic assumption) or not be taken into account at all (conservative assumption).

b) Dilution Factor: the factors have been selected in order to cover a wide range of possible situations. As consequence, there are factors where the dilution is relevant as in the case of disposal of decommissioning materials in landfills or piles of scrap in a foundry and more conservative factors which do not contemplate the dilution of the material, as in the case of ingestion.

c) Skin contamination: it is assumed that there is no dilution of the suspended material in the environment. This is an conservative assumption.

d) Density of the materials: the density of the materials has little effects on the results, given that in the materials of higher density selfabsortion becomes relevant. It is adequate to assume an homogeny density of a 1.5 g/cm^3.

e) Annual ingestion rate: the rate of ingestion for workers is around 10g/y. If the scenario contemplates public members, like a child that inadvertently ingests contaminated material, the value increases up to 25g/y. For low probability exposure situations the rate increases up to 50g/y.

f) Dust concentration in air: Dust concentration in air depends of various factors, among them, the physical condition and quantity of the managed material. Given the difficulties of predicting the dust concentration, reference concentration values that vary between 10^{-5} a 10^{-3} g/m^3 are applied.

2.2.3 Calculation of annual doses relating to the unit specific activity (1 Bq/g) for each radionuclide.

The activity concentration levels arise as the lowest values obtained from the following approaches:

- Calculations with realistic scenario parameter values using an effective dose criterion of 10 μSv/year.
- Calculations using a set of low probability scenario parameter values with an effective dose criterion of 1 mSv/a and a skin equivalent dose limit of 50 mSv/a.

2.2.4 Identification of the limiting scenario for each set of calculations.

Although the limiting scenario could be different for each country due to possible differences in the specific parameters, such as working hours, shape of transport vehicles or geometries factors, the results are conservative enough as not to justify the need of development of national scenarios.

2.2.5 Derivation of the radionuclide specific activity concentration values by dividing the reference dose level (10uSv/a or 50mSv/a, as appropriate) by the annual dose calculated for 1 Bq/g for the limiting scenario for that nuclide.

Once identified the critical pathway, highest dose per unit activity, it is compared to the dose criteria corresponding to that pathway obtaining the clearance value for the given radionuclide. Clearance levels are shown in Table 3.

Table 3: Clearance values for artificial radionuclides

Radionuclides	Level (Bq/g)
I-129	0.01
Na-22; Sc-46; Mn-54; Co-56; Co-60; Zn-65; Nb-94; Ru-106; Ag-110m; Sb-125; Cs-134; Cs-137; Eu-152; Eu-154; Ta-182; Bi-207; Th-229; U-232; Pu-238; Pu-239; Pu-240; Pu-242; Pu-244; Am-241; Am-242m; Am-243; Cm-245; Cm-246; Cm-247; Cm-248; Cf-249; Cf-251; Es-254	0.1
C-14; Na-24; Cl-36; Sc-48; V-48; Mn-52; Fe-59; Co-57; Co-58; Se-75; Br-82; Sr-85; Sr-90; Zr-95; Nb-95; Tc-96; Tc-99; Ru-103; Ag-105; Cd-109; Sn-113; Sb-124; Te-123m; Te-132; Cs-136; Ba-140; La-140; Ce-139; Eu-155; Tb-160; Hf-181; Os-185; Ir-190; Ir-192; Tl-204; Bi-206; Th-232 [1], U-233; U-235 [2]; U-238 [3] Np-237; Pu-236; Cm-243; Cm-244; Cf-248; Cf-250; Cf-252; Cf-254	1
Be-7; F-18; Cl-38; K-40; K-43; Ca-47; Mn-51; Mn-52m; Mn-56; Fe-52; Co-55; Co-62m; Ni-65; Zn-69m; Ga-72; As-74; As-76; Sr-91; Sr-92; Zr-93; Zr-97; Nb-93m; Nb-97; Nb-98; Mo-90; Mo-93; Mo-99; Mo-101; Tc-97; Ru-97; Ru-105; Cd-115; In-111; In-114m; Sn-125; Sb-122; Te-127m; Te-129m; Te-131m; Te-133; Te-133m; Te-134; I-126; I-130; I-131; I-132; I-133; I-134; I-135; Cs-129; Cs-132; Cs-138; Ba-131; Ce-143; Ce-144; Gd-153; W-181; W-187; Pt-191; Au-198; Hg-203; Tl-200; Tl-202; Pb-203; Po-203; Po-205; Po-207; Ra-225; Pa-230; Pa-233; U-230; U-236; Np-240; Pu-241; Cm-242; Es-254m	10
H-3; S-35; K-42; Ca-45; Sc-47; Cr-51; Mn-53; Co-61; Ni-59; Ni-63; Cu-64; Rb-86; Sr-85m; Sr-87m; Y-91; Y-91m; Y-92; Y-93; Tc-97m; Tc-99m; Rh-105; Pd-109; Ag-111; Cd-115m; In-113m; In-115m; Te-129; Te-131; I-123; I-125; Cs-135; Ce-141; Pr-142; Nd-147; Nd-149; Sm-153; Eu-152m; Gd-159; Dy-166; Ho-166; Er-171; Tm-170; Yb-175; Lu-177; Re-188; Os-191; Os-193; Ir-194; Pt-197m; Au-199; Hg-197; Hg-197m; Tl-201; Ra-227; U-231; U-237; U-239; U-240; Np-239; Pu-234; Pu-235; Pu-237; Bk-249; Cf-253; Es-253; Fm-255	100
Si-31; P-32; P-33; Fe-55; Co-60m; Zn-69; As-73; As-77; Sr-89; Y-90; Tc-96m; Pd-103; Te-125m; Te-127; Cs-131; Cs-134m; Pr-143; Pm-147; Pm-149; Sm-151; Dy-165; Er-169; Tm-171; W-185; Re-186; Os-191m; Pt-193m; Pt-197; At-211; Th-226; Pu-243; Am-242; Cf-246	1000
Co-58m; Ge-71; Rh-103m; Fm-254	10 000

[1] The thorium series, headed by thorium-232 and constituted by ^{228}Ra, ^{228}Ac, ^{228}Th, ^{224}Ra, ^{220}Rn, ^{216}Po, ^{212}Pb, ^{212}Bi, ^{212}Po, ^{208}Tl, and ^{208}Pb.

[2] The actinium series, headed by uranium-235 and constituted by ^{231}Th, ^{231}Pa, ^{227}Ac, ^{227}Th, ^{223}Fr, ^{223}Ra, ^{219}Rn, ^{215}Po, ^{211}Pb, ^{211}Bi, ^{207}Tl, and ^{207}Pb.

[3] The uranium series, headed by uranium-238 and constituted by ^{234}Th , ^{234}mPa, ^{234}U, ^{230}Th, ^{226}Ra, ^{222}Rn, ^{218}Po, ^{214}Pb, ^{214}Bi, ^{214}Po, ^{210}Pb, ^{210}Bi , ^{210}Po, and ^{206}Pb.

3. RESULTS

Typical exposure scenarios for solid materials, including external irradiation, inhalation of dust and ingestion (direct and indirect) have been taken into account for the calculations. The activity concentration values adopted were the lowest, this means, the more restrictive ones.

The results obtained and presented in Tables 1 and 3, can assure an adequate protection level to the critical group (workers and public).

Considerations about the selected radionuclides

The set of radionuclides chosen are those that are most relevant to nuclear installations, such as nuclear power plants or fuel cycle facilities, and the application of radionuclides, including short lived radionuclides, in research, industry and medicine.

Considerations about the scenarios considered

These scenarios are based in considerations that require a certain degree of conservatism in order to cover the wide variety of exposure situations around the world. More than one scenario has been considered for each exposure pathway in order to reflect the generality of the materials that would produce doses.

Considerations about the values of the parameters

The parameters considered for normal exposure are mainly realistic, but for low probability cases including exposure situations that tend to overestimate doses, a more conservative criterion has been adopted.

4. CONCLUSION

The specifics parameters used in each scenario postulated to derive the clearance values are conservative. These values have been derived for bulk amounts of homogeneous materials, so in order to apply them it is necessary to calculate the average activity concentration within the material.

According to the assessment carried out, it was suggested that the ARN should adopt the use of Generic Clearance Levels, in order to improve the regulatory management's efficiency and to optimize the utilization of its human and economic resources. This initiative is presently in course of implementation

Finally, it is worth pointing out that the adoption of these generic values has to be universal given that the materials can be exported or imported without any restrictions based on their radioactive content. This means, one material cleared in one country, should be considered cleared in other country.

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Analysis Of Generic Clearance Levels For Radioactive Materials

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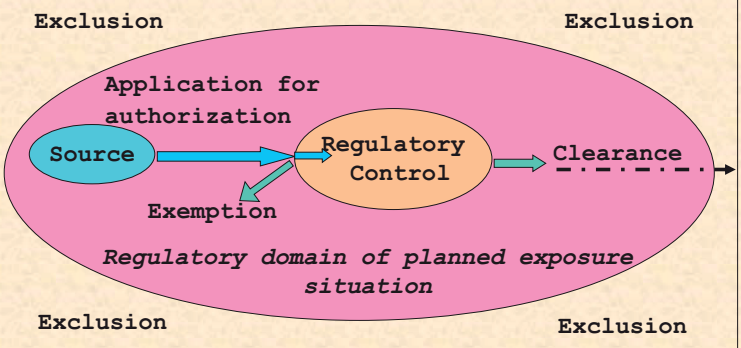
Introduction

There are cases in which radioactive materials generated in nuclear activities are not worthy of further control.

Operators of Nuclear Power Plants require Clearance Levels.

Current optimization phase of Waste Management Regulatory System.

ARN´s necessity of evaluation and assessment of clearance levels.



OBJECTIVE: Analyse the basis followed for the derivation of Generic Clearance Levels for natural and artificial radionuclides and evaluate the possiblity of their adoption by the Argentinean Nuclear Regulatory Authority.

METHODOLOGY

CRITERIA: not introducing significant changes on the natural radiation background doses

Natural Radionuclides

- Activity concentration levels similar to those existing in the environment
- Chosen by experts judgements as the optimum boundary between the ubiquitous unmodified soils concentrations an the activity concentration in ores, mineral sands, industrial residues and waste.
- Based on document of UNSCEAR

Artificial Radionuclides

- Derived from 8 scenarios postulated in Document Safety Reports Series N°44
- Scenarios cover external irradiation, ingestion and inhalation
- For realistic situations: 10 μS/y
- For low probability situacions: 1mSv/y - Skin 50mSv/y
- Activity concentration level obtained by dividing the reference dose level by the annual dose for the limiting scenario

TABLE 1. VALUES OF ACTIVITY CONCENTRATION FOR RADIONUCLIDES OF NATURAL ORIGIN

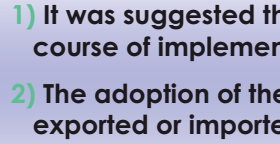
Radionuclide	Activity concentration (Bq/g)
^{40}K	10
All other radionuclides of natural origin	1

TABLE 2. VALUES OF ACTIVITY CONCENTRATION FOR RADIONUCLIDES OF ARTIFICIAL ORIGIN IN BULK (see para. 4.4)

Radio-nuclide	Activity concen-tration (Bq/g)		Radio-nuclide	Activity concen-tration (Bq/g)		Radio-nuclide	Activity concen-tration (Bq/g)
H-3	100		Mn-56	10	*	Se-75	1
Be-7	10		Fe-52	10	*	Br-82	1

Results

- ✓Scenarios and parameters conservative enough as not to justify the need to develop national scenarios
- ✓Scenarios envelop wide range of possible exposure situations
- ✓Need of calculating avarage activity concentration within the material
- ✓Materials could be reused, recycled or disposed of as non radioactive
- ✓Possible application for decommisioning of nuclear power plants, metalic scrap, radioactive wastes



CONCLUSIONS

1) It was suggested that the ARN should adopt the use of Generic Clearance Levels. This intiative is presently in course of implementation.

2) The adoption of the Generic Clearance Levels has to be universal given that materials can be worldwide exported or imported.

3) Higher activity concentration levels could be cleared based on a case by case study if it is proven that clearance is the best option.

Plan de monitoreo radiológico ambiental rutinario en las inmediaciones de las instalaciones nucleares y radiactivas del país

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PLAN DE MONITOREO RADIOLÓGICO AMBIENTAL RUTINARIO EN LAS INMEDIACIONES DE LAS INSTALACIONES NUCLEARES Y RADIACTIVAS DEL PAÍS

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1. INTRODUCCIÓN

En concordancia con el principio básico de la protección radiológica de *mantener la exposición de la población tan baja como sea posible*, se permite la descarga limitada de efluentes radiactivos. Los límites de descarga correspondientes han sido fijados por la ARN en base a los modelos de transferencia al ambiente.

La normativa de la ARN establece límites y restricciones de dosis para el público, que resultan totalmente compatibles con las recomendaciones internacionales, basadas en décadas de investigación, y que recoge la extensa experiencia de nuestro país en materia de protección radiológica.[1]

Un adecuado programa de monitoreo ambiental, en conjunto con el monitoreo de las descargas, provee información útil para mejorar el conocimiento del comportamiento de los efluentes y la dispersión de material radiactivo en diferentes sectores del medio ambiente

El tipo de programa de monitoreo, así como también la escala y la extensión del mismo deben estar en concordancia con las características de la fuente, inventario radiactivo, tasa de descarga, las diferentes vías de exposición, características del sitio, hábitos de la población y las magnitudes de las dosis individuales potenciales [2].

Los programas de monitoreo deben estar basados en las distintas vías de exposición:

- acuática
- atmosférica

A continuación, los gráficos muestran las distintas vías de exposición para las dispersiones en los cuerpos de agua (Fig.1) y en la atmósfera (Fig.2).
La importancia de cada vía de exposición depende de:

- Las propiedades radiológicas del material liberado.
- Las propiedades físico- químicas.
- Mecanismo de dispersión y migración en el ambiente.
- Características del ambiente.
- Los hábitos y costumbres de los individuos expuestos.

2. MARCO LEGAL DEL MONITOREO RADIOLÓGICO AMBIENTAL

En el año 1997 mediante la Ley N° 24.804 denominada Ley Nacional de la Actividad Nuclear se crea la Autoridad Regulatoria Nuclear (ARN) como sucesor del Ente Nacional Regulador Nuclear. En el capítulo II, artículo 16, inciso *m* se establece como función de la ARN “Evaluar el impacto ambiental de toda actividad que licencie, entendiéndose por tal aquellas actividades

de monitoreo, estudio y seguimiento de la licencia, evolución o posibilidad de daño ambiental que pueda provenir de la actividad nuclear licenciada." Posteriormente en el Decreto Reglamentario N° 1390/98 se reglamenta el artículo 16 inciso *m* según se detalla a continuación: "Entiéndese que la evaluación del impacto ambiental al que hace referencia el inciso *m* del capítulo 16 de la Ley N° 24.804 se refiere exclusivamente a la evaluación de los estudios y análisis realizados por los licenciatarios y que la intervención de la ARN en lo que a ambiente humano se refiere se limita al impacto ambiental radiológico que puede provenir de la descarga de efluentes radiactivos." [3,4]

La ARN en su Norma Básica de Seguridad 10.1.1. Revisión 3 en el punto 148 establece que "el responsable de una Instalación Clase I, Clase II o de una práctica no rutinaria debe comunicar a la Autoridad Regulatoria la información que ésta establezca para cada caso y dentro de los plazos fijados, debiendo detallar como mínimo lo siguiente: Los resultados del monitoreo ambiental alrededor de la Instalación cuando esto corresponda." [1]

Así mismo para aquellas instalaciones licenciadas que requieran un plan de monitoreo radiológico ambiental, en la licencia de operación de las mismas se especifica con qué frecuencia las instalaciones deben informar a la ARN los resultados de los monitoreos radiológicos ambientales que llevan adelante.

La IAEA ha sugerido criterios para definir qué tipo de instalaciones requerirían un monitoreo radiológico ambiental [5].

3. OBJETIVOS Y CRITERIOS

El objetivo principal del plan de monitoreo radiológico ambiental es verificar que las instalaciones no producen impacto radiológico significativo en el medio ambiente mas allá de lo autorizado por la licencia de operación. Esta tarea es complementaria del monitoreo de descargas.

Los objetivos específicos del monitoraje radiológico ambiental rutinario llevado a cabo por la Subgerencia de Control Ambiental (SGCA) de la ARN son:

- Verificar los resultados del monitoreo de descargas y detectar posibles emisiones inadvertidas.
- Verificar predicciones de los modelos dosimétricos y que los límites de dosis a los grupos críticos no son excedidos.
- Analizar la presencia y evolución en el tiempo de radionucleidos en el ambiente.
- Proveer información al público a través del sector de Comunicación Institucional de la ARN.

Del análisis de las recomendaciones internacionales y de la bibliografía especializada en el tema [6-10] se extrajeron una serie de criterios a partir de los cuales se elaboraron los planes de monitoreo:

En cuanto a los radionucleidos en estudio, el criterio adoptado es cubrir todo el espectro de radionucleidos para los cuales se han fijado límites derivados de descarga. De acuerdo al porcentaje del Ki normalmente descargado, al tiempo de decaimiento y a su relevancia en cuanto a la dosis producida en el grupo crítico, se utilizan análisis específicos para los radionucleidos que se consideran indicadores y técnicas de screening para el resto. En el caso de aquellas instalaciones que no producen descargas al medio ambiente y ya no se encuentran en operación se realiza un análisis de los posibles escenarios de dispersión de radionucleidos (ejemplo: control de las colas de minerales en el caso de los yacimientos de uranio).

Puntos de muestreo: Se deben incluir como mínimo 3 puntos de muestreo:

- Un punto aguas arriba o vientos arriba situado entre los 15 y 30 kilómetros que no estará influenciado por las descargas autorizadas de una determinada instalación. El mismo se denomina *Punto Blanco*.
- Un punto de muestreo ubicado en la zona de máxima concentración esperada de radionucleidos. Se denomina *Punto de máxima.*
- Un punto que debe coincidir con el grupo crítico real o hipotético a partir del cual se podría hacer un cálculo de dosis y verificar los modelos utilizados *Punto Grupo Crítico.*

Hasta el momento se está utilizando el programa PC-Cream para ajustar los puntos de muestreo asociados a las descargas gaseosas y un modelo genérico recomendado por la IAEA [11,12] para determinar el punto de mezcla total en los ríos.

Es importante aclarar que pueden agregarse puntos de muestreo y/o matrices adicionales asociados a las necesidades de información de la población en las inmediaciones de las instalaciones nucleares y radiactivas. Estos puntos son denominados puntos de interés público.

En cuanto a las matrices a muestrear, se decidió tomar muestras de aquellas matrices relacionadas con las vías directas de exposición: Aire (tasa de dosis ambiental, material particulado en aire, aerosoles en aire, condensado de humedad) y Agua (aguas superficiales y agua subterránea). También es importante contar con muestras de matrices integradoras de radionucleidos en el tiempo (sedimento y suelo). Finalmente, se obtienen muestras de matrices de alimentos para la verificación de modelos de cálculo de dosis en el grupo crítico (peces, vegetales, leche y agua potable). Estas últimas matrices suelen ser de interés público.

En cuanto a la frecuencia de muestreo, el criterio general indica una mayor frecuencia de análisis para aquellos radionucleidos más relevantes desde el punto de vista de aporte a la dosis. Así mismo debe tenerse en cuenta las características de la matriz, en el caso de las matrices integradoras la frecuencia de muestreo deberá ser más espaciada.

4. DESARROLLO DEL PLAN DE MONITOREO RADIOLÓGICO AMBIENTAL RUTINARIO

En base al contexto legal presentado anteriormente la SGCA de la ARN revisa y audita los planes de monitoreo radiológico ambiental de las instalaciones nucleares y radiactivas y lleva adelante un plan de monitoreo radiológico ambiental propio e independiente.

La ejecución de este plan propio incluye la toma de muestras, análisis y medición de las mismas en los laboratorios de la ARN ubicados en el Centro Atómico Ezeiza y el análisis de los resultados.

Cabe aclarar que los procedimientos para muestreo de aguas, espectrometría gamma, tritio, uranio por fluorometría y fosforescencia cinética (KPA) se encuentran acreditados bajo la norma Norma IRAM 301 – Norma ISO/IEC 17025.

Los resultados de las mediciones de concentración de actividad en las muestras analizadas correspondientes al monitoraje radiológico ambiental rutinario, se comparan con los valores establecidos en distintas recomendaciones y normas nacionales e internacionales vigentes [13 – 18]. También son comparados con los valores obtenidos a partir de los modelos de cálculo aplicados por la ARN para estimar la dosis en los individuos más expuestos. Finalmente se

realiza una comparación con los datos históricos obtenidos de cada instalación para realizar análisis de tendencias.

Las instalaciones, alrededor de las cuales la ARN efectúa los monitoreos radiológicos ambientales son: las centrales nucleares de NASA: Atucha I (Provincia de Buenos Aires) y Embalse (Provincia de Córdoba); el Centro Atómico Ezeiza (Provincia de Buenos Aires el Centro Atómico Bariloche y el Complejo Tecnológico Pilcaniyeu (ambos en la Provincia de Río Negro), la Planta de Conversión de Dióxido de Uranio de DIOXITEK y la Regional Centro de la CNEA, ambas en la Ciudad de Córdoba; el Complejo Minero Fabril Sierra Pintada, en San Rafael, y el Ex Complejo Minero Fabril Malargüe (ambos en la Provincia de Mendoza), los Ex Complejos Minero Fabriles Los Gigantes (Provincia de Córdoba), La Estela (Provincia de San Luis), Tonco (Provincia de Salta), Pichiñán (Provincia de Chubut) y Los Colorados (Provincia de La Rioja).

A modo de ejemplo, en las tablas 1 y 2 se muestra un esquema de los planes de monitoreo llevados a cabo en la CNA I y el Ex complejo Minero Fabril Tonco, respectivamente.

5. CONCLUSIONES

Desde su conformación, la ARN ha desarrollado y llevado a cabo planes de monitoreo radiológico ambiental rutinarios para las instalaciones más relevantes, en forma independiente.

Actualmente la SGCA de la ARN diseña y lleva adelante dichos planes de manera que le permita auditar más eficientemente los planes propios de las instalaciones reguladas.

Los resultados arrojados por todas las muestras analizadas, obtenidas a partir de los distintos planes de monitoreo radiológico ambiental rutinarios que la ARN ha venido llevando a cabo desde su conformación, indican que se cumple con los límites y restricciones de dosis para las personas del público establecidos en la normativa de este organismo, así como en las recomendaciones internacionales vigentes. Asimismo, se ha verificado que los valores se corresponden con los obtenidos a través de los modelos de cálculo aplicados por la ARN para estimar la dosis en los individuos más expuestos.

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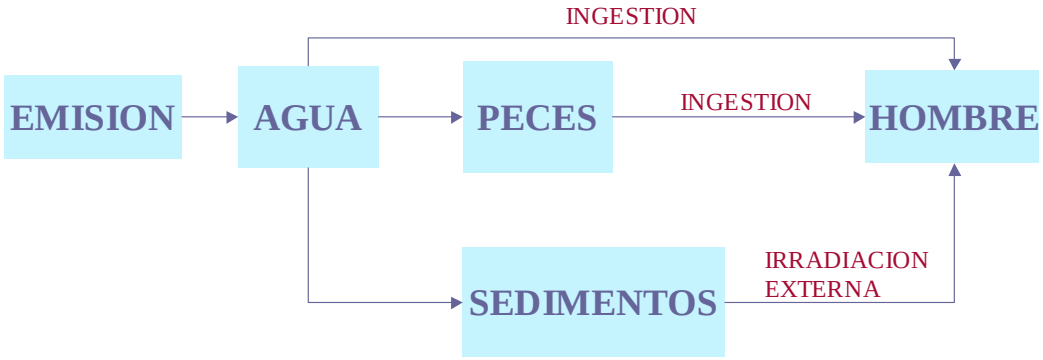

Figura 1. Modelo de dispersión para descargas en cuerpos de agua

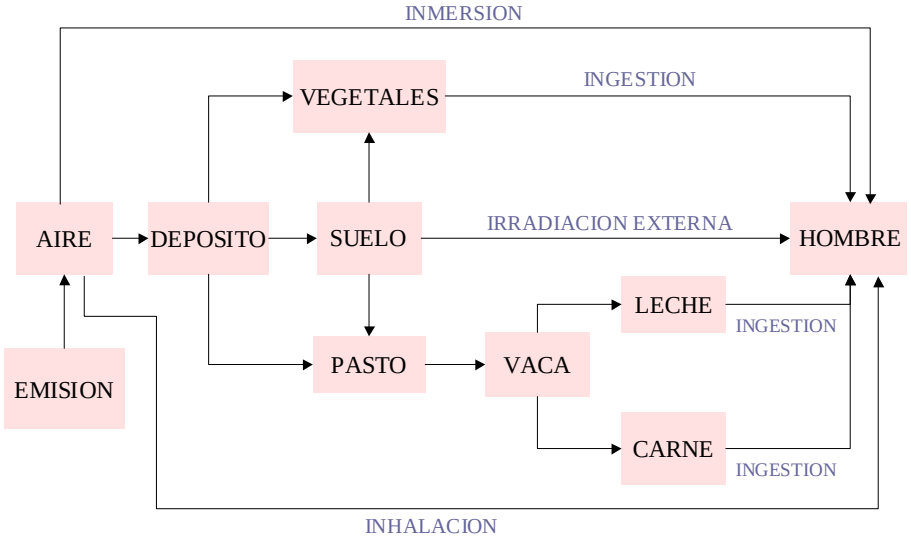

Figura 2. Modelo de dispersión para descargas a la atmósfera

Tipo de muestra	Radionucleido a analizar	Frecuencia de muestreo	Frecuencia de ensayo	Puntos de Muestreo
Tasa de dosis	Emisores gamma	Continua, con dosímetros	Anual	5
Particulado en aire	Emisores gamma	Anual (muestra integrada de 1 semana)	Anual	3
	Sr–90			
	U			
Condensado de humedad	H-3	Continua	Semanal	4
Leche de vaca criada en la zona	I-131	Semanal	Mensual (se analiza muestra de 4ta semana)	1
	H-3			
	Emisores gamma		Pool trimestral	
	Sr-90			
Vegetales cosechados en la zona (verduras de hoja, verduras de raíz, otras verduras y frutas).	H-3	Mensual	Mensual	2
	Emisores gamma	Mensual	Pool Semestral	2
	Sr-90			
Agua superficial (río)	H-3	Contínuo[7]	Mensual[7]	1
		Trimestral	Trimestral	1
	Emisores gamma	Contínuo[7]	Pool trimestral[7]	1
	Sr-90	Trimestral	Trimestral	1
	Emisores alfa y beta	Trimestral	Trimestral	2
Agua de consumo	H-3	En este caso coincide con el agua de napa. El agua de consumo de Lima proviene de pozos de agua		
	Emisores gamma			
	Sr-90			
Agua de napa	H-3	Mensual	Mensual	3
	Emisores gamma		Pool trimestral	3
	Sr-90			
	Emisores alfa-beta	Trimestral	Trimestral	3
Sedimentos de río	Emisores gamma	Semestral	Semestral	2
	Emisores alfa-beta			
Peces	Emisores gamma	Semestral	Semestral	1
	Sr-90			
Suelos	Emisores gamma	Semestral	Semestral	3
	Emisores beta			

Tabla 1. Esquema del plan de monitoreo radiológico ambiental rutinario llevado a cabo por la Subgerencia de Control Ambiental en la Central Nuclear Atucha I.

Tipo de muestra	Radionucleido a analizar	Frecuencia de muestreo	Frecuencia de ensayo	Puntos de Muestreo
Agua superficial	U	Anual	Anual	19
	Ra –226			
Agua de Lago	U	Anual	Anual	1
	Ra –226			
Agua Potable	U	Anual	Anual	3
	Ra –226			
Sedimentos de río	U	Anual	Anual	22
	Ra –226			

Tabla 2. Esquema del plan de monitoreo radiológico ambiental rutinario llevado a cabo por la Subgerencia de Control Ambiental en el ex Complejo Minero Fabril Tonco.

Subcutaneous Heterotopic Calcification Following Abdominal Wall Irradiation

Portas, M; Coppola, A.; Dovasio, F. and Di Giorgio, M.

Presentado en: Conferencia Internacional (ASN) “Modern Radiotherapy: Challenges and Advances in Radiation Protection of Patients”
París, Francia, 2 al 4 de diciembre de 2009

SUBCUTANEOUS HETEROTOPIC CALCIFICATION FOLLOWING ABDOMINAL WALL IRRADIATION

[1]Portas, M; [1-2]Coppola, A.; [2]Dovasio, F. and [3]Di Giorgio, M.

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Argentina

Radiation therapy plays a fundamental role in the local treatment of many tumours. Necrosis, ulceration and fibrosis are well known late effects of therapeutic radiation. Heterotopic calcification (HC) is a rare phenomenon regarded as end-stage damage following high dose radiotherapy.

HC of the abdominal wall is an unusual complication with characteristic findings which allow its diagnosis. Differential diagnosis against osteoradionecrosis and radiation-induced sarcoma is required.

From 1997 to 2008 over 70 patients were referred to the Radiopathology Committee of Hospital de Quemados del Gobierno de la Ciudad de Buenos Aires (Burn Hospital), for the diagnosis and therapy of Cutaneous Radiation Syndrome. Three patients with HC were identified, two of which received abdominal wall irradiation.

The aim of this study is to describe these 2 cases:

The first is a young man who received betatherapy on a colecistectomy scar, in 1984, for hypertrophic scar control. He referred the appearance of blisters on the right lateral abdominal wall, few weeks post exposure, which evolved into a deep ulcer with necrosis. During 2000, the patient was assisted for the first time at the Burn Hospital, showing delayed healing of the wound and began with the protocol treatment: topic administration of trolamine or silver sulfadiazine with lidocaine, associated with systemic administration of pentoxiphiline and anti-oxidants. There was a favorable wound recovery after one year treatment.

He abandoned systemic treatment in 2004 and a new skin lession appeared in the centre of the scar. He was assisted at the Burn Hospital and the protocol was applied. The evolution was favorable for 3 years, after which he abandoned treatment again. During 2008, a polypoid mass lesion associated with heterotopic calcification was observed through both ultrasonographic and clinical evaluation.

The second case is an old woman, irradiated in the 70‘ s for an ovarian tumor. In 2000 she had her first appointment at our hospital presenting with two localized ulcers in the lumbar region, and beginning treatment protocol with a good evolution. However, the patient interrupted treatment. A necrosis (1 x 1 cm) appeared in the left side of the abdomen. After a few months, the lesion was deeper and painful. She attended the hospital and continued with full treatment.

In 2008 there were local and clinical complications (bacterial infection). Treated with I.V. antibiotics and saline solutions for recovery.

The patient needed surgery to clean up the wound, and during that procedure, we identified heterotopic calcifications at the bottom, over rectus abdominis muscles, also observed by ultrasonography. This material was excised to stimulate growth of the granulation tissue. The wound was treated with the use of vaccum to drain the detritus.

As the evolution was torpid, and assuming radiation induced vascular damage as one possible causes of calcification, the patient was treated with hyperbaric oxygen therapy.

In vitro radiosensitivity test results indicated that both patients presented a greater risk than average individuals of developing radiation toxicity and were characterized as hypersensitivity patients.

In both cases there are concurrent features: abdominal wall irradiation, increased reaction to ionizing radiation (e.g. a deficiency in DNA repair), treatment interruption, vascular damage and repetitive inflammatory waves.

In conclusion, we emphasize the importance of being alert to the appearance of HC as a late radiation effect, its prompt differential diagnosis with malignant or bone complications, and its excision to accelerate healing.

SUBCUTANEOUS HETEROTOPIC CALCIFICATION FOLLOWING ABDOMINAL WALL IRRADIATION

[1]Portas, M; [1-2]Coppola, A; [1]Ortega, J.C.; [2]Dovasio, F; [3]Di Giorgio, M.
1 - Hospital de Quemados del G.C.B.A., quemados_dtocirugia@buenosaires.gov.ar
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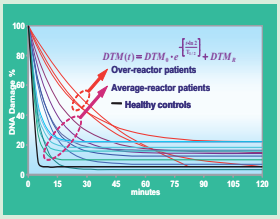
INTRODUCTION

Radiation therapy plays a fundamental role in the local treatment of many tumors. Necrosis, ulceration and fibrosis are well known late effects of therapeutic radiation. Heterotopic calcification (HC) is a rare phenomenon regarded as end-stage damage following high dose radiotherapy. HC of the abdominal wall is an unusual complication with characteristic findings which allow its diagnosis. Differential diagnosis against osteoradionecrosis and radiation-induced sarcoma is required.

OBJECTIVE: From 1997 to 2008 over 70 patients were referred to the Radiopathology Committee of Hospital de Quemados del Gobierno de la Ciudad de Buenos Aires (Burn Hospital), for the diagnosis and therapy of Cutaneous Radiation Syndrome. Three patients with HC were identified, two of which received abdominal wall irradiation. The aim of this study is to describe these 2 cases.

MATERIALS AND METHODS

- The therapeutic response was evaluated through clinical follow-up, serial photographic record and complementary tests: tele-termography, high frequency ultrasonography and histopathology. Therapeutic response and its correlation with radiosensitivity test (alkaline single-cell microgel electrophoresis - comet assay) results were studied.
- DNA repair capacity was evaluated for initial damage and after specific times of repair. Captured images were analyzed by CASP image analysis software, quantified by the Olive tail moment and fitted by a mono-exponential model.

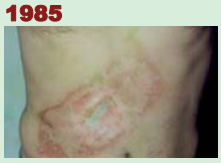


RESULTS AND DISCUSSION

CASE 1

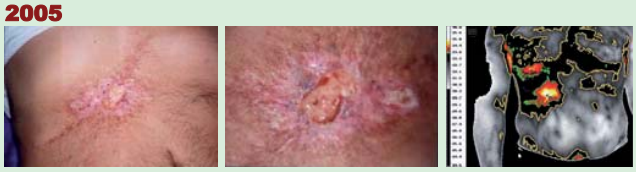
A young man who received betatherapy on a colecistectomy scar, in 1984, for hypertrophic scar treatment. He referred the onset of blisters on the right lateral abdominal wall, few weeks post exposure, which developed into a deep ulcer with necrosis. During 2000, the patient was assisted for the first time at the Burn Hospital, showing delayed healing of the wound and began with the protocol treatment: topic administration of trolamine or silver sulfadiazine with lidocaine, associated with systemic administration of pentoxiphiline and anti-oxidants. There was a favorable wound recovery after one year treatment. He abandoned systemic treatment in 2004 and a new skin lesion appeared in the centre of the scar. He was assisted in our hospital and the protocol was reinstalled. The evolution was favorable for 3 years, after which he interrupted treatment again.

1985



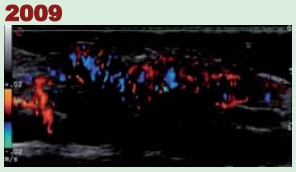
6º day postirradiation: deep ulcer with necrosis in the middle of the scar.

2005



20 years postirradiation: deep ulcer with necrosis in the middle of the scar. Teletermography: a temperature difference of 2 degrees between lesional and perilesional tissues is observed.

2009



Ultrasonography: Increased dermal thickness with a loss of dermoepidermal interfase. Hipodermal increased ecogenicity. The lesion compromises the superficial muscular plane. Increased blood flow both dermal and perilesional.

Patient with a radiological burn (deterministic effect) who develops an exofitic area in the center of the lesion that was biopsied and reported as an Ackerman carcinoma (stochastic effect) 24 years after exposure to beta radiation for cosmetic purposes. Histological evaluation, *Dr. Giongrande - Pathologist -.*

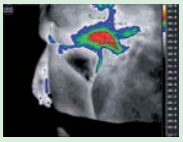
CASE 2

An old woman, irradiated in the 70's for an ovarian tumor. In 2000 she had her first appointment at our hospital presenting localized ulcers in the lumbar region, and beginning treatment protocol with a good evolution. However, the patient interrupted treatment. A necrosis (1 x 1 cm) appeared in the left side of the abdomen. After a few months, the lesion was deeper and painful. She attended the hospital and continued with full treatment. In 2008 local and clinical complications (bacterial infection) appeared. Treated with I.V. antibiotics and saline solutions for recovery.

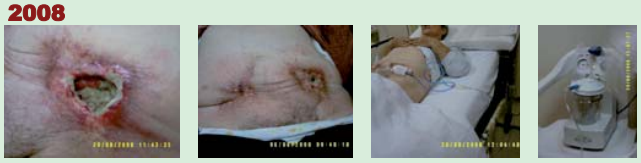
2000

Two lumbar healed ulcers are observed

Teletermography 30 years postirradiation shows differential temperature between the lesion and surrounding tissues



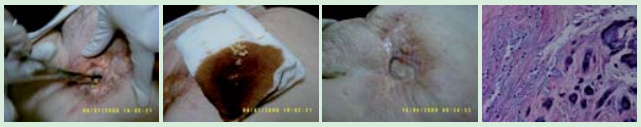
2008



Vaccumm assisted wound closure

2009

Sonography showed a 9 x 8.5 mm ulcerated lesion with increased blood flow in the margins using color Doppler, and multiple calcifications at the bottom. Muscular plane was not compromised.



Removing the HC from the wound during surgery

At present the wound is partially closed

The histopathology shows HC.

CONCLUSIONS

In vitro radiosensitivity test results indicated that both patients presented a greater risk than average individuals of developing radiation toxicity and were characterized as hypersensitivity patients.

In both cases there are concurrent features:

- ✓ abdominal wall irradiation,
- ✓ increased reaction to ionizing radiation (e.g. a deficiency in DNA repair),
- ✓ treatment interruption, vascular damage and repetitive inflammatory waves.

Awareness of the appearance of HC (as a late radiation effect) because this phenomenon delays wound healing.

Cutaneous Radiation Syndrome (CRS) - Long Term Follow-Up Case Report

Portas, M; Coppola, A.; Dovasio, F.; Tadíc, M. and Di Giorgio, M.

Presentado en: Conferencia Internacional (ASN) “Modern Radiotherapy: Challenges and Advances in Radiation Protection of Patients”
París, Francia, 2 al 4 de diciembre de 2009

CUTANEOUS RADIATION SYNDROME (CRS) - LONG TERM FOLLOW-UP CASE REPORT

[1]Portas, M; [1-2]Coppola, A.; [2]Dovasio, F.; [3]Tadíc, M. and [3]Di Giorgio, M.

[1] *Hospital de Quemados del Gobierno de la Ciudad de Buenos Aires,* quemados_informatica@buenosaires.gov.ar
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República Argentina

The present case report was selected from among 70 patients that showed acute and/o late cutaneous radiation reactions with grades 3 and 4 toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European organization for research and treatment of cancer (EORTC).

In the frame of an agreement between the Nuclear Regulatory Authority of Argentina and the "Hospital de Quemados del Gobierno de la Ciudad de Buenos Aires" (Burn Hospital), a Radiopathology Committee for a multi disciplinary approach based on diagnosis and therapy of CRS was constituted in 1997.

The aim of this study is to describe one representative case with a 2 year follow-up.

A 57 year old, female patient with heart disease, heavy smoker, who was exposed to X rays during an interventional procedure(stent) in 2005/September. Early manifestations were blisters, which were diagnosed by a dermatologist as Herpes Zoster infection. Few months later, in the same localization, a deep ulcer with severe pain appeared.

During 2006, the patient underwent a surgical plastic procedure: two rotation flaps were performed to close the wound.

Total necrosis of the rotation flaps, leaving a large ulcer near 20 by 20 cm, occurred. The chronic ulcer was treated with sugar and prone position by general surgeons.

Non specific treatment was installed due to lack of knowledge of the physiopathology of this particular entity (CRS).

Five months later, in her first medical appointment within the Burn Hospital, conservative treatment of late radiation skin lesions was performed according to our protocol as follows:

1. Cleaning of erosive-ulcerous defect,
2. Antibacterial procedure,
3. Anti-inflammatory prevention,
4. Acceleration of epithelium recovery, improvement of microcirculation and blood rheological features.

Following overexposure, the main directions of medical management for persons under care are:

1. Monitoring the health status of patients in order to early diagnose the stochastic and deterministic radiation effects, and preventing the appearance and progression of local complications.
2. Treatment of somatic diseases already present in the exposed patients.
3. Application of new diagnostic methods like serial telethermography, high resolution ultrasound and Eco-Doppler follow-up and individual radiosensitivity tests, which later conform a useful diagnostic tool towards the patient scoring and prognosis.

The following procedures are performed to achieve the goals:

1. Initial evaluation of patients, in compliance with standard protocols, applying the mentioned new diagnostic methods, for the design of personalized therapeutic strategies.
2. Treatment of patients with: topic administration of trolamine or silver sulfadiazine with lidocaine, depending on the type of wound, associated with systemic administration of pentoxifylline and anti-oxidants (vitamins C and E).
3. Evaluation of the therapeutic response monthly (or more frequently if necessary) through clinical follow-up, serial photographic record and ultrasound techniques.
4. Pain management
5. Psychological support

A progressive closure of the wound, using allograft, porcine dermis as temporary skin substitute was observed, thus improving the quality of the new epidermis, and avoiding bacterial infection.

The serial Eco-Döppler studies showed progressive vascularization, in accordance with telethermography. This success was attributed to hyperbaric oxygen procedures and pentoxifylline treatment

After 2 years treatment, under our surveillance, ulcer dimensions were reduced from 20 by 20 cm to 3 by 3 cm, changing dramatically patient's quality of life (QoL).

Quantification of QoL related to disease severity is important in patients with CRS, because such assessment provides additional information to the traditional objective clinical scoring systems.

We postulate that, for the case reported, the use of mesenchymal stem cell therapy would improve the healing of the impaired tissues reducing the successive inflammatory waves.

CUTANEOUS RADIATION SYNDROME (CRS) - LONG TERM FOLLOW-UP CASE REPORT

[1]Portas, M; [1-2]Coppola, A; [1]Ortega, J.C.; [2]Dovasio, F; [3]Tadíc, M; [3]Di Giorgio, M.
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INTRODUCTION

The cutaneous radiation syndrome (CRS) constitutes the most frequent accidental radiological event. It is caused by complex interactions between antiproliferative and proinflamatory process, following a clinically well-defined time pattern. There exist individual variations that could condition the response to ionizing radiation (IR) it is not only accidental but also planned exposures. Deficiencies in DNA repair mechanisms would be involved on hypersensitivity to deterministic effects of IR.

The "Hospital de Quemados del Gobierno de la Ciudad de Buenos Aires" (Burn Center) is one of the reference hospitals of the Medical Radiological Emergency Response Network of Argentina. In the frame of an agreement among the Nuclear Regulatory Authority of Argentina, the Hospital Italiano de Buenos Aires and the Burn Center, a Radiopathology Committee for a multi disciplinary approach based on diagnosis and therapy of CRS was constituted in 1997.

OBJECTIVE: The present case report was selected from among 70 patients treated in the Burn Center, from 1997 to 2009, that showed acute and/or late cutaneous radiation reactions with grades 3 and 4 toxicity criteria of the Radiation Therapy Oncology Group (RTOG).

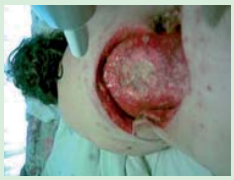
MATERIALS AND METHODS

- The therapeutic response was evaluated through clinical follow-up, serial photographic record and complementary tests (tele-termography and high frequency ultrasonography). Therapeutic response and its correlation with radiosensitivity test results were studied.
- in vitro individual radiosensitivity test applied: cytokinesis blocked micronucleus and alkaline single-cell microgel electrophoresis (comet) assays.
- Following overexposure, the main directions of medical management for persons under care are:
  - ✓ Monitoring the health status of patients in order to early diagnose the stochastic and deterministic radiation effects, and to prevent the appearance and progression of local complications.
  - ✓ Treatment of somatic diseases already present in the exposed patients.
  - ✓ Application of new diagnostic methods like serial Teletermography, high resolution ultrasound and Eco-Doppler follow-up and individual radiosensitivity tests, which constitute the CRS PROGNOSTIC SCORE PARAMETERS for the design of therapeutic strategies

RESULTS AND DISCUSSION

2005

A 57 year old, female patient with heart disease, heavy smoker, who was exposed to X rays during an interventional procedure in September. Early manifestations were blisters, which were diagnosed by a dermatologist as Herpes Zoster infection. Few months later, in the same localization, a deep ulcer with severe pain appeared.



Non specific treatment was installed due to the lack of knowledge on the CRS physiopathology

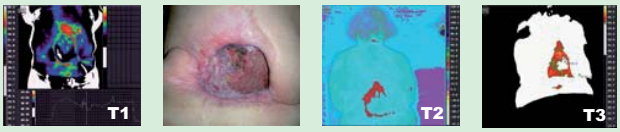
2006

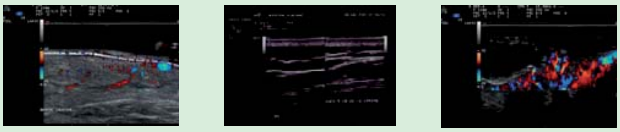
The patient underwent a surgical plastic procedure: two rotation flaps were performed to close the wound. Total necrosis of the rotation flaps, leaving a large ulcer nearly 20 by 20 cm occurred. The chronic ulcer was treated with sugar and prone position by general surgeons.

2007 - 2008

In her first medical appointment at Burns Hospital conservative treatment of late radiation skin lesions was performed according to our protocol as follows:

- Cleaning of erosive-ulcerous defect,
- Antibacterial procedure,
- Anti-inflammatory prevention,
- Acceleration of epithelium recovery, improvement of micro-circulation and blood rheological features.

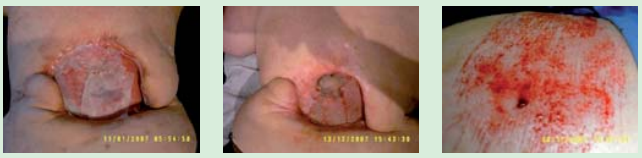




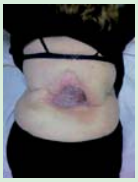
➢ In vitro radiosensitivity test: The patient showed normal radiosensitivity. Complications were attributed to radiation exposure and to comorbidity factors.

2009

Serial Eco-Döppler studies showed a progressive vascularization in accordance with Teletermography (T1-T2-T3).



allograft | autograft | Donor site on the right thigh



A progressive closure of the wound, using autograft, allograft, porcine dermis as temporary skin substitute was observed, thus improving the quality of the new epidermis, avoiding bacterial infection.

This success was attributed to hyperbaric oxygen procedures and pentoxifylline treatment.

After a 2 year treatment, under our surveillance, ulcer dimensions were reduced from 20 by 20 cm to 3 by 1.5 cm, changing dramatically patient's quality of life (QoL).

CONCLUSIONS

The Strategic Treatment is based on:

- ✓ Monitoring the health status of patients in order to early diagnose the stochastic and deterministic radiation effects.
- ✓ Initial evaluation of patients, in compliance with standard protocols, applying the mentioned new diagnostic methods: Teletermography , high resolution ultrasound and Color Döppler follow-up and Individual radiosensitivity tests for the design of personalized therapeutic strategies in each case.
- ✓ Treatment of patients with: topic administration of trolamine or silver sulfadiazine with lidocaine, depending on the type of wound, associated with systemic administration of pentoxifylline and anti-oxidants.
- ✓ Monthly evaluation of the therapeutic response or more frequently if necessary, through clinical follow-up, serial photographic record and ultrasound techniques.
- ✓ Pain management.
- ✓ Psychological Support.
- ✓ Quantification of QoL related to disease severity is important in patients with CRS,
- ✓ For the case reported, the use of mesenchymal stem cell therapy would improve the healing of the impaired tissues reducing the successive inflammatory waves.

Particularidades de las facilidades de disposición final de residuos radiactivos y su potencial impacto en el proceso de licenciamiento

Lee Gonzales, H.; Medici, M.A.; Alvarez, D.E. y Biaggio, A.L.

Presentado en: XXXVI Reunión Anual de la AATN “La Energía Nuclear en el Mundo Actual”
Buenos Aires, Argentina, 16 al 20 de noviembre de 2009

PARTICULARIDADES DE LAS FACILIDADES DE DISPOSICIÓN FINAL DE RESIDUOS RADIACTIVOS Y SU POTENCIAL IMPACTO EN EL PROCESO DE LICENCIAMIENTO

Lee Gonzales, H.; Medici, M A.; Alvarez, D.E. y Biaggio, A.L.

Autoridad Regulatoria Nuclear
Argentina

Resumen:

Las etapas que componen el proyecto de una instalación de disposición final de residuos radiactivos (RR) son: diseño, construcción, operación, cierre y post-cierre. Mientras que las etapas de diseño y pre-operación tienen características similares a las de otros tipos de facilidades nucleares o que trabajan con material radiactivo, las etapas de construcción, operación cierre y post-cierre tienen un significado especial en el caso de las facilidades de disposición final de RR.

Consecuentemente el proceso de licenciamiento, que acompaña las distintas etapas del desarrollo del proyecto, puede verse afectado por las particularidades de las facilidades de disposición final (o repositorios) de RR, apartándose de lo que sería el procedimiento "standard" de licenciamiento para otro tipo de instalación.

En este trabajo se describen las características particulares de las etapas de un sistema de disposición final de RR y se indica que debería preverse un sistema de licenciamiento específico para este tipo de instalación.

1. INTRODUCCIÓN

El licenciamiento de una instalación nuclear es un proceso gradual que acompaña las diferentes etapas de su vida. Para la mayoría de las instalaciones, diseño, construcción, operación, cierre y desmantelamiento (post-cierre cuando se trata de sistemas de disposición final) tienen un significado claro y directo. No ocurre lo mismo en el caso particular de facilidades para disposición final de RR, donde construcción, operación, cierre y post-cierre tienen significados especiales que deben ser considerados en el proceso de licenciamiento.

2. CARACTERÍSTICAS RELACIONADAS CON EL LICENCIAMIENTO DE LAS FACILIDADES DE DISPOSICIÓN FINAL DE RR

Mientras que las etapas de diseño y pre-operación son, en cierta medida, similares a las de otro tipo de facilidades nucleares o que trabajan con material radiactivo, las etapas de construcción, operación, cierre y post-cierre tienen un significado especial en el caso de facilidades para disposición final de RR lo cual podría impactar en el proceso de licenciamiento. Al respecto, se pueden identificar las siguientes particularidades:

(a) La etapa de "construcción" de un sistema de disposición concluye sólo después que todos los RR han sido colocados definitivamente en el repositorio (es decir durante la etapa denominada como "cierre").

(b) Lo que normalmente se denomina como "operación" es el período de tiempo durante el cual los RR están siendo colocados en el repositorio.

(c) En muchos casos es esperable que el período de tiempo entre el comienzo y fin de la "operación" sea bastante prolongado, del orden de varias décadas o incluso sobrepasar el siglo.

(d) Como fue indicado anteriormente, la etapa de "cierre" es aquella en la cual, después de haber colocado en su lugar todos los RR a disponer, los estudios finales confirman que el nivel de seguridad es apropiado y la construcción es finalizada (es posible que, además, se introduzcan modificaciones al diseño original). En cierto sentido, es similar a la etapa de puesta en marcha de un reactor de potencia.

(e) En lugar de desmantelamiento ("decommissioning") la etapa final en el caso de facilidades para disposición final de RR es la de post-cierre, que en realidad es la etapa en la cual el sistema de disposición comienza a operar como tal.

(f) Dependiendo del tipo de instalación (residuos de bajo, medio o alto nivel) el período de post-cierre (que es la real etapa de operación de estas instalaciones), puede abarcar desde siglos a miles de años.

(g) Por último, pero no menos importante, la responsabilidad del operador es transferida al gobierno inmediatamente después de la etapa de cierre o al comienzo de la etapa de post-cierre.

Debido a estas particularidades, en el caso de disposición final la licencia para cada etapa deberá tener características y limitaciones singulares como se explica a continuación.

2.1. Construcción

La licencia de construcción es otorgada cuando las características del sitio y del diseño son considerados satisfactorios. No obstante, solo una parte de la construcción será efectuada antes de que la etapa denominada normalmente como "operación" comience. La etapa de construcción en realidad finalizará después que todos los RR a disponer hayan sido colocados en la facilidad, lo cual puede ocurrir varias décadas o incluso más de un siglo después del inicio. Obviamente al momento de finalizar la construcción las reglas del arte y el conocimiento científico pueden haber cambiado y eso debe ser tenido en cuenta tanto por el operador como por la Autoridad Regulatoria. Es posible entonces que en esta etapa se introduzcan modificaciones al diseño original.

2.2 Operación

Para la mayoría de las facilidades del ciclo combustible nuclear está muy claro qué significa la etapa de operación. Por ejemplo, para una planta nuclear de potencia operación implica que el reactor nuclear está en marcha entregando energía, que es su finalidad.

El objetivo en el caso de un repositorio es colocar los RR en una facilidad específica sin intención de recuperarlos [1]. Entonces, ¿cuál es el significado de "operación" en este contexto? Normalmente se asocia el comienzo del período operacional de un repositorio al momento cuando se reciben por primera vez RR. En realidad, operativamente podría considerarse esta etapa como el comienzo de una especie de "almacenamiento prolongado". Pero teniendo en cuenta cuál es su objetivo final, parece apropiado considerar que la "operación como repositorio" comienza una vez que se a llenado con los RR y el período de cierre ha finalizado, lo cual, como se indicó anteriormente, puede ocurrir varias décadas después de comenzado el "almacenamiento". Asimismo, el significado de "licencia de operación" también podría tener distintas interpretaciones en el caso de instalaciones de disposición final.
Existe consenso sobre la conveniencia de implementar "paso a paso" el proyecto de un sistema de disposición final, incorporando en cada etapa las mejoras en el estado del arte que se vayan produciendo para mejorar la seguridad, considerando también los conceptos de reversibilidad y la posibilidad de recuperar el material como parte de la gestión de los RR [2, 3]. Paralelamente, el licenciamiento de dichas instalaciones debería ser un proceso gradual que acompañe las diferentes etapas del proyecto. Esto podría asimilarse al proceso de licenciamiento de un reactor de potencia, donde inicialmente se presenta un informe preliminar de seguridad, que se completa luego con un informe final de seguridad adecuado que permita otorgar la licencia de operación.

2.3 Cierre

Una instalación de disposición final de RR se considera "cerrada" cuando todo los RR previstos fueron colocados, la evaluación final confirma que el sistema de disposición es seguro y la construcción está terminada [4]. En otras palabras, la etapa de "cierre" del repositorio sería equivalente a la etapa de "puesta en servicio" ("commissioning") de una instalación nuclear o radiactiva convencional; es decir, aquella en la que se han efectuado todas las pruebas y evaluaciones que indican que la instalación puede operar en forma segura, quedando habilitada para pasar a la siguiente etapa del proyecto.

La fase operativa de la instalación de disposición final comienza cuando el sistema está cerrado y comienza la "digestión" de los RR. El objetivo fundamental es la protección de las personas y el medio ambiente contra sus efectos, permitiendo el decaimiento en un sistema aislado de aquellos nucleidos cuya vida media lo permita y asegurando una baja tasa de liberación de RR para nucleidos de vida media extremadamente largo, donde no es físicamente posible considerar que el decaimiento cumplirá un rol relevante.

2.4. Post-cierre y Control Institucional

El período de post-cierre implica que el sistema de disposición está totalmente operativo. Como la seguridad de una facilidad de disposición final de RR está basada exclusivamente en sistemas "pasivos", no tiene sentido

hablar de “programa operacional” como en otras facilidades nucleares. No obstante, usualmente se prevén algunas actividades de post-cierre, como por ejemplo el “control institucional” que se establece durante un cierto período para instalaciones de disposición final cercanas a la superficie (“near surface”).
Obviamente, cuando se aplica control institucional u otra medida que abarque un período extenso (un siglo o más), el control debería ser asumido por el Estado, y en ese caso es muy importante asegurar el compromiso a nivel local y nacional así como la infraestructura necesaria, y los recursos humanos para la preservación y transferencia del conocimiento. Es importante destacar que, entre otras cosas, una licencia para post-cierre normalmente implica que el operador es liberado de su responsabilidad en relación a la seguridad del sistema de disposición.

3. PERÍODOS DE TIEMPO ASOCIADOS A LA DISPOSICIÓN DE RR

Cuando se piensa en la disposición final de RR es muy posible que la primera idea que venga a nuestras mentes sea “tiempo”. Largos períodos de tiempo (posiblemente varias décadas) son asociados normalmente a la etapa de llenado de la instalación y períodos de tiempo aún más largos son asociados a la etapa de post-cierre. Esta situación particular implica que las condiciones de seguridad así como el contexto socio político existentes al inicio del proyecto pueden ser diferentes de las condiciones relevantes existentes al momento del cierre del repositorio, posiblemente más de un siglo después de comenzado el llenado. Esta particularidad debería ser tenida en cuenta en el proceso de licenciamiento, sobretodo en repositorios a gran escala donde el período de tiempo entre el comienzo de la “operación” (en realidad almacenamiento) y cierre puede ser considerable (por ejemplo el caso disposición a gran profundidad en formaciones geológicas).

4. LICENCIAMIENTO Y SUS PARTICULARIDADES

Considerando los períodos de tiempo asociados a las etapas de una facilidad de disposición final, es conveniente que el proyecto sea implementado en un proceso “paso a paso”, suficientemente flexible como para adaptarse a nuevos requerimientos que podrían surgir como consecuencia del progreso tecnológico y/o variaciones en las condiciones socio-económicas o del contexto político. Esto implica que los conceptos de reversibilidad y posibilidad de recuperación de los RR (“retrievability”) deberían ser tenidos en cuenta y considerados aplicables incluso después de que el repositorio sea cerrado [2].

Una de las mayores preocupaciones del regulador se debe a que una vez otorgada la licencia de operación de una instalación de disposición final podría interpretarse que automáticamente se está garantizando la autorización para el cierre de la misma. Además, el regulador debe tener presente que después del cierre la responsabilidad por la seguridad pasa al Estado.
Un modelo de licenciamiento razonable para este tipo de instalación debería tener cierta flexibilidad como para facilitar el desarrollo del proyecto (especialmente en su etapa inicial), dejando abierta la posibilidad de incorporar cambios en los requerimientos regulatorios acordes con la evolución del estado del arte a lo largo de la vida del repositorio.

En Argentina, la Norma AR 0.0.1 establece los lineamientos generales para el “Licenciamiento de Instalaciones Clase I”. No obstante, en el caso de instalaciones de disposición final de RR debería desarrollarse un procedimiento especial adicional que contemple las particularidades de las mismas.

5. CONCLUSIÓN

El proceso de licenciamiento que se aplica a la mayoría de las facilidades nucleares o que trabajan con materiales radiactivos no es extrapolable a las instalaciones de disposición final de RR. En estas facilidades debería aplicarse un sistema de licenciamiento que se ajuste a sus características particulares.

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Particularities of Radioactive Waste Disposal Facilities and their Potential Impact on the Licensing Process

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PARTICULARITIES OF RADIOACTIVE WASTE DISPOSAL FACILITIES AND THEIR POTENTIAL IMPACT ON THE LICENSING PROCESS

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Abstract. During the lifetime of a radioactive waste disposal facility it is possible to identify five stages: design, construction, operation, closure and post-closure. While the design, and pre-operation stages are, to some extent, similar to other kind of nuclear or radioactive facilities; construction, operation, closure and post-closure have quite special meanings in the case of radioactive waste disposal systems.
This paper describes the unique characteristics of these stages of final disposal systems, that lead to concluded that their licensing procedure can not be assimilated to the standard licensing procedures in use for other nuclear or radioactive facilities, and explores, in general terms, alternatives of tailored operational licensing procedures.

1. INTRODUCTION

Licensing of a nuclear facility is a gradual process that encompasses different stages along its lifetime. For most of the facilities, design, construction, operation, closure and decommissioning (post-closure when dealing with final disposal systems) are stages with a straightforward meaning. Nevertheless, in the particular situation of radioactive waste disposal facilities, construction, operation, closure and post-closure have quite special meanings that should be considered in their licensing process.

2. LICENSING RELATED CHARACTERISTICS OF RADIOACTIVE WASTE DISPOSAL FACILITY

While design and pre-operational stages are, to a reasonable extent, similar to other kind of nuclear or radioactive facilities, construction, operation, closure and post-closure of a radioactive waste disposal facility have unique meanings. The following characteristics of radioactive waste disposal facilities have been identified as having a potential impact on their licensing procedures:

(a) The “construction” of a final disposal system is finished after all the waste has been placed into the facility (i. e. during the so called “closure” stage).
(b) The so-called “operation” is the period of time when radioactive waste is being placed into the facility.
(c) Usually the time frames between the start and the end of the “operation” is quite long, embracing several decades or even more than a century.
(d) As indicated above, the “closure” stage is the stage where, after having in place all the radioactive waste intended to be disposed of, all the final safety studies confirm that the level of safety is appropriate and the construction is finished. In some sense, it is similar to the stage of start up of a nuclear power reactor.
(e) Instead of decommission, we have a “post-closure” stage that is in fact the start up of the operation of the final disposal system as such.
(f) Depending on the type of facility (low level waste, medium level waste or high level waste) the post closure period may involve from centuries to thousands of years.
(g) Last but not least, the operator responsibility is transferred to the government immediately after the closure stage or at the beginning of the post closure stage.

These particularities imply that each license granted by the Regulatory Bodies has characteristics and limitations that make them unique as explained below.

2.1. Construction

A construction license is granted when the site characteristics and the design are considered satisfactory by the Regulatory Bodies. However, only part of the construction will be carried out before the so called "operation" start, and such construction will be finalized after all waste intended to be disposed of have been placed into the facility (i.e. several decades or more than centuries later). It is obvious that at the time the construction is finished the state of the art and the scientific knowledge would not be the same and both the operator and the Regulatory Bodies should consider this.

2.2 Operation

In most of the nuclear fuel cycle facilities, there is a clear understanding about what operation stage denotes. For instance, in a nuclear power plant, operation implies that the nuclear reactor is running in a critical status and the facility is delivering energy, which is its objective.

The objective of radioactive waste disposal is the emplacement of waste in a specific facility without the intention of retrieval [1]. So, ¿what is the meaning of "operation" in this case? Usually the beginning of the disposal operational period is associated to the moment when the first waste is received. Nevertheless, this activity should be more properly consider as the operational beginning of some kind of "storage". Bearing in mind the final objective of a radioactive waste disposal facility, it seems appropriate to consider that the "operation as a disposal" begins once its capacity is completed and the closure stage is finished, which, as indicated above, may occur several decades after the starting of this "storage" period. Therefore, the meaning of "operation license" seems to be quite different in the case of disposal facilities.

Confirmation of this interpretation of the meaning of "operation" for final disposal systems seems to be confirmed because during this stage it is recommended a "step by step" program aimed at completing and improving the safety case and, nowadays, also considering the concepts of *reversibility* and *retrievability* as part of the waste management [2, 3]. This can be easily assimilated to the preliminary safety report of a nuclear power plant and the steps taken for completing a satisfactory final safety report for supporting the application for the operating license. Once the "storage" is completed, the disposal system would be ready for the final closure and the "sealed" of the facility.

2.3 Closure

A final disposal facility is "closed" when all the foreseen radioactive waste was introduced in it, the final assessment confirms that the disposal system is safe and the construction is finished [4]. In other words, the "closure" stage of a final disposal facility seems to be equivalent to the commissioning stage of a conventional nuclear or radioactive facility; i.e. all the tests and assessments carried out indicate that the installation can operate safely and then it is possible to proceed to the next stage.

When the system is closed and the "digestion" of the radioactive wastes starts, either by assuring the decay (for those radionuclides whose half life allow it) or by assuring a sloe release of the radioactive waste (for extreme long lived radionuclides where it is impossible to consider that decay will play a significant role) or when the combination of isolation followed by limited release takes place (for half life in between these two extreme situations) the operational phase of the final disposal facility begins.

2.4. Post-closure and Institutional Control

The post-closure period indicates that the disposal system is fully operating. As the safety of a final disposal facility is based only on passive safety systems there is not an "operational program" like in

other nuclear facilities. However, some post-closure activities are usually foreseen, as for instance when "institutional control" is established, particularly for near surface facilities.

When institutional control or other long term active measures apply, they may lasts for a century or more so, it is obvious that such control should be assumed by the State, being very important to keep the support at local and national levels as well as the necessary infrastructure, and human resources for the preservation and transfer of the knowledge. It should be noted that, inter alia, a post closure license usually implies that the operator is released from their responsibility regarding the safety of the disposal system.

3. TIMEFRAME ASSOCIATED WITH RADIOACTIVE WASTE DISPOSAL

When we think about radioactive waste final disposal the first idea that comes into our mind is "time". The long timeframes associated with post closure final disposal are well known as well as the fact that once a repository has been built it will take several decades to fill it up. This particular situation implies that the safety conditions and political and social context at the initial stages of a final disposal facility could be different than the relevant conditions at the time of closure, perhaps a century later. This particularity should be specially considered in the license process, mainly in great scale repositories where the gap in time between starting "operation" (in fact storage) and closure could be considerable (e.g. deep geological disposal).

4. LICENSING ALTERNATIVES

Considering the long timeframes involved at each stage of a waste disposal facility, it is convenient that the development of the project being implemented in and step by step process, be flexible enough as to adapt to new requirements that would arise as a consequence of technology improvements or due to variations in the socio-economical and political conditions. That implies that reversibility and retrievability should be taken into account even after the repository is closed [2].

The licensing process should be gradual and should accompany the development of the different stages of a repository, showing the same flexibility [3]. One of the main concerns that the regulator would face is that whenever an operation license of a final disposal facility is granted it seems that what is really authorizing is its closure. Furthermore, the responsibility is transferred from the operator to the State after the closure of the repository.

Taking into account these considerations, the following alternatives for issuing the operation licensing for a radioactive waste facility are presented:

- Granting directly the operation license for a final disposal facility before starting the initial "storage" stage.

- Granting a license to operate as "storage" with the option of in the future of a license for final disposal conditioned to satisfy the requirements applicable by the end of the storage life time.

Taking into account the reasons presented above, the first option does not seem appropriate. Perhaps it could be convenient in the case of a very simple disposal facility where the time span between the start of operation and closure is expected to be very short (e. g. lest than a decade).

The second option seems to be a reasonably and practical solution for all the parts since it may simplify the process to start the activities at the initial stages, preserving at the same time the possibility to

incorporate changes in the regulatory requirements, according with the evolution of the state of the art along the repository lifetime. However, this option should not aim at relaxing the safety requirements and the long-term safety should be addressed from the design stage.

5. CONCLUSIONS

No direct extrapolation of licensing process applied to other nuclear or radioactive facilities can be made to final disposal facilities. On the contrary, the unique characteristics of these facilites make it necessary to develop a tailored license system.

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Application of Generic Exemption Levels for Radioactive Material

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APPLICATION OF GENERIC EXEMPTION LEVELS FOR RADIOACTIVE MATERIAL

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Abstract. In essence, exemption is an authorization granted by the regulatory body, which, once issued, releases the user of the radioactive source from the requirements that would otherwise apply, in particular, the requirements relating to notification and authorization. The exemption figures included in the Basic Safety Standards BSS 115 were derived from scenarios postulated in the document "Radiation Protection 65" of the Commission of the European Communities considering quantitative exemption criteria. This paper briefly describes and analyses these scenarios and also, describes the status of an implementation guide of these levels in the Argentinean Regulatory System.

KEYWORDS: Exemption, Generic Exemption Levels, Generic Exemption Guide.

1. INTRODUCTION

Exemption is an important tool for improving the efficiency of the radiological control. Conceptually it implies not to spend unnecessarily resources in time and effort of the regulator to control situation where [1]:

- The associated dose (individual and collective) could be considered as "trivial", or,
- The effort to control is judged to be excessive compared to the associated risk.

Argentina has incorporated the exemption concept in the Nuclear Regulatory Authority - ARN regulations, in the following terms: individual effective dose in the most exposed individuals should not exceed 10 μSv/y and the annual collective effective dose should be below 1 man Sv.[2]

The figures mentioned above related to individual dose are based in the fact that 10 μSv/y represent an insignificant change in the background radiation and therefore, the risk level related to this dose is considered trivial (10^{-7}). The collective dose criterion is founded in the ALARA concept. If the collective dose is small, e.g. on the order of one man Sv per year, then protection is often assumed to be optimized, given that regulatory provisions will produce little or no improvement in dose reduction. [3]

The concept exemption was also defined by the document Radiation Protection – 65 [3] as …"*a relief from the obligation to comply with a condition imposed by law or by the public authority. Consequently, the word "exemption" should never stand alone and one should always specify from which requirements or provisions there is exemption*"…

In order to facilitate the application of the exemption concept, the Commission of the European Communities has developed "Generic Exemption Levels" [3] in terms of activity or activity concentration. Basically, if these figures are not exceeded then the exemption could be granted to the user of radioactive material without any further consideration, to the extend determined by each regulatory authority. These figures were later adopted by the IAEA in the BSS 115 [4].
With regard to activity concentration, it should be noted that this generic levels are applicable to moderate quantities of radioactive material (less than one ton) and in cases where the usage of sources is previously justified.

2. SCENARIOS OF EXEMPTION

The Commission of the European Communities (CEC) developed different scenarios, described in detail in the document “Radiation Protection 65” (RP-65), published in 1993, from which Generic Exemption Levels were derived. In the RP-65, the Generic Exemption Levels were calculated for both activity concentration (Bq/g) and total activity (Bq). A total of 3 scenarios and 24 exposure pathways were identified as the most relevant.

A brief description of the scenarios considered is listed below:

- The Normal Use (workplace) scenario represents the use of radionuclides in industry etc, in the manner for which they are intended, and involves external exposure and inadvertent intakes of radioactive materials.

- The Accidental (workplace) scenario represents abnormal procedures or incidents that might occur during the routine use of small amounts of radionuclides. These situations may lead to exposures via a range of external, inhalation and ingestion pathways.

- The Disposal (public) scenario represents a member of the public becoming exposed after the disposal of the source. This situation may lead to external, inhalation and ingestion pathways. Both normal and accidental situations are considered.

3. GENERIC EXEMPTION LEVELS AND DOSE CRITERIA

The Generic Exemption Level for a given radionuclide is defined, as the ratio between the Annual Individual Dose Criteria (Sv/y) and the Dose per unit Activity (Sv/Bq) or the Activity Concentration (Sv/(Bq/g)), as follows:

$$Generic\ \ Exemp\ \ Level\ \ (Bq\ or\ \ Bq/g) = \frac{Annual\ \ \ Individual\ \ \ Dose\ \ \ Criteria\ \ (Sv/y)}{Dose\ (Sv/y)\ \ per\ \ unit\ \ Activity\ \ (Bq)\ or\ \ Act.Concentrat\,ion\ \ (Bq/g)}$$

The Annual Individual Dose adopted corresponds to an effective dose of 10 μSv. In case of skin irradiation an equivalent dose of 50 mSv/year to deal with the possibility of deterministic effects. For potential exposures (fire, spillage) the generic level was derived considering an effective dose of 1 mSv with a probability of 10^{-2} per year is adopted. Doses to individuals in the workplace and to members of the public are obtained for an activity concentration of 1 Bq/g and a total activity of 1 Bq. It is assumed that the initial inventory of radioactive substances remains constant at any time. Each of the scenarios considered give rise to doses via one or more pathways. Doses from the relevant pathways are to derive the Generic Exemption Levels.

Although exemption criteria are based on limits to both individual and collective dose, it should be noted that the latest does not play a significant role. For example, by limiting the maximum individual dose to 10 μSv/year and taking a conservative ratio between the mean and maximum dose of 1/10, the restriction that the collective dose should not exceed 1 man.Sv/year would only be relevant if at least one million individuals were exposed. This situation is almost impossible when dealing with exempted sources, due to the small amounts of radioactive material managed within them.

4. CONSIDERATIONS ABOUT THE SCENARIOS

The scenarios described above embrace a wide range of exposures that may rise from the use of radioactive material. Those scenarios were evaluated by the ARN [5] and the result confirms that conservative parameters have been adopted, maximizing the resultant doses. Specially, it should be stressed out, that the physic and chemicals forms adopted in every case were the most conservative ones resulting in an overestimation of the dose.

According to the assessment carried out, it was suggested that the ARN should adopt the use of the recommended Generic Exemption Levels, in order to improve the regulatory management's efficiency and to optimize the utilization of its human and economic resources. This initiative is presently in course of implementation through the development of a ARN Regulatory Guide.

5. CONSIDERATION ABOUT THE GENERIC EXEMPTION GUIDE

This guide is intended to apply for exemption from certain regulatory requirements related to radiation protection, primarily those of registration by the Nuclear Regulatory Authority.

The Generic Exemption Levels for the use of radioactive substances are presented jointly with the criteria to be taken into account in its application.

The dose criterion used in the Guide is the one that was established in the Argentinean Standard AR 10.1.1 [2] which in turn adopts the same dose value of 10 μSv/year as the RP-65 and the BSS 115 [4].

It was determined that the Nuclear Regulatory Authority (ARN) has to set the Generic Exemption Levels for those radionuclides not listed by the CEC. The ARN is able to develop these levels using the scenarios proposed for the derivation of Generic Exemption Levels.

Activities that were excluded of the application of Generic Exemption Levels are: "in vivo" medical applications, manufacturing, importation or exportation of sources.

6. CONTROVERSIAL TOPICS ARISING DURING THE GUIDE DEVELOPMENT

a. The proper identification of Exemption subject

As it was mentioned in the definition, the exemption shall always be used with a clear indication of the rule, regulation, requirement or condition from which it is exempted. In this sense, it has to be cleared that the subject of the exemption concept is the user of the radioactive substance which is released of the requirement of reporting, contrary to the case of clearance, where the "material" is released from the regulatory control.

b. Accumulation and final disposal of exempted sources

One of the most controversial points was the accumulation of exempted sources. To this end, it was decided to include the following criteria:

$$\sum_k \frac{A_k}{A_{E,k}} \leq 10 \text{ or } \sum_k \frac{C_k}{C_{E,k}} \leq 10$$

Where:

A_k is the activity (Bq) of the radionuclide "k",
$A_{E,k}$ is the activity (Bq) of the generic exemption levels for activity of the radionuclide "k",
C_k is the activity concentration (Bq/g) of the radionuclide "k",
$C_{E,k}$ is the concentration activity (Bq/g) of the generic exemption levels for concentration activity of the radionuclide "k".

This criterion was mainly included to deal with the frequent situation of storage of exempted spent sources (waiting for disposal). In this case, the maximum accumulation number of exempted sources can take a value of up to ten, based in the fact that triviality of doses is indeed a few tens of μSv/year (Safety Series 89 [6]) but given the possible exposure from more than one exempted source this value was rounded down to 10 μSv/year.

c. The case of consumers products

This is probably the wider range and useful field of application of the concept of exemption. However, in most cases the levels of activity and activity concentration exceeds the proposed Generic Exemption Levels, having to demonstrate the compliance of the general exemption criteria in a more detailed case by case analysis including types, models, activity or concentration activity of the source, etc.
In order to accelerate the application of exemption in the Argentinean's regulation it was decided to prepare two separate guides: one for application of Generic Exemption Levels (which is currently under consideration for approval) and another proposed to deal with the more general cases of exception including consumers products which have a radioactive material content that exceeds the generic levels.

7. CONCLUSIONS

Presently, exemptions in Argentina are granted by the application of the exemption criteria established on the regulations AR 10.1.1. through a case by case analyses. However, this procedure is slow and expensive.

To improve this situation, exemption guides are being develop with the objective of adopting on one hand, the levels recommended by the international community and on the other, facilitate the application of the Generic Exemption Levels in a more harmonized way with the international community.

The Argentinean regulatory body, with satisfactory results, performed a thorough assessment about the conservatism of the scenarios and the Generic Exemption Levels proposed by IAEA. Nevertheless, these values were not formally adopted yet. For that purpose, a regulatory guide is currently under development aiming to incorporate these generic levels in the Argentinean regulations.

The development of a second guide has been proposed to deal with potential exemption cases where the activity concentration levels or total activity exceed the Generic Exemption Level, for instance smoke detectors.

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Aplicación de los niveles genéricos de exención para materiales radiactivos

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APLICACIÓN DE LOS NIVELES GENÉRICOS DE EXENCIÓN PARA MATERIALES RADIACTIVOS

"APPLICATION OF GENERIC EXEMPTION LEVELS FOR RADIOACTIVE MATERIAL"

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1. Introducción

La exención es una herramienta fundamental para mejorar la eficiencia del control regulatorio. Conceptualmente, propone evitar el uso de recursos en tiempo y esfuerzo en el control de situaciones donde [1]:

- La dosis asociada (individual o colectiva) puede ser considerada "trivial" y,
- El esfuerzo necesario en controlar puede ser considerado excesivo en comparación con el riesgo ocasionado.

Argentina ha incorporado el concepto de exención en las regulaciones de la Autoridad Regulatoria Nuclear, bajo los siguientes términos: la dosis individual efectiva en el individuo más expuesto no debe exceder los 10 μSv/año y la dosis efectiva colectiva anual debe permanecer por debajo de 1 Sv.hombre [2].

Los valores relativos a la dosis efectiva individual se han basado en el hecho de que 10 μSv/año representa un cambio insignificante en el fondo de radiación natural y por lo tanto, el nivel de riesgo relacionado a esa dosis es considerado trivial (entre 10^{-6} y 10^{-7}).
El criterio de dosis colectiva está basado en el concepto ALARA. Si la dosis colectiva es pequeña, alrededor de un 1 Sv.hombre por año, entonces se asume que la protección está optimizada, razón por la cual el control regulatorio no es capaz de producir mejoras en la reducción de dosis [3].

Asimismo, este concepto ha sido definido por el documento Radiation Protection - 65 [3] como: …"la liberación en la obligación de cumplir con una condición impuesta por la ley o por la autoridad pública. Consecuentemente, la palabra "exención" siempre debe especificar de qué requisitos o requerimientos se está exento"…
Para facilitar la aplicación del concepto de exención, la Comisión Europea ha desarrollado los "Niveles Genéricos de Exención" [3] en términos de actividad o concentración de actividad. Principalmente, especifica que si estos valores no son excedidos entonces puede ser otorgada la exención al usuario de la fuente sin ninguna consideración adicional, salvo que la autoridad regulatoria no lo determine así. Estos valores son los que finalmente han sido adoptados por el OIEA en las Normas Básicas BSS 115 [4].

Es fundamental aclarar, que para la determinación de los valores de exención por concentración de actividad, se supusieron cantidades moderadas de material radiactivo (menores a 1 Tonelada).

En todos los modelos de cálculos se supuso el uso de fuentes previamente justificadas.

Cabe destacar que es el usuario de las fuentes o materiales radiactivos el que está exento de control y no las fuentes o el material en sí mismas. En otras palabras, los productores o proveedores de estas fuentes o materiales están sujetos a control y dicho control, debe asegurar que las fuentes o materiales que llegan a un usuario exento cumplen con los niveles genéricos aplicables.

2. Escenarios de exención

La Comisión de Comunidad Europea (CEC) desarrollo diferentes escenarios que son descriptos detalladamente en el documento “Radiation Protection 65” (RP -65), publicado en 1993, en el cual han sido obtenidos los Niveles Genéricos de Exención (NGE). En el RP-65 los NGE han sido fueron calculados tanto para concentración de actividad (Bq/g) como para actividad total (Bq).
Pueden identificarse un total de 3 escenarios genéricos conteniendo 24 vías de exposición seleccionadas como las más relevantes de entre muchas otras. Este tema fue tratado en detalle en otra publicación [5] por lo cual solo se presentan aquí los aspectos más relevantes.

Se lista a continuación una breve descripción de los 3 escenarios genéricos:

1) Uso normal en el ambiente de trabajo: Escenarios que representan el uso de material radiactivo en la industria, etc. Tiene en cuenta vías de exposición externa y la incorporación de material radiactivo.

2) Accidente en el ambiente de trabajo: Contempla situaciones anormales o incidentes que pueden llegar a ocurrir durante el uso de pequeñas cantidades de radionucleidos. Estas situaciones pueden conducir a exposiciones por irradiación externa, inhalación e ingestión.

3) Disposición (público): Contempla la exposición externa, ingestión e inhalación de miembros del público a partir de la disposición de una fuente exceptuada en un relleno sanitario o situaciones accidentales como la pérdida de dichas fuentes.

3. Niveles Genéricos de Exención y criterio de dosis

El nivel genérico de exención para un dado radionucleido es definido como, la relación entre el Criterio de Dosis Anual Individual (Sv/año) y la Dosis por unidad de Actividad (Sv/Bq) o la Dosis por unidad de Concentración de Actividad (Sv/(Bq/g)), como se transcribe aquí:

$$\text{Nivel Genérico de Exención (Bq or Bq/g)} = \frac{\text{Criterio de Dosis Anual Individual (Sv/año)}}{\text{Dosis (Sv/año) por unidad de actividad (Bq) o Concentración de Actividad (Bq/g)}}$$

La Dosis Individual Anual adoptada se corresponde con una dosis efectiva de 10 µSv/año. En el caso de irradiación de dosis en piel, se adopta una dosis equivalente en piel de 50 mSv/año para considerar la posibilidad de efectos determinísticos.

Para exposiciones potenciales como derrames o incendios, el nivel genérico de exención ha sido determinado, considerando una dosis efectiva de 1 mSv con una probabilidad de 10^{-2} por año.

Las dosis a los individuos en el lugar de trabajo o a miembros del públicos fueron obtenidas para una concentración de actividad de 1Bq/g o de 1 Bq para actividades totales. Esto asume un inventario radiactivo constante todo el tiempo.
Los escenarios considerados han dado origen a dosis por una o más vías de exposición, sin embargo solo las vías que producen mayor dosis han sido las utilizadas para la determinación de los valores de exención, dando como resultados los valores más conservativos.

4. Consideraciones sobre los escenarios

Los escenarios descriptos arriba abarcan un amplio rango de exposiciones que pueden ocurrir durante el uso de material radiactivo.
Estos escenarios fueron evaluados por la ARN [6] y el resultado confirma que los parámetros adoptados y utilizados maximizan las dosis resultantes. Se debe remarcar que en general, las formas físicas y químicas adoptadas fueron las más conservativas lo que conlleva a una sobreestimación de las dosis.

De acuerdo a la evaluación llevada a cabo, se le sugirió a la ARN la adopción de los valores Genéricos de Exención recomendados, a fin de mejorar la eficiencia regulatoria y optimizar la utilización de sus recursos humanos y económicos. Esta iniciativa está actualmente en curso de implementación a través de una Guía Regulatoria.

5. Consideraciones sobre la Guía de Exención

Esta guía pretende ser aplicada para la exención de ciertos requisitos regulatorios relacionados con la protección radiológica, principalmente aquellos como el registro o autorización previa por parte de la ARN. En ella se incluyen los NGE para el uso de materiales radiactivos junto con los criterios que deben ser tenidos en cuenta durante su aplicación.
El criterio de dosis utilizado en la Guía es el establecido la Norma Básica AR 10.1.1 de la ARN [2] que son los valores de dosis de 10 µSv/año presentados en el RP-65 y las BSS 115 [4].
También se incluye en la guía que la ARN tiene la capacidad para determinar el Nivel Genérico de Exención para aquellos radionucleidos no listado por la CEC, a través de la utilización de los mismos escenarios que fueron aplicados para la derivación de los NGE.
Se ha determinado como fuera del alcance de la guía, las aplicaciones médicas “in vivo” y la manufactura, importación y exportación de fuentes radiactivas.

6. Puntos controvertidos originados en el desarrollo de la guía

a. Identificación adecuada del sujeto exento

Tal cual fue establecido en la definición del concepto de exención, se debe indicar claramente de qué requerimientos, condiciones o reglas está el usuario exento. En este sentido se debe remarcar que es el usuario el que será exento de reporte, registro o lo que determine la Autoridad Regulatoria. En contraposición al concepto de dispensa donde el material es el que se libera del control regulatorio.

b. Acumulación y disposición de Fuentes exentas

Uno de los puntos más controvertidos fue la acumulación de fuentes exentas. Para ello, se ha decidido incluir en la guía el siguiente criterio:

$$\sum_k \frac{A_k}{A_{E,k}} \leq 10 \text{ o } \sum_k \frac{C_k}{C_{E,k}} \leq 10$$

Donde:

A_k es la actividad (Bq) del radionucleido “k”,
$A_{E,k}$ es la actividad (Bq) del nivel genérico de exención de actividad para el radionucleido “k”,
C_k es la concentración de actividad (Bq/g) del radionucleido “k”,
$C_{E,k}$ es la concentración de actividad (Bq/g) del nivel genérico de exención para concentración de actividad del radionucleido “k”.

Este criterio se incluye a fin de abarcar las situaciones de acumulación de fuentes gastadas exentas a la espera de la disposición. En este sentido, el número máximo de acumulación de 10 está fundamentado en el hecho de la trivialidad de la dosis aún para algunas décimas de µSv (establecido en el Safety Report 89 [7]) que considerando la múltiple exposición a fuentes exentas se ha redondeado al valor a 10 µSv/año.

c. Productos de consumo masivo

Los productos de consumo masivo, quizá constituyan el uso más generalizado del concepto de exención. Sin embargo, en la mayoría de los casos la actividad o la concentración de actividad excede los niveles de exención genéricos, teniendo así que comprobar el cumplimiento con los criterios de dosis de la exención en una demostración caso por caso.
En ese análisis es necesario incluir el tipo, modelo, actividad o concentración de actividad de la fuente, radionucleido, etc.
Para acelerar la aplicación del criterio de exención en las regulaciones de la ARN, se decidió preparar dos documentos separados: uno sobre los niveles genéricos de exención (el cual está siendo evaluado para su posterior aprobación) y otro dirigido a los casos generales de exención que exceden los niveles genéricos.

7. Conclusiones

Actualmente, las exenciones en Argentina son otorgadas a través de la aplicación del criterio de exención establecido en la regulación AR 10.1.1 en un análisis caso por caso. Sin embargo este procedimiento es lento y costoso.

La Autoridad Regulatoria Nuclear Argentina, con resultados satisfactorios, ha evaluado el conservatismo de los escenarios y los NGE propuestos por el OIEA. Sin embargo, estos valores aún no han sido adoptados.
Con este propósito se está desarrollando la Guía de exención dirigida a incorporar los niveles genéricos de exención recomendados por la comunidad internacional; y facilitar la aplicación de estos niveles de una manera armonizada con la comunidad internacional.

El desarrollo de un segundo documento para abordar los casos potenciales donde los niveles genéricos sean superados, como por ejemplo, en el caso de los detectores de humo, se prevé luego de finalizar la guía sobre aplicación de los niveles genéricos de exención.

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Software to Generate the Accountings Reports and Auditting Files in Text Formats (ICAIFE)

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SOFTWARE TO GENERATE THE ACCOUNTINGS REPORTS AND AUDITTING FILES IN TEXT FORMATS (ICAIFE)

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Abstract. With the objective of improving the security and speed up the processing of the accounting information received at the Nuclear Regulatory Authority, it was requested that the operators of the Argentine facilities send the accounting reports in text files (ASCII format) and using secure e-mail. Additionally, the reception of the accounting reports in text files (ASCII format) make it possible to reduce the time used in processing and evaluating them, from some days to some hours, allowing to send the reports to ABACC (Brazilian-Argentine Agency for Accounting and Control of Nuclear Materials) without introduce any delay. Besides, during the ABACC/IAEA joint inspection, some accounting information (inventories changes updating and itemized list) is required by the agencies in text files in a format previously established to be used in its auditing software. Consequently also it was requested for the operators to prepare these files and give them to the international agency inspectors in the referred formats. In order to provide the operators with a tool to fulfill these tasks, the ICAIFE software (**I**nformes **C**ontables **A**rchivos **I**nspección en **F**ormato **E**lectrónico) was developed by ARN and was fully implemented using Fox Pro. The main function of ICAIFE is to generate the accountings reports (ICRs, MBRs, PILs and Concise Notes) and the auditing files (inventories changes updating and itemized list) in the appropriate ASCII formats based in the information contained in the operator accounting ledgers and in the itemized list and, at the same time, to diminish the quantity of errors contained in them. In this paper the main function and advantages of the software are described. Two workshops for facility operators were given to clarify and train them in the new procedures related with ICAIFE applications. The installation of the software in all Argentine facilities was completed in 2006 and started to be used in routine basis in the first semester of 2007. The software is continuously updated taken into account the comments and observation made by the operators. The two years of experience using the software has shown to be satisfactory to fulfill the ARN proposed objectives.

1. INTRODUCTION

In December 1991, the Agreement between Brazil and Argentina for the Exclusively Peaceful Use of Nuclear Energy entered into force [1]. The agreement, determines the control over all nuclear materials in all nuclear activities in both countries. To verify this commitment, the Common System of Accounting and Control of Nuclear Materials (SCCC) was established and the (ABACC) was created to administer and apply the SCCC [2].

The Quadripartite Agreement (INFCIRC/435), signed among Argentina, Brazil, the International Atomic Energy Agency (IAEA) and Brazilian-Argentine Agency for Accounting and Control of Nuclear Materials (ABACC), entered into force on 4 March 1994 [3]. It is essentially a comprehensive safeguards agreement, based on the INFCIRC/153 model with some modifications due to the existence and the role of ABACC as a binational organization.

In Argentina, the Safeguards Division of the Nuclear Regulatory Authority was appointed as the National Authority (NA) with the responsibility to comply with the commitments assumed in the Bilateral and Quadripartite Agreements.

The Regional System encourage the NA to updated his accounting system in order to improve the security of the accounting information sent to ABACC and, at the same time, reduce the

numbers of mistakes contained the reports. The steps that was taken by the NA to follow this recommendation are shown in the paper.

ACCOUNTING REPORTS

According to the provisions of the SCCC, the NA) must send the Inventory Change Reports (ICRs) to ABACC within 20 days of the end of the month in which the inventory change occurred. The Argentine National Regulations established that the Facility Operators must send the ICRs to the NA, within 5 workings days of the end of the month in which the inventory change occurred. The Material Balance Reports (MBRs) and Physical Inventory Listings (PILs) have the same time limits but with respect to the completion of the Physical Inventory Taking (PIT). This means that NA has, in the best of the cases, a maximum of 10 working days to input, process, evaluate and send the accounting reports to ABACC without introducing any delay**.** It must be considered that the report evaluation includes the detection of mistakes in order to make, whenever possible and with the approval of the respective operators, the necessary correction before sending them to ABACC.

Until the first semester 1996 the reports were sent to ABACC in hard copy by diplomatic mail. In the second semester of 1996 it was implemented the SCMN software (**S**istema de **C**ontrol de **M**aterial **N**uclear) with the capabilities of error detection and the generation of the reports in ASCII format. Consequently the reports began to be sent in diskette until the ending 1999 and since then by secure e-mail [4].

Although the SCMN software has the capacity to input the accounting reports in ASCII format, the facilities operators continue sending them by mail or fax. Consequently a significant part of the 10 working days that NA have for sending the reports to ABACC is used to enter the data manually with the possibility of introducing transcription errors.

Also it is important to point out that the level of security of the accounting reports sent to the NA (mail or fax) is considerably inferior to the one used to transmit the same information to ABACC (diplomatic mail or secure e-mail).

With the objective to solve these disadvantages, in June of 2005, it was decided by the NA:

- to receive the accountings reports only in text files (ASCII formats) according the structure established in the Code 10 of General Procedures of the INFCIRC 435 (the same format that is utilized to send the reports to ABACC),
- to receive by secure mail the text files with the objective to improve its level of security and to make it compatible with the used one to send the same information to ABACC. This means, that the NA must receive the accounting reports only by email encrypted and with the operator's digital signature, using the concept of Public Key Cryptography [5] and the Certificate Authority of the Argentine National Government [6]

To make this points mandatory to the facility operators an official safeguards requirement (RQ SV 01/06) was generated, which was distributed in February to be applied from. May , 2006.

2. AUDITING FILES

In June 1994, the inspections at the Argentine Facilities began under the Quadripartite Agreement. The inspections have been carried out jointly by ABACC and the IAEA including the records auditing activity applying each organization their own procedures.

In 1999 ABACC developed the SARA (**S**oftware de **A**uditoria de **R**egistros de **A**BACC) software for records auditing to be utilized in field during the inspections using a notebook and started to be used in routine basis in the beginning of 2000 [7,8]. By the ending of 2000, ABACC and IAEA decided introduce some modifications in the SARA software in order to implement a joint system for auditing accounting records during inspections. The new **S**oftware

for **J**oint **A**uditing of **R**ecords (SJAR) was fully implemented on September of 2004 and is utilized in all joint inspection carried out since then by the agencies [9].

The SARA/SJAR offer the possibility to introduce some accounting information (inventories changes updating and list of items) in text files in order to reduce significantly the time consumed in this activity and diminish the number or errors due to manually inputting data. In the beginning of 2000, the NA agreed to induce the operators to provide these files in a diskette to ABACC/IAEA inspectors, but only a few installation have been able to give these archives since then.

By June 2005, the NA considered that it is very convenient to provide the auditing files in text format, therefore, it was decided to turn the supply of such files mandatory for the facility operators. Consequently, an official safeguards requirement (RQ SV 02/06) was generated and distributed in February to be applied from May 2006.

3. IMPLEMENTATION

As it was said in the preceding sections, in June 2005 it was decided to implement the requirements RQ SV01/06 and RQ SV02/06 to be effective as of May 2006. The time between the decision and the effective put into force of the requirements is related to the fact that it was decided to use that period to make a software to provide the operators with a tool for the generation of the files necessary to fulfill the RQs.

The ICAIFE software (**I**nformes **C**ontables **A**rchivos **I**nspección en **F**ormato **E**lectrónico) was developed between June and October of 2005 and was fully implemented using Fox Pro. The main function of ICAIFE is to generate the accountings reports (ICRs, MBRs, PILs and Concise Notes) and the auditing files (inventories changes updating and itemized list) in the appropriate ASCII formats from the operators general ledgers. The ICAIFE main characteristics are:

- to define the number and period of the reports,
- to check all the information entered, for example, MBA codes, sign of element/isotope weight, enrichment, etc.,
- to check if the input fields fulfill the Code 10,
- to generate the MBRs automatically,
- to generate the PILs automatically from an itemized list,
- to display the inventory for comparison with the declared one in the operator ledger,
- to calculate the value of physical inventory for each element,
- to input the itemized list from CSV file type,
- to check the relationship between different fields to assure that the numeric information entered is correct, for example, the correlation between gross, net and tare weights,
- to avoid duplication input of equivalent information.

In November 2005, two workshops for facility operators were made with the purpose of:

- clarifying the requirements RQs SV 01-02/06,
- presenting the ICAIFE software giving training on its use,
- explaining how to send secure e-mails and how to obtain the public and private keys from Certificate Authority of the Argentine National Government.

In February 2006, the NA completed the installation of the ICAIFE in all Argentine facilities and started a test period. During the workshops and the test period the operators made comments and suggestions that lead to further improvements in the software.

It is important to point out:

- all the accounting reports are received in text files via e-mail from March 2006 with a significant reduction of the errors,
- the auditing files are being given to the ABACC/IAEA inspectors from July 2006,
- the use of secure e-mail was completely fulfill in the second semester of 2006.

In November of 2007, was made a new workshop with the participation of the ICAIFE users in which they gave his experiences and suggestion to improve the software. Also during 2007 is received the experiences from ABACC and IAEA inspectors

Based in the comments received, during 2008 is written the version 2.0 of the software improving essentially the format of the file with the itemized list and the prints of them.. In the second semester will be given new courses for the operators for the version 2.0 and in the will be completed their installation in all the argentine facilities.

4. CONCLUSION

The development of ICAIFE software was possible in a considerable short time and has been permanently improved taking into account the comments and suggestion of the facility operators. The software developed has shown to be highly satisfactory to fulfill the objective of the requirements RQ SV01/06 and , partially, of the RQ SV02/06.

Practically all the accounting reports are received by secure e-mails increasing significantly their security level. The reception of the accounting reports in text files (ASCII format) make it possible to reduce the time used in processing and evaluating them, from some days to some hours, allowing the NA to send the reports to ABACC without introduce any delay and , at the same time, with practically no mistakes.

With the ICAIFE 2.0 is to be hoped to resolved the problem referred to the itemized list and, consequently, reduce the time consumed by the inspector in this activity.

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New Medical Practices: a Challenge for Regulatory Bodies

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NEW MEDICAL PRACTICES: A CHALLENGE FOR REGULATORY BODIES

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Abstract: The Regulatory Bodies should face the regulation for new medical practices to assess the radiation protection of workers and patients, the safety of the installation and reduce subjectivity in their regulatory decisions. In many cases this could result in adapting or preparing new regulations, developing new licensing requirements and adjusting their regulatory processes.
It is known the nuclear regulators difficulty regarding the radiation exposure to patients for medical purposes. So that, in this paper, those topics that could contribute positively for optimizing the radiation exposure to patients, like cooperation with professional societies in general and the medical profession in particular, are analyzed with the aim of proposing new strategies to deal with.
Finally, the case of workers is analyzed considering the increase of new medical practice involving radiopharmaceuticals and a proposal for a revision of occupational exposure surveillance to assure their radiological protection is presented.

1. INTRODUCTION

Medical exposures are the most important contribution to the human exposition from artificial ionizing radiations. Since statistics indicate an increasing number of practices and facilities, it is relevant to assure the radiation protection of workers and patients and the safety of the installation and Regulatory Bodies plays a significant role in promoting a high level of radiation protection.

It is of interest to focus on how to improve the regulatory process to face new medical practices since a balance should be achieved between: too many or not enough. The challenge for the regulator is to establish a regulatory structure that helps to minimize unintended risks, while avoiding undue interference in medical judgments.

Too many regulations can result in medical or technological needless delay while too few regulations can lead to an increase in misadministrations and the likelihood for patients, medical staff, and the public to receive unjustified exposures.

A careful balance must be attained in establishing an appropriate regulatory regime. Regulation should provide the appropriate vehicle for reducing radiation risks, avoiding unnecessary doses and maximizing the beneficial uses of medicine.

2. A PROPOSAL FOR FACING THIS REGULATORY BODY CHALLENGE

Based on the experience in some countries, the cooperation between radiation users and Regulatory Bodies seems to be the best approach for optimizing the radiation patients exposures, and for reducing workers exposures. The next topics of this point addressed possible ways for achieving this aim:

2.1 Regulatory Bodies guides

The need for producing and revising the Regulatory Bodies guides could come through changes of regulation or arise from the issues identified during regulatory control activities.

Radiation users meet inspectors from Regulatory Bodies regularly on the installation visits, but it seems not enough. Other positive interaction should be the promotion and the developed of specific guides in collaboration between them.

2.2 Regulatory Bodies Research and Development (R&D) Projects

The R&D Projects could be the bases for supporting new regulations or new licensing requirements.

The Regulatory Bodies could constitute multidisciplinary expertise teams specialized in performing measurements of radiological parameters of interest for occupational control of workers exposure. It means, teams with the capability to design and implement integral monitoring including area monitoring (activity air measurements, dose rates, sweep test) and individual monitoring (internal and external) for assessing the effective dose of workers in routine operations in order to verify the radiological safety conditions.

The outcomes of these R&D projects could be of help to identify the need to update Regulatory Bodies requirements for new medical practices.

2.3 Regulatory Bodies in education and training

The Regulatory Bodies should actively promote the organization of workshops for radiation users. Some of them have professional associations that organize their periodic meetings, but radiation protection issues are not traditionally included in the program of such meetings or particular radiation protection problems are not addressed to the extent necessary.

The promotion and participation in these activities could be made possible to promote discussions and will play a major role in creating common strategies for education and training in radiation protection. The Regulatory Bodies could illustrate actual situations showing the outcomes of R&D projects and giving advice on possible radiation protection actions aimed at improving the current situation.

2.4 Regulatory Bodies in users procedures

The Regulatory Bodies jointly to radiation users associations should establish workgroups for preparing procedures to minimize radiation exposure during normal operation and to prevent the occurrence of potential exposures.

Valuable information could be exchange for deciding the best modality for future training in the implementation of procedures. The role of the Regulatory Bodies would be mainly as coordinator and contributor through the participation of their experts.

2.5 Regulatory Bodies and the continuously improving

The information reported by the inspectors could be useful as a baseline for new cooperative training and for the optimization of new medical practices. All the abnormal incidents or situations occurred or suspected should be reported in an annual report on radiation protection. The discussion in an annual openly meeting should be promoted so that lessons should be learned and some weaknesses could be foreseen.

These activities should be an opportunity for Regulatory Bodies to disseminate relevant concepts published by the IAEA, [1], [2], and recommendations from ICRP on this field [3], [4], [5], [6]. Particularly, ICRP Committee 3 is concerned with protection in medicine and in recent years has produced many publications with detailed advices on different aspects of the radiological protection of patients. The most recent, Publication 105: “Radiological Protection in Medicine” [7], was written as a foundation document for the Commission’s 2007 Recommendations.

3. CONCLUSIONS

This paper proposed that the challenge for Regulatory Bodies since the increasing of the new medical practices may be better face through the collaboration with radiation users, particularly the development of Regulatory Guides, the implementation of Regulatory R&D Projects and the involvement in education and training activities.

The advantage of the cooperation between Regulatory Bodies and radiation users could be to maximize the special knowledge with minimal resources.

The competence of the authority could be strengthened with the practical knowledge from radiation users and the radiation protection will be consolidated by applying the approaches summarized above.

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National Authorithy Role in the Implementation of SNRI Regime to a Fuel Fabrication Plant in Argentina

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NATIONAL AUTHORITHY ROLE IN THE IMPLEMENTATION OF SNRI REGIME TO A FUEL FABRICATION PLANT IN ARGENTINA

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ABSTRACT

The Short Notice Random Inspection (SNRI) regime has been approved to be applied to the commercial Fuel Fabrication Facility (FECN) in Argentina since June 2008.

This facility comprises two separate production lines that handle natural and low enrichment uranium (LEU) on a continuous production regime. The current design capacity is the processing of 119 tons per year of natural uranium to produce 5000 CANDU type fuel elements and 94 tons per year of low enriched uranium to produce 500 ATUCHA I fuel assemblies.

In 2009, is foreseen the starting of the Atucha II fuel assemblies production campaign, which would increase the capacity for processing natural uranium up to 220 tons per year by adding a third separate production line.

The introduction of this new safeguards regime involves the implementation of some innovative elements that have impact on the operation of the facility such as the retention periods on nuclear material subject to be transferred and the operational mailbox declarations following a predetermine agreed schedule. In addition, the access to the nuclear material has to be supported by daily updated inventory lists, in order to fulfill the IAEA and ABACC inspection requirements.

Despite the small capacity of the facility, the application of this new safeguard approach has implied a challenge due to the characteristics and operational schedule of the facility. In this regard, the National Authority (ARN) has played an important role, in order to train either the operator or national inspectors in the related inspections procedures and to encourage the operator to improve the housekeeping at products and raw material stores in order to facilitate the inspection activities.

This paper presents the activities done by the ARN regarding training, field trials, specific arrangements, etc., not only with the facility staff but also with the national inspectors. Besides, it shows the experience obtained after one year of SNRI applications and the next steps to follow.

Keywords: FFP safeguards approaches, domestic transfer verification methodologies,

1.- INTRODUCTION

Since 1994, full safeguards procedures have been applied to all fuel fabrication facilities in Argentina. According to the new version of the Safeguard Criteria, the SNRI regime must be applicable in those facilities handling inventories/throughput higher than 2 SQ. At present, there are four fuel fabrication facilities in Argentina, but only the commercial one met the condition to apply the new regime. This facility produces simultaneously fuel assemblies of natural uranium required in Embalse and Atucha II NPP and low enriched uranium fuel assemblies for Atucha I NPP. All of them are on load reactors consequently, the commercial facility operates under continuous production regime.

Until 2006, the Safeguards Criteria required the verification of the inventory of nuclear material once a year and at least 20% of the nuclear material, per category type, involved in domestic and international transfers. Other objectives like the verification of strategic points, operator's measurement system, blending activities and other inventory changes, were normally addressed in connection with the PIV or interim inspections activities. In addition, provisions to cover the borrowing scenario have to be taken

when applicable. Verification activities serving timely detection purposes are not foreseen in this type of facilities since none of these facilities operates with plutonium or high enriched uranium.

The commercial facility of Argentina is a fuel fabrication plant that receives the UO2 powder and produces pellets, fuel rods, LEU fuel assemblies, NU fuel bundles and NU fuel assemblies. At present, the design capacity is approximately 240 tons of natural uranium to produce 5000 CANDU type fuel bundles and 500 Atucha II fuel assemblies, and 100 tons of LEU to produce 500 Atucha I fuel assemblies in a year. To obtain 0.85 % low enriched uranium required for fuelling the PHWR Atucha I NPP, blending of LEU up to 5% enrichment is carried out with natural uranium at the facility. The major domestic receptions are natural UO2 powder produced in a conversion facility. The major domestic shipments are the transfers of fuel assemblies and fuel bundles to the on load reactors and, occasionally, scrap material is shipped to the conversion facility to be recovered. The major international transfers are occasional imports of LEU powder. Up to two receipts per month of natural UO2 powder and normally up to two shipments per month for each on load reactor are foreseen under normal production schedule.

During 2006, ABACC informed Argentina that an SNRI regime will have to be in place by the end of year. At that moment, the goal was to start in 2007 the evaluation of the fuel fabrication plants and conversion facilities according the new criteria. Taking under consideration the additional burden on the operators and national authorities introduced by the new regime, immediate discussions started among the parties. Due to some particular characteristic of our regional system, special provisions were necessary related with channels of communications, operational declarations, triggering and coordination of joint inspections, formal notification to the facility operators, etc. In particular, the methodology for international receipts verifications was reviewed.

As final agreement was only reached by July 2008, the Fuel Fabrication Plant did not meet the safeguards goals on 2007. During 2008, the simultaneous application of the old and new approaches allows the achievements of the safeguards goals.

Until now, it was not possible to reach an agreement on the conversion facility yet.

2.- PRO AND CONS OF THE NEW REGIME

The inspection activities and methodologies considered in this new regime are aimed at achieving the following objectives:

a) To improve the safeguards effectiveness through the introduction of unpredictable interim inspections.
b) To make possible 100% coverage of the flow term of the annual mass balance.
c) To make the borrowing scenarios more susceptible to be detected.
d) To make false reporting more difficult to be concealed.
e) To improve the detection probability of abrupt diversion.
f) To provide a better confirmation that the facility operates as declared.

The new regime is considered more effective than the old verification strategy. However, from the operational point of view, its implementation reduced the flexibility in the operational program, it introduces undesirable death time in the availability of the feed material and final products and required extensive and more frequent provision of data. Consequently, extra burden on the operators and national authorities is required.

3.- ISSUES RELATED TO SNRI REGIME IN THE REGIONAL SYSTEM.

The implementation of this new approach required the introduction of changes in old practices. In order to avoid duplication of efforts between ABACC and the IAEA, new arrangements regarding notifications, coordination of inspection activities and verification of international transfers had been discussed and agreed with the state parties.

a) Provisions to avoid the duplication of efforts.

The Quadripartite Agreement establishes the duplication of efforts should be avoided whenever possible. In this regard, a joint inspection program was adopted as the most efficient strategy. Argentina as a state party requested an average number of 3 interim inspections/year over a three years period in order to give enough flexibility to IAEA/ABACC inspection programs. In addition, all inspection activities were required to be completed in one day in order to avoid excessive burden on the operator. No restrictions on the quantity of inspector per team were introduced.

b) SNRI notifications arrangements

Under the traditional approach, the IAEA notifies in advance to the regional system the inspection activities and the regional system is responsible for the coordination with the state parties.

The triggering organization assumes the responsibility to notify the other ones, and the national authority its intention to carry out a SNRI. The notification must be received by the state party 24h in advance. It was agreed that the triggering organization will coordinate the inspection.

The National Authority assumes the responsibility to notify the inspection to the operator timely.

The identification of the inspectors, their documentation, and the inspection starting time must be included in the notification to the State Party.

This arrangement is valid only for SNRI notification. All the other inspections will follow the traditional practice, according to the Quadripartite Subsidiary Arrangements

c) Verification of international transfers

The General Procedures of the Common Accounting and Control System of Nuclear Materials (SCCC) established under the Bilateral Agreement for Peaceful Uses of the Nuclear Energy - signed between Argentina and Brazil- requires the verification by ABACC of all the international transfers of more than one effective kilogram. In order to facilitate the application of SNRI approach, this arrangement was modified.

Only for fuel fabrication facilities with SNRI regime implemented, the international transfers will be verified at the moment the SNRI takes place. Due to the fact that the imported material is immediately required as feed in the fabrication process, *the remainder material not yet processed, available at the facility at the moment the SNRI takes place, will be verified in order to confirm the international transfer.* In addition, retention period will not be requested for imported materials under SNRI regime.

d) List of item subject to verification.

The main objectives of the SNRI inspections are the verification of nuclear material involved in domestic and international transfers and to cover the internal borrowing scenario. The nuclear material under verification must be included in a List of Inventory Items (LII). This List must be provided to the inspectors upon arrival at the facility.

As the SNRI regime deals with the flow term of mass balance equation, nuclear material corresponding to intermediate compounds are not submitted to verification. All the nuclear material received and produced under the retention period shall be available for verification. In addition, the nuclear material received and not yet processed and the nuclear material ready to be shipped, with retention period concluded and available for verification at the facility, shall be included in the list.

Nuclear material involved in domestic and international transfers, previously verified and still available at the facility, shall also be included in the list and identified. This material will be verified differently following the borrowing scenario provisions.

e) Verification of nuclear material

All nuclear material involved in domestic transfers included in the list and not yet verified will be verified applying a fixed sampling plan.

All nuclear material involved in international transfers, if present at the facility, shall be verified with medium detection probability at the same level of the fixed sampling plan.

All nuclear material included in the list and identified as previously verified will be verified for gross defect with low detection probability.

In this approach a fixed sampling plan is defined based on the annual throughput. This plan establishes the quantity of items to be verified and the level of verification (gross, partial and/or bias defect) n per stratum. The quantity of items to be verified per stratum in the plan is not related with the total population available for verification at the moment the SNRI takes place.

Consequently, different criteria are applied. Fixed sampling plan is used for domestic transfers and traditional sampling plan for international transfers and internal borrowing scenario.

f) Operator declarations to support SNRI

Requirements to provide the information indicating expected dates for international transfers of nuclear material and the annual operational programs are clearly established in the Subsidiary Arrangements of the Quadripartite Agreement.

In addition to these provisions, the new regime requires weekly SNRI declarations to support the verification activities. In the traditional practice, all the operational and accounting information from the states parties were sent to IAEA through ABACC. In order to support the new approach, ABACC and the states parties have accepted that the SNRI declaration will be provided simultaneously to ABACC and IAEA, via encrypted e-mail.

Besides the information foreseen in the SNRI declaration regarding each item within the retention period, each two month, the operator provides additional information on voluntary basis. This information consists on the identification of the UO2 powder drums fed to the process and the fuels sent to the NPP. This confirmation helps the inspectors to define the population of items subject to verification at the beginning of the inspection.

Any voluntary information is reviewed by the national authority before their inclusion in the SNRI declaration.

g) Records and report auditing.

In order to follow the provision in the Quadripartite Agreement regarding non duplication of inspection efforts, it was agreed that in case the non-triggering organization cannot participate in the SNRI, only the SNRI declarations will be checked for correctness and consistency against supporting documentation. The complete book auditing will be performed in the next joint inspection.

h) Retention periods

The retention period is the period of time when the nuclear material involved in domestic transfers cannot be processed or shipped to be available for verification at the facility. It was established 6 working days, introducing special provisions regarding quality assurance of the fuel assemblies and DA sampling of UO2 powder. The fuel elements can be included in the SNRI declaration before concluding the quality assurance control and the drums can be sampled during the retention period while the labels are updated. Rejection of fuel elements is introduced as correction in the next SNRI declaration. As result, in this particular case the retention period became double.

4.- ON JOB TRAINING

To apply the procedure it was necessary the introduction of some modifications in the format requested by the agency regarding SNRI declarations in order to avoid additional burden on the operator regarding weekly declarations. In the case of shipments (produced fuel assemblies or UO2 powder and scraps) it was decided the use of integrated and accumulative electronic list with the corresponding packing list attached in electronic form. For domestic or international receipts (UO2

powder), due to the electronic packing list is normally not available before the reception date, it was decided to provide a scanned copy of the packing list as SNRI declaration. Even though this solution diminishes the operator burden but increase the size of the electronic file.

Two field trails were coordinated with the agencies to identify issues that could affect the duration of the inspection and to train the operator regarding the daily updating of the inventory list, operational practices in order to speed up the counting and identification activities in the raw material and product storage. As result of the fields trials it was concluded that at least three inspectors for each agency should be necessary to complete the inspection activities in one day. The first team is responsible to consolidate the list of material under verification, book auditing and DA sampling. The second team is in charge of neutron collar mounting and set up, and fuel elements verification. The third team is in charged of powder verification.

As the facility normally works with high inventory in the powder storage the verification of this stratum is the most time demanding, it was necessary to improve some operational practices in order to facilitate the inspection activities in this KMP. Some recommendations were provided to the operator by the National Authority regarding to assure an easy visual access to tags data in order to speed up the counting and identification inspection activities.

Finally, it was decided to carry out the national inspection without advance notification in order to train the operator and to detect any other problem with the implementation of the new procedure. During 2008, it was necessary to carry out six national inspections to adjust details of the SNRI procedure.

5- CONCLUSIONS

Since July 2008, the new regime is being satisfactorily applied in the commercial fuel fabrication facility (CONUAR SA). Three joint ABACC and IAEA SNRI inspections, including the field trial, were carried out for 2008 material balance period. Two additional joint SNRI have been triggered for the present period.

Even though, the new regime has required additional effort from the national authority and the operator side, it is important to highlight that the changes introduced in the operational practices to apply the new regime, have had a positive impact on the safeguards application at facility level. The last physical inventory verification was less time consuming, the MUF was significantly lower than the value obtained under the old regime and the coverage of domestic and international transfer was higher than 20%. Finally the accuracy of the inventory lists improved significantly.

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Down Regulation of *HLA-G* in Melanoma Cell Line Non Uniformly Irradiated by Exponentially Decreasing Low Dose Rate of Beta Particles

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DOWN REGULATION OF *HLA-G* IN MELANOMA CELL LINE NON UNIFORMLY IRRADIATED BY EXPONENTIALLY DECREASING LOW DOSE RATE OF BETA PARTICLES

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INTRODUCTION AND OBJECTIVES

Beta-emitting radiopharmaceuticals are finding wider applications in cancer treatment, such as radio immunotherapy, bone-seeking radiopharmaceutical therapy, and in brachytherapy applications, but in each situation, non-uniform dose deposition exists.

The HLA-G molecule is a non classical HLA class I antigen and contribute to tolerance of fetus by inhibiting maternal immune response, and its expression in tumor cells may favor their escape from host immune surveillance. The objective of this work was to analyze HLA-G expression in a human melanoma cell line after external inhomogeneous beta irradiation at different dose and dose rate.

MATERIALS AND METHODS

Melanoma cell line (FON), HLA-G+, was continuously irradiated by an external ^{32}P source at 37°C until the programmed total dose was obtained. The absorbed dose was calculated applying MCNPX 2.5f Monte Carlo code for the 25 cm^2 tissue culture flasks.

Membrane HLA-G detection was performed by flow cytometry with specific antibodies at the end of irradiation.

RESULTS

The final dose ranges from 100% in the center of the flasks to the 67% at the external limit. The value of dose and dose rate shown represent the average value calculated by the Monte Carlo code.

The cells were irradiated at 30 and 10 Gy with initial dose rate of 250 ± 30 mGy/hour.

The median fluorescence index (MFI) for HLA-G expression was 0,60 and 0,78 with respect to controls. For cells irradiated at 10 Gy with 45 mGy/hour the MFI was 0,82 and with doses ranging from 1 to 3 Gy at 25±5 mGy/hour the MFI was 0,85%. There was not induction of down regulation with 1 Gy at 4 mGy/hour.

CONCLUSIONS

For high doses (10-30 Gy) the down regulation of HLA-G at the same dose rate is dose dependent.

At relatively low doses (1-3 Gy) and low dose rate (25 mGy/h), HLA-G down regulation is still induced. The data suggest that dose rate about 4 mGy/hour could indicate a threshold for this effect.

This synergism between HLA-G down regulation expression and the killer activity of beta particles could increase neoplastic cells rejection by immune system.

Increasing Cooperation between IAEA, ABACC and the National Safeguards System in Argentina

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INCREASING COOPERATION BETWEEN IAEA, ABACC AND THE NATIONAL SAFEGUARDS SYSTEM IN ARGENTINA

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ABSTRACT

Several points in the Quadripartite Agreement establish cooperation activities that must be performed with regard to nuclear safeguards. Following these directives, the ABACC and the IAEA have been working together in the development and improvement of safeguard approaches, in modern and secure communication systems, inspector training and on the resolution of implementation problems.

There is a permanent request from the state system to both agencies to coordinate their task, with the goal of an efficient management of the cost-benefit in the safeguard activities. The cooperation within the framework of the Quadripartite Agreement is an on going activity and the success of a regional and an international safeguard system working together, relies on the good coordination between the parties.

At the state level the responsibility of the regulatory body in the safeguard area is to preserve the fulfillment of international commitments, to update the nuclear material inventories as required, to evaluate the radiological risks and their impact on the safeguards activities and to optimize the economic burden on the operator due to safeguards activities.

In this paper ARN presents its view on the permanent interaction between the Argentine National Safeguards System, the IAEA and ABACC. The review of some local regulations in line with the new safeguards approaches proposed and the recent progress on the implementation of an unattended system aimed at reduction the inspection effort dedicated by ABACC and IAEA to monitor the spent fuel transfer campaigns to dry storage at Embalse NPP including conditions to start the state of health transmission are reported.

1. - INTRODUCTION

At the end of 1980s, Argentina and Brazil reaffirmed their decision to provide mutual transparency to their nuclear programs. Both countries assume the commitment to use all nuclear materials and nuclear facilities exclusively for peaceful purposes.

It was within this context that they created the Common System for Accounting and Control of Nuclear Materials (SCCC) as a comprehensive bilateral safeguards system and the Brazilian Argentine Agency of Accounting and Control of Nuclear Materials (ABACC) as an independent regional body.

At the end of 1990s, the states parties and ABACC signed with the IAEA a comprehensive safeguards agreement based on the SCCC and on the INFCIRC/153 model. The application of a comprehensive safeguard system started when the Quadripartite Agreement entered in force in March of 1994.

The Quadripartite Agreement is the legal instrument that regulates the relationship between the States Parties, the ABACC and the IAEA. The essential part of the agreement is the SCCC, in which emphasis is made on the fact that ABACC and the IAEA are partner institutions that must work in a way to apply effective and efficient safeguards to nuclear materials.

2.- COORDINATION BETWEEN THE NATIONAL AND THE INTERNATIONAL SYSTEMS

International inspections are carried out in cooperation with the state counterpart, following certain fundamental premises as follow:

a) The inspectors should know the radiation protection, safety, and physical protection procedures that have been implemented in the facilities being inspected.

b) The inspectors should avoid the undue interference with the nuclear activities in the state.

c) ABACC and IAEA inspectors should avoid the duplication of inspection activities in the field.

d) The agencies should maintain confidentiality regarding the technological development information.

On the other hand, each state party assumes certain commitments that, in the particular case of Argentina, can be summarized as follow:

a) The state should provide the administrative and technical support, in order to assure that either IAEA or ABACC inspectors should meet their inspection goals.

b) The State party must provide access conditions that assure doses as low as possible -below the dose limits- and proper support under any potential dangerous or accidental situations.

c) Both agencies should be informed in advance about any change in the current regulations or access procedures.

3.- COOPERATION AMONG ARGENTINA, ABACC AND THE IAEA.

Several points in the Quadripartite Agreement establish cooperation activities that must be performed with regard to nuclear safeguards. Following these directives, the ABACC and the IAEA have been working together in the development and improvement of safeguard approaches, in modern and secure communication systems, inspector training and on the resolution of any implementation problem detected.

The cooperation within the framework of the Quadripartite Agreement is an on going activity and the success of a regional and an international safeguard system working together, relies on the good coordination between the parties.

3.1.- Modification of Radiation Protection Procedures to implement the SNRI regime

The national regulation in line with the international recommendations on radiological protection must be taken into account in the safeguard implementation. At the state level the responsibility is to preserve the fulfillment of international commitments, to update the nuclear material inventories as required and to evaluate the radiological risks and their impact on the safeguards activities and vice versa

Following international regulations, each organization is the responsible to apply radiation protection controls to their inspectors. In this regards, each organization provides its own dosimeters and make arrangements for periodic whole body counting measurements to the inspectors, to record the corresponding doses and to detect any potential internal contamination.

In the Argentinean case, on despite of the effectiveness of the radiation protection controls implemented by each organization, an additional national surveillance is applied. Consequently, external radiation and internal contamination control by providing whole body counting, TLD personal dosimeters and excretes assays respectively can be requested, as applicable.

This procedure has been implemented in order to enable the state fulfill the responsibility assumed within the safeguard agreement and to detect, as soon as it is possible, any unexpected exposure or contamination problems that could arise in the Argentinean facilities during safeguards inspections. Even

though these criteria reinforced the radiation protection controls, due to the previous coordination required, they represent difficulties on the coordination of the international inspections considering the new modalities that are being implemented.

Normally, for routine inspections the agencies provide the state party at least one week in advance notice concerning the arrival of the inspectors at the facilities and the activities to be carried out. However, a portion of these routine inspections can be performed on short notice or on unannounced basis with no more than 24 hours of advance notification.

Nowadays the short notice modality is becoming more frequently; consequently the regulatory body of Argentina has modified the radiation protection controls in order to avoid any undue interference with the ABACC and the IAEA activities.

In the framework of the responsibility assumed under the Quadripartite Agreement, the application of national regulations on individual monitoring has been reviewed in order to optimize the protection of international safeguard inspectors on duty. In this regard, excretes analysis is required on case by case basis, if applicable; whole body counting have been restricted just to those facilities handling irradiated material and TLD personal dosimeters are provided, as usual, at the beginning of the inspection program. The ARN has the right to require the international inspectors a non- routine measurement in case the results of the air and surfaces monitoring programs show abnormal results.

The immediate consequence of these modifications has been the successful implementation of the short notice random inspection regime in Argentina, during 2008, and an improvement of the cost effectiveness of IAEA and ABACC inspection effort.

3.2.- Reduction of the inspection effort adopting an Unattended Monitoring System

From the safeguards point of view, the spent fuel transfer campaign in the Candu reactor at Embalse NPP is the most demanding safeguard inspection activity in Argentina. At present the IAEA/ABACC inspectors must be present at the facility during the transfer campaign in order to ensure the continuity of knowledge over the spent fuel inventory. Normally, two campaigns per year are scheduled and the average extension of each campaign is around 2,5 month.

Many efforts have been done by ABACC and the IAEA to reduce the manpower associated with this activity. The One plus One Procedure implemented in the past allowed both agencies 50% of reduction in the Person-day of inspection (PDI). Nevertheless, additional optimization of the manpower is still possible through the introduction of an unattended monitoring system to follow the transfer of spent fuels to dry storage.

While these fuel elements are stored in the reactor pools, the access for verification purpose is normal and does not require any special arrangement. The situation drastically changes when these items are packed in the baskets and sent to dry storage silos for long term storage with difficult access. Item counting is not possible any more and NDA verification is highly dependent on the design of the silo.

At present the nuclear material is normally verified before being transferred to the long-term storage and the continuity of knowledge is maintained applying containment and surveillance measures and requesting the presence of ABACC and IAEA inspectors at the facility while the transfer campaigns take place.

The IAEA has proposed ARN the implementation of an unattended monitoring system similar to those approved in other Candu type reactors in Asia and Europe.

The major objective to implement an Unattended Monitoring System (UMS) is to maintain the continuity of knowledge over the spent fuels during all the steps of the transfer process and to eliminate the need of the continuous presence of international inspectors during such campaigns.

The following conditions have been requested by the National Authority to accept the unattended monitoring system (UMS)

a) The technical failure of any UMS components will not require the transfer activities to be back warded.

b) The system should cover all the credible diversion scenarios with the same level of confidence introduced by the presence of the inspectors.

c) The system should have adequate redundancy in order to assure that all the components of the containment and surveillance system applied have a full back up.

The spent fuels became difficult –to access items once the basket containing 60 spent fuels have been transferred to be welded in the hot cells. The safeguards criteria requires that the spent fuels have to be counted and verified by attribute testing through NDA measurement before they became difficult-to-access items. Consequently, the primary NDA verification has to be done in the spent fuel pond while the fuels are being loaded into the basket. For the subsequent steps, the welded basket is the item.

The transfer process has been subdivided into three major sub- processes:

1) Loading of the transfer basket in the spent fuel pond.

2) Drying, welding and transfer of the basket to the dry storage area (silo).

3) Storing the baskets into the concrete silo.

The activities included in the first sub-process are monitored using underwater surveillance cameras and gamma detectors installed in the spent fuel pond.

The activities included in the second sub-process are monitored through mobile neutron detectors mounted on the top of the transfer cask, a combination of mobile and fixed surveillance cameras and Yes/No gamma detectors.

The activities included in the last sub-process are monitored with gamma detectors mounted in the verification tubes of the silos on the top. The gamma measurements on the unloaded basket are complemented with surveillance cameras mounted on the crane.

The surveillance system on each step has been complemented with weekly mailbox declarations and an unannounced inspections regime.

The unannounced inspections are introduced as a deterrence element to avoid tampering of the detection system and with the following additional purposes:

a) To confirm the information provided in the mailbox.

b) To check the performance of the UMS components on random basis.

c) To perform inspection activities according the status of the transfer process.

The operator mailbox declarations are provided on weekly basis and include the ID number of the baskets transferred, the content of spent fuels transferred, the ID number of the silo loaded, and the position of the basket in the silo. Reference to the starting time of each step and any modification introduced in the planned schedule are also included in the declaration.

The conceptual design of the unattended monitoring system has been approved by ARN. ABACC and the IAEA would share the costs of the new system. It is expected that during the second half of 2009 ABACC and the IAEA would provide components of the surveillance system and gamma and neutron detectors. Mounting of the system is planned during the first semester of 2010 and testing is foreseen during the second half of the year.

4.- CONCLUSIONS

The cooperation between the states, the regional system and the IAEA, allows the optimization of the technical capacity and the economic and human resources. The successful application of the SCCC, the atmosphere of mutual confidence and cooperation between the state members, ABACC and the IAEA,

The implementation of the SNRI/unannounced inspection regime shows an effective contribution to the nuclear non-proliferation regime in South America. The adoption of the unattended monitoring system at Embalse NPP could result in an important reduction of the current inspection effort. The new system could reduce more than 30% the current IAEA and ABACC person-day of inspection.

Even though the mailbox declarations and the unannounced inspections imply additional burden for the operators, this complementary measures permit more flexibility regarding the scheduling of the spent fuel transfer campaigns and provide an equivalent level of confidence to the continuous presence of the inspectors during such campaigns.

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Uranium Mining Environmental Restoration Project in the Republic of Argentina

Domínguez, C.A.

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URANIUM MINING ENVIRONMENTAL RESTORATION PROJECT IN THE REPUBLIC OF ARGENTINA

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Nuclear Regulatory Authority
Argentina

SUMMARY

The Argentine National Atomic Energy Commission (CNEA) was preparing to restart mining operations at its Sierra Pintada uranium deposit in Mendoza province, in the central-west region of the country. The mine has been shut since 1997 and should be up and running by October 2003. The local Chamber of Commerce (Cámara de Comercio, Industria y Agropecuaria de San Rafael) joins the opposition against the reopening of the Sierra Pintada uranium mine, since the mine would have severe impacts on the regional economy.

Argentina's atomic energy commission CNEA pushed ahead with administrative procedures to enable it to reopen the. The CNEA will present an environmental impact study (EIS) for the project.

Ongoing negotiations were aimed at resolving the question of environmental legacies resulting from previous operations at the mine.

On July 27, 2004, Argentina's atomic energy commission (CNEA) has handed over to Mendoza provincial authorities the environmental impact study (EIS) to revive the Sierra Pintada uranium mine, located in Mendoza's San Rafael district. CNEA wants Sierra Pintada, which has a capacity of 120t/y, to produce close to 2,500t of uranium over 20 years. The 1800-page document was prepared by the Technical University of Avellaneda.

The Federal Court of San Rafael has ordered the prohibition of all activities associated with the re-opening of the Sierra Pintada uranium mine. The decision was taken at the request of, an organization comprising about 40 local NGOs, and having repeatedly spoken out against the reopening of the mine before the environmental liabilities of nearly 20 years of uranium mining have not been cleaned up.

The mine could then be reopened in mid-2007. For resumption of mining, in addition, a new license has to be obtained from the nuclear authority Auctorial Regulatory Nuclear (ARN).

CNEA has scheduled the beginning of the reclamation of the Sierra Pintada uranium mine for mid-2006. CNEA maintains, however, that the requested complete reclamation of the old workings is not possible, since most backfilling could only be done after the final closure of the mine. For the reclamation work, approval of the provincial government is required.

Frightened by the possible contamination of the Diamante River and the environment, hundreds of inhabitants marched on June 2, 2006, through the downtown streets of San Rafael to demand that the Sierra Pintada uranium mine should not be reopened nor any other uranium mine should be permitted.

On October 16 - 20, 2006, a public hearing will be held on the reopening of the Sierra Pintada uranium mine. Provided the Provincial Government issues a declaration of

environmental impact, the reclamation of the environmental liabilities from former mining at the site could start by the end of the year. The reclamation work would take two years; CNEA had a total budget of $ 17 million for it.

The CNEA had opened an information centre at San Rafael to inform the public on the proposed reopening of the Sierra Pintada uranium mine.

The public hearing scheduled on Nov. 2, 2006, for discussion of CNEA's Environmental Impact Study for the reclamation of the abandoned Sierra Pintada uranium mine was suspended upon receipt of a notification issued by the Fourth Civilian Court of San Rafael at the request of *the environmental organization.*

A powerful coalition of vineyards, organic farmers and local businesses is up in arms, warning residents that their water, air and soil are at risk of being poisoned and their livelihoods, export markets, tourist industry and health could be ruined. The issue is so explosive that for now, there is no official talk of restarting the Sierra Pintada mine complex. A public hearing was scheduled for February 17, 2007, to discuss the National Atomic Energy Commission's (CNEA) plan to clean up uranium waste that has been left at the site since operations halted a decade ago. Opponents say the plan, presented to the provincial government a year ago, is flawed and merely "environmental window dressing". The group coalition said waters in the Tigre stream, which flows through the mine and into the Diamond River that supplies semi-arid San Rafael with drinking water, contain up to 75 micrograms of uranium per litre - which they said was more than twice the levels permitted in the US, Canada and Australia. The CNEA says the water is naturally high in uranium and independent studies have proved there is no contamination.

The wine producers of the San Rafael river basin fear that the reopening of a uranium mine in the Sierra Pintada area endangers the prestige that their wine has in the exporting market, mainly American and European. In an attempt to measure the real impact of the uranium, they summoned specialists of the National University of La Plata (UNLP) to analyze water, grape juice, and products of the region.

The World Bank is interested in financing the restart of the Sierra Pintada uranium mine, provided that a solution is found for the reclamation of the former operations.

At the request of a member of the oppositional organization, a federal judge ordered that no works preparing production may be performed at the Sierra Pintada uranium mine. The judge summoned a hearing on June 26, 2007.

A report prepared by the Nuclear Regulatory Authority (ARN) found that concentrations of natural uranium and radium in Río Diamante were below national and international guideline values during the monitoring period 1998-2007, despite the impacts of the inactive San Rafael uranium mine site.

CNEA expected to begin the works to repair the effluent ponds at the former Sierra Pintada uranium mine. This is a prerequisite for future resumption of the mine operation.

The Federal Chamber of Appeals of the province of Mendoza ordered the CNEA to abstain from reopening the San Rafael uranium mine (that is inactive since 1995), because it is potentially harmful for the environment.

I. INTRODUCTION

Back in the 1950's, Argentina set up a uranium mining and extraction industry to supply nuclear fuel to its nuclear power generating plants and medical and research facilities. In the 1980's and 1990's, when the global market price of uranium lowered its domestic production cost and some of the ores became exhausted, most of the facilities were closed down or put on hold. As the extraction of uranium from its ores requires a concentration factor of several orders of magnitude, the approximate 2,500 tons of uranium produced left behind a legacy of over 6.7 million tons of mining and processing residue, 'tailings' in the technical jargon. These tailings pose a potential source of radiation hazard to the population and the environment. Indeed, two of the defunct facilities are located in the immediate proximity to urban population centers.

The National Atomic Energy Commission of Argentina (*CNEA*) is in charged of the preparation and implementation of a project for environmental restoration of all the sites associated with uranium mining and processing (*PRAMU*). The objective of the *PRAMU*, a three-phase project, is to achieve the environmental restoration as comprehensively as possible in terms of economic and technical feasibility. In order to address public concerns, this Project involves active public participation in decision making, as well as institutional strengthening of the implementing agency.

For any one of the sites slated for restoration under this Project, a site specific Environmental Assessment (EA) has to be carried out in accordance with Argentine national and provincial requirements.

Each of these sites needs first to be characterized to identify the types of contaminants, their extant and potential environmental impacts and possible contaminant pathways. Based on internationally accepted best practices and standards, effective solutions for the management of the tailings and site restoration would be then developed.

The accompanying Program-wide EA provides the framework for subsequent individual site EA's. The nature of this type of project in Argentina, combined with the heightened public concern about radiological risks, has induced active public participation as a means for decision making.

This report provides an overview of Argentina's nuclear industry and the uranium mining sector, describing the *PRAMU*'s master plan and also summarizes the legal framework at national and provincial level that is pertinent to environmental management and restoration activities of the sector and on the public consultation processes that accompanied the EA preparation.

Finally, the report contains a brief about a legal case in which a group of residents of San Rafael, Province of Mendoza, involved in different activities, companies and organizations, began important movements against the reopening of the Manufacturing Complex San Rafael (or Sierra Pintada mines).

II. ARGENTINA'S URANIUM MINING SECTOR: EVOLUTION, CURRENT STATUS AND ASSOCIATED ENVIRONMENTAL ISSUES AND POLICIES

The operation of uranium ores started in the 1950's with the development of mining projects in different Provinces. Uraniferous ores occur in stratiform sandy deposits and in veins in granites, along the eastern flank and foothills of the Andes Range. Due to a combination of adverse economic factors (competition and low price on the international market and high domestic production costs), most of the mines and mineral processing facilities are now either closed or operating on a maintenance basis only. Today, there are only two major deposits that, under favorable international market conditions, are capable of producing uranium ore. The Sierra Pintada deposit (San Rafael, Mendoza Province) has 9,200 tons of mineral reserves (today in stand-by) and the Cerro Solo deposit (Chubut Province) containing about 5,200 tons of uranium reserves. Consequently, about 100 tons of uranium concentrates are purchased annually on the international market and only a small quantity is still supplied domestically.

Argentina has two nuclear power plants (Atucha I and Embalse) and a third (Atucha II)[1] under construction and put on hold. The reactors use natural uranium as fuel and heavy water as moderator and cooler. With an installed generation capacity of 940 MWe, the annual fuel consumption is about 150 tons of uranium6. Presently, nuclear power provides about 11.5% of the country's total power

During the 1980's, the production infrastructure of the nuclear fuel cycle was completed with the construction of UO_2 manufacturing (the raw material for nuclear fuel), heavy water production plants, as well as facilities for the manufacturing of fuel elements for research and power reactors. Argentina has also developed, through private - and state - owned facilities, a well-established experience in the production of radioisotopes for medical and industrial uses, for both domestic consumption and export.

Overview of the Environmental Problems Associated with Argentina's Uranium Sector[2]

Until the early 1990's, Argentina's uranium extraction industry evolved in a radiological regulatory frame with some gaps in the environmental standards (the environmental protection chapter of the mining Code was set up in 1995). This activity resulted in environmentally harmful accumulation of solid and liquid waste associated with the uranium mining and processing sites. Mining took place primarily in hard rock open pits, generating waste piles of sterile overburden or low-grade (marginal) ore. Milling and leaching of the ores required installation of buildings and mechanical equipment and the construction of large leaching pads. These processes generated liquid wastes containing acids, metals and residual uranium compounds, as well as heap-leach residues[3] (for brevity, all referred to in this report as 'tailings'). The primary contaminants associated with the uranium industry are radionuclides, heavy metals and anions and acid effluents.

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[1] Once the third nuclear plant becomes operational, the installed generation capacity would increase to 1640 MWe, corresponding to an annual consumption of 300 tons of uranium.

[2] Information based on the National Joint Convention on the Safety of Spent fuel management and on the safety of radioactive waste management.

[3] A fine-grained, sand-like material from which the maximum possible quantity of uranium has been extracted by acidic solutions

Radionuclides. Milling tailings, while relatively low in concentration of long half-life radionuclides, still contain several types of contaminants that pose health risks to the workers and, through dispersion, to the public at large8. The most important radioactive components of mine tailings are primarily radium 226, which decays to produce radon 222 and thorium 230.Their exposure pathways include diffusion of radon gas via the air, where it can be inhaled or ingested when blown in particulate form and mobilization by water through leaching of the tailings and their dispersed dust particles. This may disperse radioactive and other hazardous materials to surface and/or ground water. Finally, many of the radioactive decay products in the tailings produce gamma radiation, which poses a health hazard to recipients in the immediate vicinity.

To counter adverse effects such as concern about long-term public health and access to natural resources, the environmental assessment project is developing appropriate containment and stabilization measures for each contaminated site, to reduce direct radiation and to protect the tailings from erosion and atmospheric and/or aqueous dispersion. The measures that are being adopted are based on risk analysis, availability of resources and cost-benefit considerations. They will ensure that (i) the release of contaminants to the environment is as low as reasonable

III. THE STRUCTURE OF ARGENTINA'S NUCLEAR SECTOR

When established in 1950, *CNEA* was designed as an autonomous Federal entity, responsible for the development and management of Argentina's nuclear field. Under its present charter, *CNEA* is ordained to act both in the public and private domains in all matters pertaining to the scientific, technical, industrial, commercial, administrative and financial aspects of Argentina's nuclear sector.

CNEA has been active in fundamental and applied research, uranium ore exploration, mining and production, nuclear energy generation, nuclear medicine and ionizing radiation applications, management of radioactive waste and radiological protection. Whereas *CNEA* was left in charge of many of its original functions, a new operating company NUCLEOELÉCTRICA ARGENTINA S.A. (*NA-SA*) and a regulatory agency NUCLEAR REGULATORY AUTHORITY (*ARN*)[4] were established.

The *ARN*, an autonomous entity reporting to the Federal Government, by virtue of the National Act on Activities in the Nuclear Sphere, Nº 24.804, is the State's national technical agency responsible for controlling and regulating all areas of nuclear activity in respect of radiological and nuclear safety.[5]

To fulfill some of its functions (e.g. heavy water production, UO_2 production, fuel elements manufacturing, nuclear engineering projects, etc.), *CNEA* has also established subsidiary companies that are open to private capital. Presently, *CNEA* has retained its responsibility for overall management and disposal of all types of radioactive waste and dismantling of nuclear and radioactive facilities and its mandate is evolving towards research, development and education in the nuclear field. *NA-SA*, a Federal corporation slated for privatization, operates Argentina's nuclear power plants.

[4] *Autoridad Regulatoria Nuclear*

[5] National Act on Activities in the Nuclear Sphere, Act Nº 24.804

IV. THE URANIUM MINING ENVIRONMENTAL RESTORATION PROJECT[6]

The Project will be carried out in three phases[7]:

Phase I

Restoration of top priority site (Malargüe): implementation of the actions subject to *DIA*[8] from the Mendoza Province authorities and *ARN* requirements.

Engineering studies, EIA's and public consultation process addressing two additional key sites (Córdoba and Los Gigantes)

The long-term monitoring after site closure has been successfully completed.

Developments of engineering solutions for the other sites.

Institutional strengthening of the *CNEA*, through Institutional environmental capacity building and training for a public consultation process.

Establishing the Project's Environmental Unit (*UGAMU*)

Establishing *CNEA* Environmental Management Unit (*UGA*) for Uranium Mining.

Introducing an Environmental Information and Management System

Establishment of a Project Implementation Unit (*UEP*)

Phase II

Conduct analysis and lessons learned in the preceding stage to ensure optimization of resources. This is to include an evaluation of improvements in the environmental quality as a result of the completed restoration activities and assessment of public perceptions concerning the risks associated with the restored Malargüe site.

Subject to respective DIA's, implement environmental restoration works at the Córdoba and Los Gigantes sites.

Prepare studies for the remaining sites.

Continue the institutional strengthening of the *CNEA* through Support to *UGAMU* and *SIGAMU*

Further support to the Project Implementation Unit (*UEP*)

Phase III

Restoration of the remaining sites.

THE *PRAMU* PROJECT (PHASES I AND II)

The current Project comprises Phase I and Phase II of the *PRAMU* and entails the following:

Phase I

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[6] Information based on the National Joint Convention on the Safety of Spent fuel management and on the safety of radioactive waste management.

[7] *CNEA* environmental policy regarding uranium mining is posted on the *PRAMU* web site.

[8] The term *DIA* (*Declaración de Impacto Ambiental*) in the Argentine context is interchangeable with EIA (Environmental Impact Assessment) in the international context.

Implementation of restoration works at the Malargüe site into a green space, including the relocation of over 700,000 tons of tailings and soils, to prevent further groundwater contamination and formation of harmful dust and abate radiation and radon emanation.

Preparation of studies for the restoration of two sites in the Córdoba Province, including public consultation process, EIA, the preparation of engineering plans and designs for the removal of about 57,600 tons of tailings, soils and equipment from the Córdoba City site and site restoration into a green space.

Phase II

Restoration of the Los Gigantes site, including the closeout and decontamination of the mine area and concentration plant, stabilization of 4,000,000 tons of mining waste and tailings' dumps and other mitigation measures to prevent soil, ground water and air contamination.

Upon completion of preliminary site studies, a *DIA* and a public consultation process, the subsequent steps towards the implementation of each of the individual Project phases would entail selection of a mitigation plan, engineering design, authorization by the applicable regulatory agencies, contracting and execution and finally, long-term monitoring.

Following preliminary site studies, the first step towards authorization of the Malargüe Project required the preparation of a *DIA* that contains the devised restoration plan, assessment of its environmental impact and demonstration of its compliance with site-specific regulatory standards.

CNEA's engineering restoration plans for the Malargüe site have been approved by *ARN* and by the Mendoza Province and some preliminary restoration work has already been carried out at the site. Similar plans were under development for the closing of the Córdoba manufacturing plant and the Los Gigantes mine.

Table 1 summarizes the waste quantities at the *PRAMU* sites, the current sites status and, to the degree available, the respective environmental restoration scope. For site locations.

Table 1. The *PRAMU* Sites: Waste Quantities, Current Status and Restoration Plans

SITE PROVINCE	FACILITY TYPE	WATE QUANTITIES AND DESTINATION	STATUS AND RESTORATION SCOPE
MALARGÜE Mendoza	Processing	~700-t milling tailings.	Relocate within the site, cap and divert drainage to depress groundwater level. Once restored as green space, relinquish title to provincial authorities.
SAN RAFAEL Mendoza	Processing	1,895-t milling tailings. 21,936-t sterile residues. 376-t marginal ore. 35-t low-grade ore.	Under study to assess scaled-down operation vs. closing. Once restored, relinquish title to provincial authorities.
HUEMUL Mendoza	Mine	31.2-t sterile residues, 4.0-t marginal ore.	After operation ceased in 1974, CNEA implemented closure procedures; needs to be re-evaluated.
CÓRDOBA Córdoba	Processing,manufacture of UO_2	57.6-t milling tailings.	Unspecified amount of manufacturing equipment. Plant and tailings to be relocated outside the densely populated urban area; designated as a green space.
LOS GIGANTES Córdoba	Mine	2,400-t heap-leach tailings. 1,000-t sterile residues. 600-t marginal ore.	While in an unpopulated area, its up-basin location from tourist areas is of particular concern. A possible repository for Córdoba's tailings.
PICHIÑÁN Chubut	Processing	145-t milling tailings.	Closed since 1980, requires only minor management works. Needs to be reevaluated.
TONCO Salta	Processing	57.6-t milling tailings.	Unspecified amount of manufacturing equipment. Plant and tailings to be relocated outside the densely populated urban area; designated as a green space.
LA ESTELA San Luis	Mine	70-t milling tailings 1,140-t sterile residues.	Following cessation of operations in 1990, restoration of mine and tailings by operator was approved by *ARN*.
LOS COLORADOS La Rioja	Mine	135-t milling tailings 1,000-t sterile residues.	Following cessation of operations in 1996, restoration of mine and tailings by operator was approved by *ARN*.

V. THE CONSULTATIVE PROCESS

Consultation within the framework of project preparation has been carried out mainly in relation to the development of this EA, dealing with the objectives and planning of the *PRAMU*. A first draft of the EA was distributed to Project-entity and individuals stakeholders, including representatives of municipal, provincial and national legislatures and governmental authorities, universities and NGO's. The initiative for the establishment of a project-wide "dialogue group" started with the participation of national level NGO's19, as well as institutions directly involved in the project, including the *ARN*.

VI. THE LEGAL AND INSTITUTIONAL FRAMEWORK

The pertinent legislation and regulatory framework applicable to the operation and management of Argentina's nuclear sector is summarized in the following.

Federal vs. Provincial Jurisdictions.

Argentina's environmental legislation started evolving with the introduction of the constitutional reform in 1994. The recent evolution of both the Federal and local environmental legislation reflects a growing societal concern with environmental quality.

The Republic of Argentina is a Federal system, where the national Government coexists side by side with autonomous provincial governments. Article 41 of the Federal Constitution (i) guarantees the rights of the citizenry to a healthy environment, balanced with the needs for human development. (ii) Empowers the Federal Government to establish the minimum standards for environmental protection and (iii) gives the provinces powers to complement the national requirements, but not to modify them.

In the nuclear sector, Article 41 is promulgated in the National Nuclear Activity Law (No. 24.804 of 1994) that assigns the Federal Government the lead role on policy, R&D, regulation and funding *vis a vis CNEA* and *ARN*. Decree No. 1540/94 practically separates between the implementing agency and the regulatory agency, by creating Argentina's Nuclear Regulatory Authority (*ARN*) and assigning it the authority to "issue regulatory standards in reference to radiological and nuclear safety".

Law No. 25.018, Plan for Managing Nuclear Waste, specifies *CNEA*'s obligations to (i) manage the residues derived from the mining of uranium and those that result from abandoned mineral deposits or closed out milling facilities and (ii) recover sites impacted by uranium mining. This law also stipulates that *CNEA* has to coordinate its activities with the local authorities.

Argentina's regulatory structure is characterized by concurrent authorities. According to the Federal Constitution, the environmental protection of a given domain is the responsibility of the jurisdiction that owns the title to that domain. Consequently, the provincial governments are empowered to set up complementary environmental standards, as long as they are no less stringent than the Federal standards.

Relevant environmental legislation is mainly at the provincial level, with the most comprehensive regulations having been established in the Province of Mendoza. The responsibility for the environment is at the level of Minister and the law provides for a process of EIA, resulting in a formal for specific projects. The legislation also provides for public hearings as part of the evaluation process.

Córdoba and all the other Provinces that host uranium production sites have broadly similar legislation, under the Federal Mining Code and its provincial complementary standards, but without the formal provisions for public hearings.

Mining and Mining Regulation

The mining sector in Argentina is subjected to the authority of the Office of Mining, within the ministry of Production. Decree No. 214/02 defines its responsibilities to include, among others, setting up mining policy and managing the nation's mining activities; promoting the introduction of innovative technologies and the establishment and management of a central database of geological and mining information.

Argentina's nuclear regulatory approach, is performance-based[9]. However, the environmental section of Argentina's Mining Code also incorporates oversight of nuclear activities by a concurring (i.e., Provincial) authority.

There are no specific Argentine standards or guidelines for restoration, stabilization and control of inactive uranium mining sites. The radiological impacts of such sites and their mitigation are subject to the basic standard on radiological protection (AR 10.1.1)[10] This law applies to all sources of radiation as well as all phases of the production of nuclear fuels and also to contamination resulting from past practices. Overall, the Argentine approach is consistent with ICRP[11] recommendations and in line with approaches in a number of other countries.

VII. ENVIRONMENTAL ASSESSMENT OF THE MALARGÜE PROJECT SITE

GENERAL BACKGROUND

Objective and Scope

The mitigation of the Malargüe site is to include relocating the tailings to a higher (and better drained) ground within the site, provision of surface drainage to divert runoff away and underground drainage to depress the extremely shallow phreatic aquifer, sealing the substrate designated to accept the relocated tailings and capping the relocated tailings with low-permeability, natural material. Finally, the site is to be decontaminated, leveled and replanted, then subjected to institutional control to enforce limited access.

VIII. IMPACTS – ESTIMATES OF THE PRESENT RISKS

In the absence of physical hazards at the site, the two major risk sources to humans are the inhalation of radon 222 and its decay products and exposure to gamma radiation.

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[9] Under this approach, the operating organization of a nuclear facility bears the ultimate responsibility for ensuring the safety of the facility at each and every stage. The only role assigned to the regulatory authority is that of critically reviewing the operators' safety specifications.

[10] AR 10.1.1. "Basic Radiation Safety Standard". In accordance with the provisions of article 16, section a) of Act 24,804, the ARN shall have power to establish regulations relating to radiation and nuclear safety, physical protection and nuclear materials use control, the licensing and control of nuclear facilities, international safeguards and transport of nuclear materials with regard to its radiation and nuclear safety and physical protection aspects.

[11] International Committee on Radiological Protection

Projection of the Radiological Risk

Two cases are presented to demonstrate the risk of contacting cancer as a result of radon inhalation and exposure to gamma radiation. In the first case, a hypothetical resident living permanently on the top of the tailings (with no shielding) for 7,000 hrs of annual exposure would receive a combined dose of 157 mSv/year. According to published life expectancy reduction models, this will shorten his life expectancy by almost 10 years. In the second case, living on the perimeter of the site will result in a combined dose of 6.8 mSv/year, which would shorten his life expectancy by about ½ year.

However, the amount of radiation projected for individuals who pass through the site frequently or just visit it occasionally (e.g., 1,000 hrs/yr. of radiation exposure) is well within the international standards.

It is concluded that the radioactive residues at the *CFM* would pose a radiological risk to a hypothetical group that would choose to live at the site's perimeter, but not to occasional visitors. On the other hand, the radiological effect on the town's population is insignificant.

IX. THE MALARGÜE SITE PUBLIC CONSULTATION PROCESS

CNEA has some experience in public consultation, as a result of the Malargüe site EIA development process and its concurrence by the Mendoza Province authorities. During the preparation of the restoration plans, numerous conferences, discussions and workshops with individuals and groups took place. Different options to deal with the tailings were discussed in a public hearing. In addition, as required for EIA approval under the legislation of Mendoza Province (Law No. 5961 and a derived regulation), two public hearings were held to discuss engineering concepts and detailed planning of engineering works and monitoring

X. PROJECT PERFORMANCE VERIFICATION AND LONG TERM MONITORING

The proposed repository is a standard design utilized for mill tailings in the U.S. and other countries in the last two decades. While considered state-of-the-art, the long-term performance of such repositories has not yet been established. This explains the need for the long term monitoring plan proposed under the Project. During an estimated period of 20-years, the performance of the system and its components will be verified, by monitoring fluctuations in the level of the phreatic aquifer, the hydrochemistry of ground water and surface water, the emanation levels of radon gas and emerging gamma radiation.

Modifications will be introduced, as necessary, to address system malfunctions. In the longer-term, a monitoring plan will be implemented that would address the physical conditions at the site as well as control the water and air in the site's sphere of influence.

XI. POST-CLOSURE MONITORING

As stated above, post-closure monitoring for an estimated period of twenty years is required to verify the performance of the Project's design. The monitoring will be carried out by the *UEP* of *CNEA.*

Simultaneously, the *ARN* and provincial authorities would be involved as well in the verification plan. All field and laboratory measurements will be executed under a Quality Assurance Program.

The *Complejo Fabril Córdoba (CFC)* site covers 9.2 Ha in the Alta Córdoba suburb of the city and was initially established for chromium production during World War II. In 1952 the facility was converted to an experimental uranium leaching plant processing various types of domestic ores. From 1963 to 1976 the plant also processed uranium pre-concentrate for further extraction. At a later stage, uranium purification (in 1976) and uranium dioxide conversion (in 1982) have been introduced with annual installed capacity of 150 tons, to provide uranium fuel for Argentina's two nuclear power reactors and for research reactors. The production process entails dissolution of uranium di-uranate or U3O8, purification, evaporation, precipitation as ammonium uranyl carbonate, concentration to UO2, homogenization, storage in drums and treatment of the effluents.

Proposed Restoration Measures

The available data suggest that rather than only relocating the tailings, an integral remedial solution for the whole site should be prepared and *CNEA* has been ordered by the *ARN* to restore the whole Córdoba site. An agreement has been reached between *CNEA* and the Córdoba Province and the City of Córdoba to move the existing *Dioxitek* plant and production equipment to another site and to restore the site into a green space. The plant transfer is scheduled to take place in the near future, following which tailings' removal and site restoration could begin.

Considering the low levels of radioactivity monitored at and around the site, the radiological benefits to be gained from removal of the contaminated materials are small. However, one of the major benefits of the site's restoration will come from the release of the land in the heart of the city, together with the impacts on the value of adjoining land and property of converting an industrial site into public open space.

No detailed implementation plans for the restoration have yet been finalized. The *PRAMU* will launch a wide public consultation process to identify an acceptable set of site restoration measures. The selection of a site for the disposal of the materials has so far been proven as the major issue. The Province of Córdoba has passed legislation prohibiting the creation of any new "nuclear sites", including sites for the disposal of the Córdoba tailings. A technically acceptable solution has been explored, involving the incorporation of the tailings and unredeemable debris from the dismantled facilities into the restoration of the Los Gigantes mine site (see below). It is estimated that 27 daily trips of a 15-ton capacity truck for 7-8 months would be required to complete the transfer. However, transportation of the materials would be difficult because of the distance (100Km) and the need to pass through several municipalities.

XII. THE LOS GIGANTES SITE

The closed Los Gigantes mine is located at 1700 meters a.s.l.**,** in the largely unpopulated rocky mountainous Sierra Grande area (Córdoba Province), about 30 km upstream of the city of Villa Carlos Paz.

Contamination Sources

Mining and milling waste. 1.6 million tones of mining waste and marginal grade mineral, as well as 2.4 million tons of heap-leach residues are deposited at the site. Due to intensive weathering, combined with earlier exposure to sulfuric acid, the residues are rapidly disintegrating to sand.

Restoration Approaches

Since the site is so remote from population centers, the main concern is with its potential impact on spreading contamination down stream by eroded waste rock or polluted run-off from the site. *CNEA* is considering tailings' stabilization strategies such as reinforcing and enlarging the principal dike such that it would become an impoundment for Cordoba's relocated tailings and the building of small dikes in streams to capture sediment in tailing areas. While the contamination sources are presently basically contained, the primary goal of the restoration works will be to maintain in the longer-term leaching and off-site tailings' transport to a minimum. Wind could carry some material a short distance. However, the greater concern is surface water runoff and leaching into ground water. Calculations are ongoing to estimate potential human intake of dissolved contaminants via surface water, as well as studies to characterize the hydrogeology and the aquifers' potential as a future source of drinking water.

The logic behind stabilization at Los Gigantes, instead of more complex engineering solutions, is lack of local population. The geomorphology, altitude, climate and paucity of arable soil imply that permanent settlement near the mine is highly unlikely. However, engineering plans will take into consideration the long-term performance objectives – a minimum of 200 years – to be achieved by the restoration works. Currently, *CNEA* is also actively researching and testing methods of removing contaminants from the effluents collected in the main dam.

Environmental Assessment of the Córdoba Province Projects

The *CFC* and Los Gigantes, the two sites for which planning and environmental assessments will be carried out under this project are both in Córdoba Province and therefore subject to the same broad regulatory requirements. The sites are quite separate physically and are different in character. However, there is a potential linkage between them since the mine site at Los Gigantes has been identified as a possible final repository for the tailings that are to be removed from the *CFC* at Córdoba City. Consequently, the environmental processes for both sites will be carried out more or less in tandem.

There is a considerable amount of background information and data already available for both sites, held by *CNEA* and by other Provincial and local agencies.

XIII. LEGAL PRECEDENT

Sierra Pintada Uranium District, Mendoza

"Asociación Multisectorial del Sur en defensa del desarrollo sustentable vs. C.N.E.A" Multisectorial Association of the South in defense of the sustainability development vs. CNEA"

XIV CONCLUSIONS

Strategic environmental assessment (SEA) is evolving as a mechanism that attempts to assess systematically the environmental impacts of decisions made at, what is conventionally called, levels of strategic decisions. Evidence is emerging in different countries on specific SEA approaches including institutional frameworks, assessment and review mechanisms, and results achieved in specific case applications. Experience is as yet too limited to conclude how effective such systems are but is nevertheless instructive on particular issues implicated in the development and implementation of SEA. Many governments and environmental assessment (EA) administrators are currently showing great concern regarding the potential environmental consequences of decisions made at policy, planning, and programmatic levels.

A comprehensive review of existing SEA practical approaches was undertaken with the purpose of understanding the existing status of SEA and identifying key practical issues raised by practitioners in different countries. Such practical issues reflect the strengths and weaknesses experienced with the adoption of particular approaches. This article highlights and reflects on some of the most fundamental; technical procedure, policy, legal and institutional framework.

The legal case pointed out in this report reflects strengthens and weaknesses. On one hand, a serious technical work and on the other hand the lack of credibility because of doubts, public concerns, lack of information and uncertainties. The community must not feel alone in experimenting with public hearing, in time they will come to understand that other nations have accepted and embraced similar changes following the nuclear energy as a safety option, which contributes with sustainability. The strength of a society and sustainability lies in freedom of information and truth, which is what an unbiased government, justice and media will have to provide seriously and timely.

In conclusion, an effective SEA implies a commitment in a variety of capacities and technical knowledge. Public consultation is a key component of the communication policy, setting in motion a decision making process based on the participation of any sector, institution or individual that can contribute to different aspects of an Environmental Restoration Project or of an Environmental Assessment.

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Evaluación de impacto ambiental en instalaciones nucleares. Marco legal de la Autoridad Regulatoria Nuclear

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EVALUACION DE IMPACTO AMBIENTAL EN INSTALACIONES NUCLEARES MARCO LEGAL DE LA AUTORIDAD REGULATORIA NUCLEAR

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Argentina

I- INTRODUCCIÓN

Se puede definir "Evaluación de Impacto Ambiental" como aquel instrumento de la gestión ambiental preventiva utilizado para proteger y administrar eficientemente los recursos naturales y el medio ambiente; a través de éste se identifica, previene, mitiga y compensa los impactos ambientales que pueda generar una actividad o proyecto sobre el medio ambiente, permitiendo a la Administración adoptar las medidas adecuadas a su protección.

Esta práctica y obligación jurídica de advertir a terceros ha dado origen a la obligación ambiental básica de estudiar y difundir los efectos directos e indirectos, individuales y colectivos, mediatos e inmediatos, presentes y futuros de toda actividad susceptible de perjudicar al ambiente.

De esta forma, con la EIA se incorporan a la toma de decisiones todos los aspectos que hacen a la calidad de vida de la población y que se encontraban tradicionalmente desplazados por los términos económicos de la ecuación de conveniencia. En el ámbito nuclear esta práctica es también significativa en cuanto contiene aspectos técnicos, legales y de opinión pública que se interrelacionan.

Un proceso de evaluación de impacto ambiental no es en sí mismo un instrumento de decisión; esta última corresponde a la autoridad competente y responsable en cada caso.

La presentación del trabajo desarrolla el ámbito, el alcance y la legislación aplicable, así como las instituciones y sectores involucrados, los aspectos radiológicos de estudio, y casos relacionados con la industria nuclear.

II- ESTRUCTURA DEL SECTOR NUCLEAR

En el año 1994 con el dictado del Decreto Nº 1540/94 se reorganizaron las funciones desarrolladas por la COMISIÓN NACIONAL DE ENERGIA ATÓMICA (CNEA), se constituyo la SOCIEDAD NUCLEOELÉCTRICA ARGENTINA SOCIEDAD ANÓNIMA (N.A.S.A.) y se creó al ENTE NACIONAL REGULADOR NUCLEAR (ENREN).

El ENREN fue creado como un organismo autárquico en jurisdicción de la Presidencia de la Nación, designándole las funciones de regulación y fiscalización de la actividad

nuclear con independencia funcional de las demás actividades de la CNEA, las cuales se centran en la investigación y desarrollo de la actividad nuclear.

Posteriormente, y conforme con la Ley Nº 24.804 -Ley Nacional de la Actividad Nuclear- la AUTORIDAD REGULATORIA NUCLEAR (ARN) actúa como entidad autárquica en jurisdicción de la Presidencia de la Nación siendo la sucesora del Ente Nacional Regulador Nuclear, y teniendo por funciones la de regulación y fiscalización de la actividad nuclear, en materia de seguridad radiológica y nuclear, protección física y fiscalización del uso de materiales nucleares, licenciamiento y fiscalización de instalaciones nucleares y salvaguardias internacionales, como así también la de otorgar y revocar permisos individuales y/o autorizaciones de operación a las personas físicas o jurídicas que desarrollen actividades nucleares en la República Argentina.

La Ley Nº 24.804, establece que el Estado Nacional fijará la política nuclear y desarrollará funciones de investigación y desarrollo a través de la CNEA y las de regulación y fiscalización por medio de la ARN. Los Artículos1º, 7º, 14º, 15º, 16º, 18º, 25º y 26º de la Ley, detallan las funciones, facultades y obligaciones conferidas a la ARN. Los Artículos 2 a 6, 12 y 13 detallan las funciones, facultades y obligaciones conferidas a la CNEA.

El Decreto Nº 1390/98, reglamenta la Ley N° 24.804 definiendo sus alcances y los procedimientos que facilitan su aplicación.

II- AUTORIDAD REGULATORIA NUCLEAR –ARN-

II-1. ATRIBUCIONES

La ARN, según lo dispone el Artículo 8º de la Ley 24.804, debe desarrollar las funciones de regulación y control asignadas por ley, con los siguientes fines:

- Proteger a las personas contra los efectos nocivos de las radiaciones ionizantes.
- Velar por la seguridad radiológica y nuclear en las actividades nucleares desarrolladas en la República Argentina.
- Asegurar que las actividades nucleares no sean desarrolladas con fines no autorizados por esta ley, las normas que en su consecuencia se dicten, los compromisos internacionales y las políticas de no proliferación nuclear, asumidas por la República Argentina.
- Prevenir la comisión de actos intencionales que puedan conducir a consecuencia radiológicas severas o al retiro no autorizado de materiales nucleares u otros materiales o equipos sujetos a regulación y control en virtud de lo dispuesto en la presente ley.

El artículo 16 de la Ley Nº 24.804 faculta a la ARN, entre otras funciones, a dictar las normas regulatorias[1] referidas a seguridad radiológica y nuclear, protección física y fiscalización del uso de materiales nucleares, licenciamiento y fiscalización de instalaciones nucleares, salvaguardias internacionales y transporte de materiales nucleares en su aspecto de seguridad radiológica y nuclear y protección física.

[1] Las Normas Regulatorias tienen un carácter de performance, no son prescriptivas sino de cumplimiento de objetivos de seguridad. El “como” se alcanzan esos objetivos se basa en la apropiada toma de decisiones por parte de la organización que se ocupa del diseño, puesta en marcha y operación de la instalación.

El incumplimiento de las Normas Regulatorias habilita a la ARN a la aplicación del Régimen de Sanciones.[2] que corresponda de acuerdo a la instalación involucrada que ha infringido las condiciones de seguridad radiológica y nuclear.

II-2. ACTIVIDADES

- La ARN en su función de verificar la seguridad radiológica y nuclear de diferentes prácticas e instalaciones radiactivas y nucleares realiza evaluaciones, inspecciones, auditorías y pruebas que permiten controlar el estado y el funcionamiento de las mismas. Esta tarea se desarrolla en forma sistemática durante las etapas de diseño, construcción, puesta en marcha, operación y retiro de servicio de las instalaciones. Para su ejecución cuenta con un grupo de inspectores y evaluadores que le permiten, en forma autónoma e independiente, fiscalizar el cumplimiento de las normas de seguridad radiológica y nuclear.

- La ARN cuenta con laboratorios e instalaciones ubicadas en el Centro Atómico Ezeiza, partido de Ezeiza, provincia de Buenos Aires, que le permiten efectuar mediciones y determinaciones necesarias para cumplir con su función regulatoria. Las principales tareas llevadas a cabo en esta área son:

Desarrollar sistemas de medición de dosis que permitan establecer el cumplimiento de niveles apropiados de protección de las personas.
Determinar la presencia de radionucleidos en el ambiente, alimentos y otras matrices biológicas.
Participar en la verificación del cumplimiento del Tratado de Prohibición Completa de los Ensayos Nucleares.
Realizar la vigilancia radiológica ambiental en los alrededores de instalaciones nucleares y radiactivas del país.
Evaluar, a través de dosímetros físicos y biológicos, situaciones de sobreexposición accidental.
Asesorar sobre la conducta médica a seguir en caso de accidente por radiación.
Efectuar estudios sobre los efectos biológicos de las radiaciones.
Realizar estudios sobre transferencia de radionucleidos en el ambiente para ser luego utilizados en modelos de evaluación de dosis en el público.
Realizar desarrollos electrónicos en hardware y software como soporte a distintas tareas regulatorias.

III- EVALUACIÓN DE IMPACTO AMBIENTAL

La ley General de Medio Ambiente, Ley Nº 25.675 en su Artículo 8 establece cuales son los instrumentos de la política y la gestión ambiental y menciona entre ellos la evaluación de impacto ambiental.

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[2] *REGÍMENES DE SANCIONES*

- *PARA SANCIONES PARA INSTALACIONES CLASE II Y III, PRACTICAS NO RUTINARIAS Y TRANSPORTE DE MATERIALES RADIACTIVOS, Resolución ARN N° 32 –26/8/02*
- *PARA CENTRALES NUCLEARES Resolución ARN N° 63 –5/5/99*

POR INCUMPLIMIENTO DE LAS NORMAS DE SEGURIDAD RADIOLÓGICA Y NUCLEAR, PROTECCIÓN FÍSICA, SALVAGUARDIAS Y NO PROLIFERACIÓN NUCLEAR EN INSTALACIONES RELEVANTES Resolución ARN N° 24 – 11/11/99

Por su parte, el artículo 11 de la citada ley dispone que "Toda obra o actividad que, en el territorio de *la Nación, sea susceptible de degradar el ambiente, alguno de sus componentes, o afectar la calidad de vida de la población, en forma significativa**, estará sujeta a un procedimiento de evaluación de impacto ambiental, previo a su ejecución."***

En el mismo sentido la declaración de Río sobre el medio Ambiente y el Desarrollo de 1992, en su principio 17 establece que "deberá emprenderse una evaluación de impacto ambiental, en calidad de instrumento nacional, respecto de cualquier actividad propuesta que probablemente haya de producir impacto negativo considerable en el medio ambiente y que esté sujeta a la decisión de la autoridad nacional competente"

Actualmente existe una obligación genérica de realizar evaluaciones de impacto ambiental, sin embargo esta obligación aún no se encuentra reglamentada.

Uno de los principios básicos que desde hace décadas está contenido en las políticas ambientales más avanzadas es el de la prevención, que trata de evitar, con anterioridad a su producción, la contaminación o los daños ecológicos, más que combatir posteriormente sus efectos.

Una EIA debe comenzar a elaborarse desde el momento en que se concibe el proyecto. Las evaluaciones de impacto ambiental son herramientas de predicción, y como tales adquieren sentido sólo si pueden influir en el desarrollo futuro de un proyecto. Por ello su aplicación debe hacerse en las etapas de prefactibilidad o de diseño de los proyectos de inversión.

En Argentina se han identificado a nivel nacional una serie de normas que contemplan la EIA como procedimiento administrativo o proceso de evaluación ambiental. Cabe destacar que son muchas las provincias argentinas que incorporan la EIA como procedimiento en diversas etapas de la planificación o autorización de emprendimientos. Sin perjuicio de ello, a nivel federal no existe un régimen general de EIA entendido como procedimiento administrativo. Sí existen, por el contrario, regímenes sectoriales o específicos que pueden caracterizarse como procedimentales per se.

Ejemplos sectoriales de regímenes procedimentales de EIA se encuentran en el Código de Minería modificado por la Ley Nº 24.585 (Artículos 8 a 11, Título Complementario). Este régimen, sin embargo no contempla una instancia clara de participación pública, como elemento integrante del procedimiento.

En 1994, la Ley Nº 24.197 fue vetada por el Poder Ejecutivo, mediante Decreto 1096/93. Dicha norma establecía la obligatoriedad de llevar a cabo un procedimiento de EIA para todo emprendimiento público que pudiera tener un impacto ambiental significativo. El veto aducía defectos en la implementación del esquema de EIA propuesto.

Similarmente, la Ley Nº 24.354[3] establece requisitos que deben ser observados por parte de los emprendimientos cuando estos integren proyectos de inversión pública.

Los instrumentos técnicos de EIA en Argentina, varían de sector en sector, atendiendo al hecho de carecer de un sistema o régimen general. La técnica se encuentra más perfeccionada a nivel provincial. En general los regímenes sectoriales reflejan el grado de evolución de la sofisticación en la EIA como instrumento técnico.

III-1. AUTORIDADES DE APLICACIÓN

En la legislación que establece el Procedimiento Técnico Administrativo se designa la Autoridad de Aplicación encargada de ejecutarlo en todas sus etapas, quedando esta competencia en manos de la correspondiente Autoridad Ambiental de la Administración.

El Estudio de Impacto Ambiental es elaborado por quien presenta el proyecto y debe reunir una serie de requisitos en general explicitados en la legislación. En ningún caso la EIA puede ser llevada a cabo por el organismo, público o privado que presenta el proyecto pues esto significa claramente, no solo una violación a la ley, sino aceptar que se puede actuar simultáneamente como juez y parte.

III-2. INSTRUMENTOS TÉCNICOS DE LA EIA

Como se ha señalado precedentemente, existen diversos regímenes de naturaleza sectorial que establecen la obligatoriedad de EIA para la aprobación de emprendimientos. Entre otros, además de los señalados previamente, pueden destacarse:

En el ámbito federal por ejemplo, la Ley de Residuos Peligrosos y su reglamentación contempla en forma específica a las áreas sujetas a recuperación. Los términos de esta categoría, sin embargo, no son precisas en cuanto al requisito de cumplir con la EIA como herramienta.

Tal como se ha señalado, existen diversas normas de naturaleza sectorial que exigen una EIA como estudio técnico. A nivel nacional, estas normas se encuentran dispersas con articulación institucional en diferentes ámbitos de incumbencia. Como ejemplos de estas exigencias, caben destacarse algunas leyes que ratifican acuerdos internacionales, tales como la Convención Internacional sobre Seguridad Nuclear (Ley Nº 24.776). Por otra parte, la Ley Nº 24.804 y la Ley de Gestión de Residuos Radiactivos (Ley Nº 25.018) Estas normativas revisten importancia para el presente trabajo, atenta las implicancias que poseen para las obras de instalaciones nucleares.

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[3] La Ley 24.354 Crea el Sistema Nacional de Inversiones Públicas cuyos objetivos son la iniciación y actualización permanente de un inventario de proyectos de inversión pública nacional y la formulación anual y gestión del plan nacional de inversiones públicas. La citada Ley en su Anexo I hace una referencia a los planes de inversión pública, sin tratarse de un verdadero sistema de EIA para programas o políticas públicas.

En el orden interno, la Ley Nº 24.228 que constituye el acuerdo federal minero, en su cláusula 14, establece la exigencia de EIA para todo proyecto minero a establecerse en el territorio de las provincias signatarias.

Como complemento del marco regulatorio aplicable a la minería en la década del 90, la Ley Nº 24.585 incorporó un Título Complementario al Código de Minería que exige la presentación de un EIA para todo proyecto minero, que debe ser actualizado cada dos años (Arts. 6 y 7).

El cumplimiento con los requisitos de las matrices ambientales dependerá sin embargo de la jurisdicción en la cual se encuentre, que según el régimen específico vigente podrá recaer en autoridades provinciales o nacionales.

En igual sentido, tanto la Ley Nº 24.051 y su Decreto reglamentario (Decreto Nº 831/93) que establecen el régimen federal en materia de residuos peligrosos establecen un régimen de EIA para la radicación de plantas de tratamiento y disposición final de residuos peligrosos (Art. 34, ambas normas).

En el sector eléctrico sujeto a regulación por parte de los organismos federales (Secretaría de Energía y Ente Nacional Regulador Eléctrico), también rigen requisitos de presentación de EIA. En tal sentido la Resolución Nº 475/87 y su modificatoria Nº 718/87 establecían requisitos en cuanto a EIA para las instalaciones de generación existentes.

La Ley Nº 23.879 establece un régimen general para la EIA a partir de las grandes obras y represas hidroeléctricas. Esta norma fue implementada a raíz de los lineamientos establecidos por los organismos internacionales de financiamiento.

La mayor parte de la normativa sectorial evaluada está elaborada en función del establecimiento de actividades futuras. En los casos sectoriales analizados, donde se habla de EIA para actividades en ejecución, la terminología es más bien la que se aplica al concepto de auditoría o informe ambiental.

Los regímenes sectoriales revisados contemplan proyectos específicos o emprendimientos, aunque persiste una cierta tendencia a exigir EIA para proyectos ya iniciados. En rigor de verdad estos debieran ser clasificados como auditorías o "empadronamientos" de actividades. La Ley Nº 24.354 en su Anexo I hace una referencia a los planes de inversión pública.

III-3. EVALUACIÓN DE IMPACTO AMBIENTAL ASPECTOS DE SEGURIDAD RADIOLÓGICA Y NUCLEAR

En el sector nuclear la Ley Nº 24.804 en su artículo 16 inciso m) contempla la evaluación de impacto ambiental de orden sectorial, estableciendo que la AUTORIDAD REGULATORIA NUCLEAR tendrá, entre otras, las siguientes funciones, facultades y obligaciones: "*Evaluar el impacto ambiental de toda actividad que licencie, entendiéndose por tal a aquellas actividades de monitoreo, estudio y seguimiento de la incidencia, evolución o posibilidad de daño ambiental que pueda provenir de la actividad nuclear licenciada*".

Al respecto, el Decreto Nº 1390/98. Reglamentario del Artículo l6, inciso “m” de la Ley Nº 24.804, establece que *“Entiéndese que la evaluación de impacto ambiental a que hace referencia el inciso m) del Artículo 16 de la Ley Nº 24.804 se refiere exclusivamente a la evaluación de los estudios y análisis realizados por los licenciatarios y que la intervención de la Autoridad Regulatoria Nuclear en lo que al ambiente humano se refiere se limita al impacto ambiental radiológico que pueda provenir de la descarga de efluentes radiactivos.*

El régimen de EIA en los aspectos de seguridad radiológica permite que el licenciatario quien presenta la EIA pueda ser la misma organización que realice los estudios y análisis, esto resulta porque en los antecedentes nacionales el operador como entidad responsable además de gestionar el emprendimiento es quien detentaba el conocimiento técnico. Cabe aclarar que una instalación nuclear, desde el punto de vista de la seguridad radiológica y nuclear, tiene varias etapas de Licenciamiento. En la citada ley no se hace referencia en que etapa la ARN hará uso de la facultad de solicitud de la EIA pero si será aplicable en forma previa al licenciamiento de operación.

De esta manera, se entiende que la EIA referenciada se refiere a un informe técnico sectorial auditable por parte de la ARN. Por otra parte, las evaluaciones y estudios que se realizan en una instalación nuclear en las etapas, por ejemplo de diseño y construcción, también deben cumplir con parámetros de seguridad ambiental.

Asimismo, la Convención sobre Seguridad Nuclear (Ley Nº 24.776) precisa determinados criterios de evaluación según las diferentes fases de vida de la instalación: la elección del emplazamiento, la concepción, la construcción y la explotación.

Al elegir el emplazamiento hay que considerar, entre otras cosas, su influencia en la seguridad de la instalación y los efectos de la instalación sobre los individuos y el medio ambiente. También hay que consultar a las partes contratantes vecinas siempre que sea probable que resulten afectadas por dicha instalación.

En cuanto a la concepción y la construcción, se trata de aplicar medidas de seguridad contra la liberación de materiales radiactivos y velar por que las técnicas y equipos utilizados hayan sido verificados por la experiencia o por pruebas, por ejemplo.

La autorización para explotar una instalación se basa en un análisis de seguridad y en un plan de entrada en servicio. A continuación, la gestión de la instalación ha de ser conforme a los reglamentos adoptados por las autoridades nacionales. También hay que establecer programas de recogida y análisis de datos.

Cada instalación deberá contar con un plan de emergencia interna y externa, en caso de situación de emergencia radiológica, para garantizar la protección de los trabajadores, la población, el medio ambiente, etc.

La Autoridad Regulatoria Nuclear ha dictado normativa regulatoria de conformidad a parámetros internacionales en donde se encuentran contemplados los requerimientos de protección expuestos.

III-4. INSTRUMENTOS PROCESALES DE LA EIA

A nivel nacional los instrumentos procesales propios de un régimen de EIA, se hallan poco desarrollados. Los criterios de legalidad por los cuales se analizan los EIA se encuentran referenciados en asociación a la documentación técnica o financiera que puede requerirse para la aprobación de un proyecto.

Respecto de los criterios de razonabilidad con los cuales puede juzgarse un EIA, al no existir un régimen específico, resultarán aplicables los principios generales de legalidad y razonabilidad del derecho administrativo conforme a la Ley Nº 19.549. Toda decisión de la administración debe fundarse en los hechos y en el derecho aplicable. No existe, sin embargo mayores antecedentes en materia de apreciación respecto de la discrecionalidad administrativa. [4]

Los sistemas de contralor varían según el régimen sectorial de que se trate. Tratándose de organismos sectoriales competentes, corresponden aplicarse las reglas generales del derecho administrativo para el caso de impugnación u oposición de decisiones a recurrir. La Ley Nº 23.879 contempla en su artículo 3 una instancia de información al Congreso Nacional respecto de EIA en proceso de estudio o análisis.

III-5. INSTRUMENTOS DE CONSULTA

Consulta Pública

Al no existir un régimen general, el principio de la consulta pública no se encuentra consagrado a nivel nacional. A nivel de regímenes provinciales, sí se encuentra consagrado el sistema de consultas al público (Mendoza, Córdoba, Buenos Aires, etc.).

Consulta interinstitucional

Tal como se ha señalado, no existe un régimen general de EIA en Argentina a nivel federal. En el nivel sectorial existen diversos ejemplos de la consideración de la consulta intersectorial. Así la Resolución Nº 15/92 de la Secretaría de Energía lo requiere (Artículo 6), al igual que la Resolución Nº 16/97 del ENRE, respecto de la aprobación de los EIA para efluentes gaseosos provenientes de las centrales térmicas.

Consulta interjurisdiccional

El esquema planteado en el régimen sectorial minero contempla instancias de consulta interjurisdiccional. La Ley Nº 23.879 (Artículos 2, 3 y 5) también contempla la instancia de consulta con las jurisdicciones involucradas.

Consulta internacional

[4] Una excepción a esta falta de jurisprudencia es quizás la que ofrece el Caso "Schroeder c/ Estado Nacional (SRNyDS)" (Suplemento de Derecho Ambiental de La Ley, Diciembre 1994). La Cámara en lo Contencioso Administrativo Federal hizo lugar a una petición de un ciudadano sobre la base de los nuevos derechos constitucionales a partir de la enmienda de 1994, argumentando que no había realizado un EIA en forma exhaustiva, previa a la instalación de una planta de tratamiento de residuos peligrosos en el conurbano bonaerense.

En el ámbito del derecho internacional, sí existen casos de consulta establecida para la Argentina, si bien en estos casos, tal instancia de consulta no surge de un régimen propio de EIA. Así el Estatuto del Río Uruguay, aprobado por la Ley Nº 21.413, estatuye un régimen de consultas para diversas clases de actividades (Capítulos VII, VIII, IX y X). En igual sentido, la Ley Nº 20.645 que aprueba el Tratado del Río de la Plata, establece similares términos para las partes. Más recientemente, la Ley Nº 24.677 establece también obligaciones de consulta entre las partes, en la cuenca del Río Pilcomayo (Art. IV). En similares términos se pronuncia el Tratado de Medio Ambiente suscripto con Chile (Ley Nº 24.105) en su artículo III.

Consulta Internacional respecto de Instalaciones Nucleares

La Ley Nº 24.776 que aprueba la Convención de Seguridad Nuclear se refiere a la consulta internacional en virtud de los efectos transfronterizos que la actividad pudiera generar. Al respecto la citada ley en su Artículo 17, inciso iv) establece lo siguiente**:**

ARTÍCULO 17
Emplazamiento
Cada Parte Contratante adoptará las medidas adecuadas para velar por el establecimiento y la aplicación de procedimientos apropiados con el fin de:
iv) Consultar a las Partes Contratantes que se hallen en las cercanías de una instalación nuclear proyectada, siempre que sea probable que resulten afectadas por dicha instalación y, previa petición, proporcionar la información necesaria a esas Partes Contratantes, a fin de que puedan evaluar y formarse su propio juicio sobre las probables consecuencias de la instalación nuclear para la seguridad en su propio territorio.

IV- MATRIZ LEGAL DEL SECTOR NUCLEAR

Ley Nº 15.336. Declara de jurisdicción nacional la actividad de generación de energía eléctrica de origen nuclear. (Ley anterior a la Constitución reformada de 1994)

Constitución Nacional. Introduce un nuevo sistema de distribución de competencias, entre la Nación y las provincias. Del análisis de los Artículos 41, 121 y 124 se desprende que la competencia en materia ambiental es provincial.

Ley Nº 24.065. El Artículo 54 crea el Ente Nacional Regulador de la Electricidad (ENRE), siendo su función, entre otras la de "velar por la protección de la propiedad, el medio ambiente y la seguridad pública en la construcción y operación de los sistemas de generación, transporte y distribución de energía". La Resolución N° 555/01, del ENRE obliga a los agentes del MEM ha tener un sistema de gestión ambiental auditado y certificado por un tercero independiente.

Ley Nº 24.354. Ley de Inversión Pública Nacional. Decreto N° 720/1995, Resolución N° 175/04 de la Secretaria de Política Económica, sus modificatorias y complementarias.

Ley Nº 24.804. Ley Nacional de Actividad Nuclear

Artículo 11: **"***Todo nuevo emplazamiento de una instalación nuclear relevante deberá contar con la licencia de construcción que autorice su localización, otorgada por la Autoridad Regulatoria Nuclear con la aprobación del Estado provincial donde se proyecte instalar el mismo"*.

Artículo l6, inciso "m", establece que la Autoridad Regulatoria Nuclear tendrá, entre otras, las siguientes funciones, facultades y obligaciones: "*Evaluar el impacto ambiental de toda actividad que licencie, entendiéndose por tal a aquellas actividades de monitoreo, estudio y seguimiento de la incidencia, evolución o posibilidad de daño ambiental que pueda provenir de la actividad nuclear licenciada"*.

Decreto Nº 1390/98. Reglamentario del Artículo l6, inciso "m" de la Ley Nº 24.804, establece que *"Entiéndese que la evaluación de impacto ambiental a que hace referencia el inciso m) del Artículo 16 de la Ley Nº 24.804 se refiere exclusivamente a la evaluación de los estudios y análisis realizados por los licenciatarios y que la intervención de la Autoridad Regulatoria Nuclear en lo que al ambiente humano se refiere se limita al impacto ambiental radiológico que pueda provenir de la descarga de efluentes radiactivos.*

Norma AR 10.1.1 *"Norma Básica de Seguridad Radiológica"* cuyo objetivo es lograr un nivel apropiado de protección de las personas contra los efectos nocivos de las radiaciones ionizantes y de seguridad de las fuentes de radiación. Partiendo del concepto de protección al público se protege al medio ambiente, sin perjuicio de los valores que se representan en matrices ambientales específicas como por ejemplo el agua. Dicha norma tiene apartados que se relacionan con el tema de estudio como por ejemplo el punto D.3.3.2 "Límites y restricciones de dosis para al exposición de miembros del público" D4. "Exposiciones Potenciales" D5. Gestión de Residuos Radiactivos.

Ley Nº 25.018. Régimen de Gestión de Residuos Radiactivos:

Art. 10, La CNEA a través de Programa Nacional de Gestión de Residuos Radiactivos deberá:
e) Promover el estudio sobre seguridad y preservación del ambiente.
m) Informar en forma permanente a la comunidad sobre los aspectos científicos y tecnológicos de la gestión de residuos radiactivos.

Art. 11 El Programa Nacional de Gestión de Residuos Radiactivos incorporará la recuperación de los sitios afectados por la actividad de extracción, molienda, concentración, tratamiento y elaboración de minerales radiactivos procedentes de yacimientos de explotación y sus respectivos establecimientos fabriles, así como de yacimientos mineros abandonados o establecimientos fabriles fuera de servicio.

La aplicación del principio "impacto ambiental tan bajo como sea posible" deberá ser integrado con programas complementarios de desarrollo sustentable para las comunidades directamente afectadas y quedará sometido a los procedimientos de evaluación de impacto ambiental que dispongan las provincias o la Ciudad de Buenos Aires, según corresponda.

Art 12. - En el caso que la Comisión Nacional de Energía Atómica proponga la necesidad de emplazamiento de instalaciones para la disposición final de residuos radiactivos de alta, media o baja actividad, las localizaciones deberán ser aprobadas previamente como requisito esencial por la ley de la Provincia o de la Ciudad de Buenos Aires, según corresponda con acuerdo de la Autoridad Regulatoria Nuclear.

A tal fin, deberán realizarse los correspondientes estudios de factibilidad ambiental que contendrán una descripción de la propuesta y de los efectos potenciales, directos o indirectos que la misma pueda causar en el ambiente indicado, en su caso, las medidas adecuadas para evitar o minimizar los riesgos y/o consecuencias negativas e informando sobre los alcances, riesgos y beneficios del proyecto.

Deberá convocarse a una audiencia pública con una anticipación no menor a diez (10) días hábiles, en un medio de circulación zonal brindándose la información pertinente vinculada al futuro emplazamiento.

Norma AR 10.12.1 "Gestión de Residuos Radiactivos" que en los siguientes puntos establece lo siguiente:
30. *La Entidad Responsable de una Gestionadora de Residuos Radiactivos deberá llevar a cabo evaluaciones apropiadas de seguridad de los sistemas de disposición final de residuos radiactivos en las etapas de diseño, construcción, operación y cierre definitivo, a satisfacción de la Autoridad Regulatoria.*
31. *La evaluación del impacto radiológico de los sistemas de disposición final de residuos radiactivos deberá tener en cuenta un escenario normal, donde se considera que se cumplen los objetivos de diseño, y la situación resultante de eventos disruptivos concebibles durante el período de aislamiento previsto.*
32. *En las evaluaciones del escenario normal, las dosis estimadas que recibirán las generaciones futuras no deberán exceder las restricciones de dosis establecidas al inicio del período de aislamiento.*
Dichas evaluaciones de seguridad, en términos de dosis, riesgo u otros indicadores de seguridad apropiados para los períodos de aislamiento requeridos, deberán ser realizadas a satisfacción de la Autoridad Regulatoria.
33. *Los riesgos asociados a eventos disruptivos concebibles durante el período de aislamiento previsto no deberán exceder los niveles de riesgo aceptable establecidos al realizarse el diseño del Sistema para la Disposición Final de Residuos Radiactivos.*

Ley Nº 25.675. Ley General del Medio Ambiente. El Artículo 3 establece que la ley "regirá en todo el territorio de la Nación, sus disposiciones son de orden público y se utilizarán para la interpretación y aplicación de la legislación específica sobre la materia, la cual mantendrá su vigencia en cuanto no se oponga a los principios y disposiciones contenidas en ésta".

LEGISLACIÓN PROVINCIAL

Constitución Provincial

El Artículo 16:
Inciso "1", establece que corresponde al Gobierno Provincial ejercer los derechos y competencias no delegadas al Gobierno Federal.

Inciso “3”, establece que corresponde al Gobierno Provincial ejercer en los lugares transferidos por cualquier titulo al Gobierno Federal las potestades provinciales que no obstaculicen el cumplimiento de los objetivos de utilidad nacional.

Ley Nº 7343. Capítulo XI. Artículo 49 establece que *“Las personas, sean estas públicas o privadas responsables de obras y/o acciones que degraden o sean susceptibles de degradar el ambiente, quedan obligadas a presentar, conforme el reglamento respectivo, un estudio de evaluación de impacto ambiental en todas las etapas de desarrollo de cada proyecto”*.

Decreto Nº 2131/00, reglamentario del Capítulo XI de la Ley Nº 7343:

- Considera a la Evaluación de Impacto Ambiental (EIA), como el proceso de administración ambiental destinado a prevenir los efectos que determinadas políticas y/o proyectos pueden causar en la salud. Quedan comprendidos en el término “proceso de administración ambiental”, la documentación ambiental definida por la autoridad de aplicación, que constituirá a) Un Aviso de Proyecto, b) Un Estudio de Impacto Ambiental, o c) Una Auditoria Ambiental, que debe ser presentado por el proponente con carácter de declaración jurada. Conforman también aspectos vinculados al proceso de administración ambiental la información pública, y la valoración crítica de las actuaciones con el procedimiento final, debidamente fundado por parte de la Agencia Córdoba Ambiente Sociedad del Estado.
- Entiende por Evaluación de Impacto Ambiental al procedimiento jurídico administrativo, dictado con la participación de la autoridad correspondiente, que tiene por objetivo la identificación, predicción e interpretación de los impactos ambientales que un proyecto, obra o actividad produciría en caso de ser ejecutado, así como la prevención, corrección y valoración de los mismos.
- Entiende por Proyecto a una propuesta a desarrollar en un determinado tiempo y lugar. Puede estar referido tanto a políticas de gobierno, generales o sectoriales, programas provinciales, regionales o locales, proyectos de construcción o instalaciones, como a otras intervenciones sobre el medio ambiente natural o modificado, comprendidas entre otras las modificaciones del paisaje, la explotación de recursos naturales, los planes de desarrollo, las campañas de aplicación de biocidas, los cambios de uso de la tierra.

V- MONITOREO AMBIENTAL RADIOLÓGICO

La evaluación de impacto ambiental está económica y técnicamente a cargo de los operadores de las instalaciones nucleares. El rol de la Autoridad Regulatoria Nuclear, se limita a controlar el impacto ambiental radiológico proveniente de la descarga de efluentes radiactivos. Monitoreo Ambiental Radiológico:

La ARN controla la emisión de efluentes en las cercanías de las centrales nucleares. Las descargas emitidas por las instalaciones nucleares pueden ser líquidas o gaseosas.

Las centrales Nucleares Atucha I y Embalse se encuentran ubicadas a orillas del Río Paraná y Río Tercero respectivamente.

Para evaluar el impacto ambiental de las descargas líquidas se toman y analizan muestras de agua de los ríos, sedimentos y peces. Asimismo se realiza el monitoraje del agua potable extraída de pozos o de la red cercanos a las centrales.

Para evaluar el impacto ambiental radiológico de las descargas en la atmósfera, se toman y analizan muestras de alimentos producidos en la zona, adicionalmente se analizan muestras representativas de una dieta estándar. El pasto es analizado como indicador de depósito de material radiactivo.

Las muestras son recolectadas mensualmente y sobre ellas se detectan niveles de contaminación atribuibles al funcionamiento de las centrales. Los resultados de las mediciones no deben superar el límite de dosis establecido por la Norma AR 10.1.1[5] para el público, 1 milisiever año.

Complejos minero fabriles de uranio

La ARN lleva a cabo monitorajes ambientales periódicos en los alrededores de los complejos minero fabriles en operación y cerrados asociados a la explotación y procesamiento del mineral del uranio, con el objeto de evaluar el impacto radiológico ambiental de los mismos.

Con dicho propósito, en los alrededores de las instalaciones, se realizan muestreos de aguas superficiales y sedimentos de acuíferos que podrían verse afectados por la operación de los complejos. Asimismo, se toman muestras de aguas de napa freática y de aguas potables en zonas aledañas.

Los resultados de los análisis de estas muestras son comparados con los valores obtenidos, tanto en los estudios preoperacionales como en muestras tomadas en lugares sin influencia de la operación de la instalación.

VI- EVALUACIÓN DE IMPACTO AMBIENTAL SECTORIAL ROL DE LA ARN

ANTECEDENTES

La CNEA, con fecha 26 de febrero de 2009, dio inicio formal a la Evaluación de Impacto Ambiental (EIA) del Reactor CAREM, que estará a cargo de la Universidad Tecnológica Nacional - Facultad Regional Avellaneda (UTN-FRA).

Entre las principales tareas a desarrollar se destacan la evaluación de la condición ambiental de base y el relevamiento y análisis de los antecedentes estadísticos e históricos, información que será obtenida a partir del cruce de información con la CNEA y otros organismos relacionados.; el estudio detallado de los aspectos ambientales y de seguridad de las instalaciones nucleares y las convencionales de la central nucleoeléctrica; el análisis de las normativas vigentes para la elaboración de la Matriz Legal del CAREM; la ejecución de modelos fisicomatemáticos de difusión en la atmósfera y en el curso de agua; el análisis de potenciales riesgos; y la elaboración de la Matriz de Impacto Ambiental.
Más allá del EIA propiamente dicho, que es fundamental no sólo por la importancia de una programación y un diseño responsables con el entorno del futuro reactor, sino también para obtener por parte de las autoridades bonaerenses el permiso de construcción.

[5] Norma AR 10.1.1 Norma Básica de Seguridad Radiológica

VII- CONCLUSIONES

El proceso de Evaluación de Impacto Ambiental debe estar sustentado por una ley y/o reglamento jurídico utilizando bases conceptuales homogéneas. Cualquier herramienta jurídica debe establecer procedimientos administrativos únicos que determinen las formas de llevar a cabo el proceso, los roles y responsabilidades institucionales involucradas, la coordinación de actividades, los plazos límites para llevarlo a cabo y las formas de participación ciudadana, entre otras. Se trata entonces de un Procedimiento Técnico Administrativo integrado por una serie de etapas, que con pequeñas variantes son:

- Solicitud de categorización.
- Categorización de la actividad.
- Presentación de un Estudio de Impacto Ambiental.
- Dictamen técnico.
- Audiencia Pública de los interesados y potenciales afectados.
- Declaración de Impacto Ambiental.
- Certificado de Aptitud Ambiental.

La Autoridad Ambiental de la Administración correspondiente es la encargada de aplicar la Evaluación de Impacto Ambiental.

La normativa ambiental es muy dispersa por lo cual refleja el sesgo en la Argentina de visualizar a la EIA como un mero instrumento técnico integrador de la planificación de obras desde la perspectiva de la ingeniería o las ciencias naturales, y no como un instrumento de toma de decisión con características más amplias. Por ello, los conceptos de “screening”, “scoping”, instancias de consulta y mecanismos de revisión mediante procedimientos administrativos o judiciales, se hallan aún en ciernes, al menos a nivel nacional.

Asimismo, la Argentina posee un sistema diseminado en general signado por sistemas sectoriales y escaso sentido de la EIA como procedimiento administrativo de carácter iterativo. Es decir, Argentina, carece de un régimen común de EIA a nivel federal, entendido como procedimiento administrativo de EIA, sin perjuicio de la gran cantidad de normas que establecen sistemas sectoriales de evaluación de impacto.

Hasta el momento no existe una sólida jurisprudencia administrativa en materia de revisiones de EIA.

En el sector nuclear desde el punto de vista de la seguridad radiológica y nuclear la ARN realiza un informe técnico sectorial auditable conforme a las competencias establecidas en la Ley Nº 24.804, su Decreto Reglamentario Nº 1390/98 y Normas Regulatorias.

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Ensayos *in-vitro* e *in-vivo* del péptido marcado ^{177}Lu-DOTA-Sustancia P y evaluación de los cálculos dosimétricos en la etapa preclínica

Nevares, N.N.; López Bularte, A.C.; Puerta Yepes, N.; Zapata, A.M.; Pérez, J.H.; Rojo, A.M. y Crudo, J.L.

Presentado en: XXII Congreso de la Asociación Latinoamericana de Sociedades de Biología y Medicina Nuclear (ALASBIMN): “De la controversia a la práctica clínica”
Cartagena, Colombia, 5 al 7 de noviembre de 2009

ENSAYOS *IN-VITRO* E *IN- VIVO* DEL PÉPTIDO MARCADO ^{177}Lu-DOTA-SUSTANCIA P Y EVALUACIÓN DE LOS CÁLCULOS DOSIMÉTRICOS EN LA ETAPA PRECLÍNICA

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RESUMEN

El péptido Sustancia P (SP) es el ligando principal de los receptores de neurokininas tipo 1, los cuales se encuentran sobreexpresados en los gliomas malignos.

Se obtuvo ^{177}Lu-DOTA-SP con elevada pureza radioquímica. Se realizaron biodistribuciones en ratones normales a diferentes tiempos. Se calcularon las dosis absorbidas para los diferentes órganos del ratón (cGy/µCi). Utilizando los métodos de escalación por tiempo (A) y extrapolación directa (B), se obtuvieron las dosis en los diferentes órganos humanos. Se calcularon las máximas dosis tolerables en función de los órganos críticos (mCi/kg).

La máxima actividad tolerable que puede ser inyectada sin producir toxicidad en riñones es 11,2 mCi/kg (hombre adulto) y 11,4 mCi/kg (mujer adulta) según el método A y de 47,2 mCi/kg y 56,2 mCi/kg, respectivamente según el método B.

Hasta el momento se pudo obtener ^{177}Lu-DOTA-SP con Ae= 0,05mCi/ µg de péptido. La misma puede aumentarse utilizando el $^{177}LuCl_3$ de mayor actividad específica.

Palabras Claves: sustancia P, receptores peptídicos, lutecio.

Summary

Substance P (SP) is the main ligand of neurokin type 1 receptors, which are consistently overexpressed in malignant gliomas.

^{177}Lu-DOTA-SP was obtained with high radiochemical purity. Biodistribution in normal mice at different times, were done.Absorbed doses were calculated for different mice organs (cGy/µCi). Absorbed doses in human organs were calculated using two different methods, **escalación por tiempo (A) y extrapolación directa (B)**. Maximum tolerated doses were calculated according to critical organs (mCi/kg).

Maximum tolerated dose that can be injected without kidney toxicity is 11,2 mCi/kg (adult man) and 11,4 mCi/kg (adult woman) according to method A and 47,2 mCi/kg, 56,2 mCi/kg, respectevely accordng to method B.

So far, ^{177}Lu-DOTA-SP was achieved with a specific activity (S.a) of 0,05 mCi/ µg of peptide. This S.a can be increased using $^{177}LuCl_3$ of higher specific activity.

Keywords: substance P, peptide receptors, luthetium

1. INTRODUCCIÓN

La Sustancia P (SP) es un péptido de 11 aminoácidos (Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-NH2) y es el miembro mas importante de la familia de las taquininas que constituyen el principal ligando de los receptores de neurokininas tipo 1 (NK-1), los cuales se encuentran sobreexpresados en los gliomas malignos (1)(2). Unido al quelante DOTA puede marcarse con un radionucleido emisor β- adecuado y ser utilizado en **terapia radionucleídica de receptores peptídicos (PRRT)** para el tratamiento de tumores cerebrales. En este aspecto el Lutecio 177

(^{177}Lu) es uno de los radionucleidos más promisorios que surge como una clara elección para aplicaciones terapeúticas ya que posee un período de semidesintegración de 6,71 d con emisión de partículas β- con E max de 497 keV (78,6%), 384 keV (9,1%) y 176 keV (12,2%). También es un emisor γ de 113 keV (6,4%) y 208 keV (11%), los cuales son útiles para la localización *in vivo* y la realización de los cálculos dosimétricos empleando una cámara gamma. El objetivo del trabajo fue obtener ^{177}Lu-DOTA-Sustancia P empleando $^{177}LuCl_3$ de producción local (Planta de Producción de Radioisótopos y RA 3, CAE), con una alta pureza radioquímica (PR), la mayor actividad específica (Ae) posible y realizar los controles de estabilidad *in vitro* e *in vivo*.

2. MATERIALES Y MÉTODOS

2.1. Obtención de ^{177}Lu-DOTA-SP y control de pureza radioquímica

Para la marcación se empleó 1 mCi de $^{177}LuCl_3$ producido por la irradiación de un blanco de Lu_2O_3 enriquecido al 39,6 % en ^{176} Lu en el reactor RA 3 (CAE) con un flujo térmico de $7*10^{13}$ $n*cm^{-2}*s^{-2}$, obteniéndose una actividad específica de 2,41 Ci/mg. Se marcaron 20 µg de DOTA-SP disueltos en PBS, pH 6. La reacción se dejó incubar a 100ºC durante 30 min, pH 5,5. Se realizaron los controles de PR utilizando ITLC-SG (cromatografía instantánea en capa delgada) con sílica gel como soporte y buffer citrato (pH 5.5) como eluyente y RP-HPLC (cromatografía líquida de alta performance en fase reversa) con una columna Delta Pak C18, empleando el siguiente gradiente: H_2O/ TFA (ácido trifluoracético) (solvente A) y acetonitrilo (solvente B), 0-3 min 100% A ,3-15 min 66% A, 15 a 23 min 100% A (3).

2.2. Ensayos *in-vitro*

Estabilidad en suero humano: Se tomó una alícuota de 100µl de ^{177}Lu-DOTA-SP y se agregaron 400 µl de suero humano. La muestra se incubó a 37 º C y se analizaron muestras por ITLC con buffer citrato como eluyente a 2, 4, 24 y 48 hs.

Unión a proteínas del suero: Luego de la incubación del ^{177}Lu-DOTA-SP en suero humano (2, 4, 24 y 48 hs.), las muestras se precipitaron con 300 µl de acetonitrilo (ACN) y se centrifugaron a 2500 rpm durante 5 min, los pellets se lavaron con ACN. Se determinó el porcentaje de actividad total unida al pellet y al sobrenadante.

2.3. Ensayos *in-vivo*

Biodistribuciones de ^{177}Lu-DOTA-SP en ratones normales NIH:

Se estudió la biodistribución del ^{177}Lu-DOTA-SP (PR = 94.6%) en ratones normales. Se utilizaron 6 ratones machos NIH de 25 g aproximadamente, se les inyectó por la vena de la cola 20 µCi de péptido marcado. Luego de 2, 6, 16 y 24 hs p.i. se sacrificaron los animales por dislocación cervical y se extrajeron los órganos de interés. Los órganos se lavaron, secaron y pesaron y se midió en un contador gamma automático (Cobra II, Packard) la actividad en cada uno de ellos junto con un estándar de actividad conocida previamente medida en un activímetro. Se calcularon los valores de porcentaje de la dosis inyectada por gramo de tejido (%DI/g de tejido).

2.4. Análisis biocinético y dosimétrico

Los estudios dosimétricos se realizaron en colaboración con el Grupo de Dosimetría de la Autoridad Regulatoria Nacional. Se obtuvieron las curvas de retención de cada órgano y los tiempos de residencia en cada órgano

Con los datos obtenidos se estimaron las dosis absorbidas para los diferentes órganos del ratón NIH por unidad de actividad inyectada del radiofármaco ^{177}Lu-DOTA-SP, mediante el esquema MIRD, donde la dosis se determina como el producto entre el tiempo de residencia de cada órgano fuente y los factores S para todas las combinaciones órgano fuente-blanco

posibles. Los valores de los factores S para los órganos del ratón NIH fueron calculados de acuerdo al trabajo de Villarreal (2007) basados en el modelo de Larson et ál. (2007).

Para la extrapolación de los datos de animales a humanos son se utilizan comúnmente los siguientes métodos:

- ✓ Uso directo de datos de animales
- ✓ Escalación por masa
- ✓ Escalación por tiempo

Las investigaciones realizadas sobre los métodos de extrapolación no son concluyentes en cuanto a qué método particular es mejor. En este trabajo se utilizó el método de extrapolación directa de los datos del ratón y el método de extrapolación por tiempo. En el primero se considera que el comportamiento biocinético humano es similar al observado en el modelo animal, de modo que los tiempos de residencia determinados para los diferentes órganos del ratón se consideran iguales a los tiempos de residencia de los órganos equivalentes en humanos.

La escalación por tiempo es una transformación de la escala de tiempo, que toma en cuenta las diferencias de las tasas metabólicas entre animales con diferente masa corporal. Una aproximación sugerida para esta escalación es:

$$t_h = t_a \left[\frac{m_h^{CE}}{m_a^{CE}} \right]^{0.25}$$

Donde:

t_a es el tiempo en el cual una medición fue hecha en el sistema animal

t_h es el tiempo correspondiente asumido para el dato humano

m_a^{CE} y m_h^{CE} son las masas corporales totales de la especie animal y la especie humana, repectivamente.

El cálculo de dosis absorbida en humanos (hombre y mujer adulta) fue realizado mediante el software Organ Level Internal Dose Assessment Code (OLINDA), utilizando los factores de conversión de dosis que allí se presentan.

3. RESULTADOS

3.1. Obtención de ^{177}Lu-DOTA-SP y control de pureza radioquímica

En la marcación de DOTA-SP con $^{177}LuCl_3$ (Ae= 2,41Ci/mg) se obtuvo con una PR de 99,3% y se alcanzó una Ae=0,05 mCi/µg de péptido. El radiocromatograma (Figura 1) muestra el pico correspondiente a ^{177}Lu-DOTA-SP, Tiempo de Retención (TR)= 11,63 min (94,7%), el ^{177}Lu libre TR= 1,69 min (0,7%) y un pico TR=11,03 min (4,56%) debido, posiblemente, a especies oxidadas de los residuos de meteonina (Met) presente en el terminal amino del péptido SP.

3.2. Ensayos *in-vitro*

Estabilidad en suero humano: Los ensayos de estabilidad en suero (Figura 2) muestran una buena estabilidad del compuesto marcado hasta las 24 hs (92,5%) y una rápida degradación a las 48 hs (64%) según los controles realizados en ITLC, sería necesario caracterizar por HPLC.

Unión a proteínas del suero: El péptido marcado muestra una baja unión a proteínas 21,55 % a las 2 hs y 28,4% a las 48 hs. (Figura 3).

3.3 Ensayos *in-vivo*

Biodistribuciones de ^{177}Lu-DOTA-SP en ratones normales NIH:

Los datos de las biodistribuciones en ratones normales mostraron rápida depuración sanguínea 1,5% DI/g a 30 min p.i y excreción renal 9,44 y 2,31% DI/g a 30 min y 16 hs p.i, respectivamente. Los bajos valores de captación en hígado (menor al 1% a los 30 min p.i) son una confirmación indirecta de la excelente estabilidad *in vivo* de ^{177}Lu-DOTA-SP cuyos valores de biodistribución en dichos órganos fueron inferiores al 3%D.I./g a 30 min p.i ya que el ^{177}Lu libre es captado por este órgano.

3.4. Análisis biocinético y dosimétrico

Curvas de Retención estimadas para cada órgano

Las curvas de retención en cada órgano se encuentran graficadas en la Figura 3.

Tiempos de Residencia

Los tiempos de residencia hallados para el ^{177}Lu-DOTA-SP en los diferentes órganos del ratón, revelan que la mayoría de los eventos de desintegración se producen en la sangre seguida por los riñones. (Tabla 1).

Tabla 1. Tiempos de residencia de ^{177}Lu-DOTA-SP en los diferentes órganos del ratón

Órgano	**τ (horas)**
sangre	1,0748
hígado	0,05596
bazo	0,02303
riñones	0,537317
estómago	0,07812
pulmones	0,0447
intestino	0,1438
médula	0,129

El tiempo de residencia en médula se estimó a partir de datos de sangre como

$$\tau_{medula}\ (horas) = RMBLR^{*}\ \tau_{sangre}\ (horas)^{*}\ masa_{\ medula} / masa_{\ sangre} \quad (1)$$

RMBLR = 0,35 según trabajo de Villarreal (2007)

Masa $_{médula}$= 0,6832 g según fantoma de Larson

Masa $_{sangre}$= 2 g según trabajo de Puerta (2008)

Las dosis absorbidas para los diferentes órganos del ratón NIH por unidad de actividad inyectada del radiofármaco ^{177}Lu-DOTA-SP, se muestran en la Tabla 2.

Tabla 2. Dosis absorbidas para los diferentes órganos del ratón

Órgano de ratón	Dosis Absorbida (cGy/uCi)
hígado	0,02
pulmones	0,05
estómago	0,04
riñones	0,52
bazo	0,05
intestinos	0,02

La dosis absorbida en los diferentes órganos humanos (hombre y mujer adulta) por unidad de actividad inyectada de ^{177}Lu-DOTA-SP se presentan en la siguiente tabla (Tabla 3). Este cálculo se realizó empleando el programa OLINDA, usando los tiempos de residencia calculados mediante el método de extrapolación por tiempo.

Tabla 3. Dosis absorbidas en los diferentes órganos humanos calculados utilizando el método de extrapolación por tiempo.

Órganos	Dosis Absorbida (cGy/mCi)	
	Hombre	Mujer
riñones	3,03E+00	3,09E+00
intestino	8,07E-01	8,25E-01
estómago	1,76E-01	2,01E-01
bazo	8,01E-02	9,61E-02
pulmones	1,78E-01	2,05E-01
hígado	9,17E-02	1,22E-01
médula	3,02E-02	2,94E-02

En este caso el órgano que recibe la mayor dosis es el riñón con un valor de 3,03 cGy/mCi para el hombre adulto y 3,09 cGy/mCi para la mujer adulta.

Empleando el método de extrapolación directa se obtuvieron los siguientes datos de dosis absorbida en los diferentes órganos humanos (hombre y mujer adulta) por unidad de actividad inyectada de ^{177}Lu-DOTA-SP. Tabla 4.

Tabla 4. Dosis absorbidas en los diferentes órganos humanos calculados utilizando el método de extrapolación directa de los datos del ratón

Órganos	Dosis Absorbida (cGy/mCi)	
	Hombre	Mujer
riñones	5,75E-01	6,25E-01
intestino	1,22E-01	1,36E-01
estómago	5,40E-02	6,20E-02
bazo	4,23E-02	5,16E-02
pulmones	1,48E-02	1,86E-02
hígado	1,06E-02	1,43E-02
médula	2,48E-02	2,33E-02

Las máximas actividades tolerables calculadas para ambos métodos de extrapolación a humnos dieron los siguientes resultados. Para el método de escalación por tiempo la actividad máxima tolerable de ^{177}Lu-DOTA-SP que puede ser inyectada sin producir toxicidad en riñones es para el hombre adulto de 11,2 mCi/kg y para la mujer adulta de 11,4 mCi/kg. Para el método de extrapolación directa, la máxima actividad tolerable de ^{177}Lu-DOTA-SP que puede ser inyectada sin producir toxicidad en riñones es para el hombre adulto de 47,2 mCi/kg y para la mujer adulta de 56,2 mCi/kg. Estos datos se obtienen suponiendo que 20 Gy es la dosis máxima que pueden tolerar los riñones sin que se produzca radiotoxicidad, y que la masa del hombre y mujer adulta son 73,7 kg y 56,9 kg respectivamente, y la máxima actividad tolerable de ^{177}Lu-DOTA-SP que puede ser inyectada sin producir toxicidad en médula es para el hombre adulto de 109 mCi/kg y para la mujer adulta de 151 mCi/kg. Estos datos se obtienen usando la expresión 1 para el cálculo del tiempo de residencia para la médula, suponiendo además que 2 Gy es la dosis máxima que puede tolerar la médula sin que se produzca radiotoxicidad. Otro estudio realizado con ^{18}F-sustancia p establece que el tiempo de residencia en médula es de 0,28 h para la cual la actividad máxima tolerable estaría en el orden de 55,7 mCi/kg para el hombre y 79,2 mCi/kg para la mujer. Quiere decir que el órgano crítico que va a limitar la dosis son los riñones.

4. DISCUSIÓN

Se pudo obtener ^{177}Lu-DOTA-SP con alta PR pero una baja actividad específica (Ae= 0,05mCi/ µg de péptido) la cual no resulta útil para una aplicación terapéutica en un solo ciclo. Dicha Ae podrá elevarse en próximos ensayos cuando se emplee para la producción de ^{177}Lu un blanco de mayor enriquecimiento (82%).

Según los cálculos de dosis, el riñón recibe la mayor dosis 3,03 cGy/mCi para el hombre adulto y 3,09 cGy/mCi para la mujer adulta. Este dato es consistente con datos obtenidos experimentalmente para el 177Lu-DOTA-TATE donde se establece que la dosis en riñón va de 3,7- 8,14 cGy/mCi (Cremonesi et ál., 2006, Dosimetry in Peptide Radionuclide Receptor Therapy: A Review).

En los datos de dosis que se obtuvieron en este trabajo, se ha observado que la extrapolación directa tiende a subestimar la dosis en los órganos humanos. Por lo tanto el método de escalación por tiempo resultó el más apropiado, ya que fue el que predijo una mayor dosis en los órganos humanos.

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Figura 1. Radiocromatograma en RP-HPLC del ^{177}Lu-DOTA-SP TR=11,46 min y $^{177}LuCl_3$ TR=1,69 min.

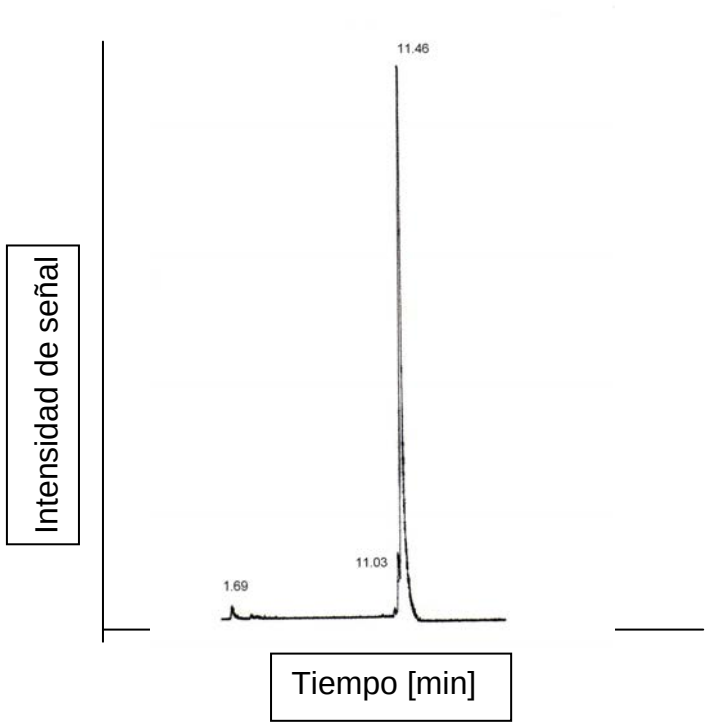


Figura 2. Gráfico de estabilidad en suero humano.

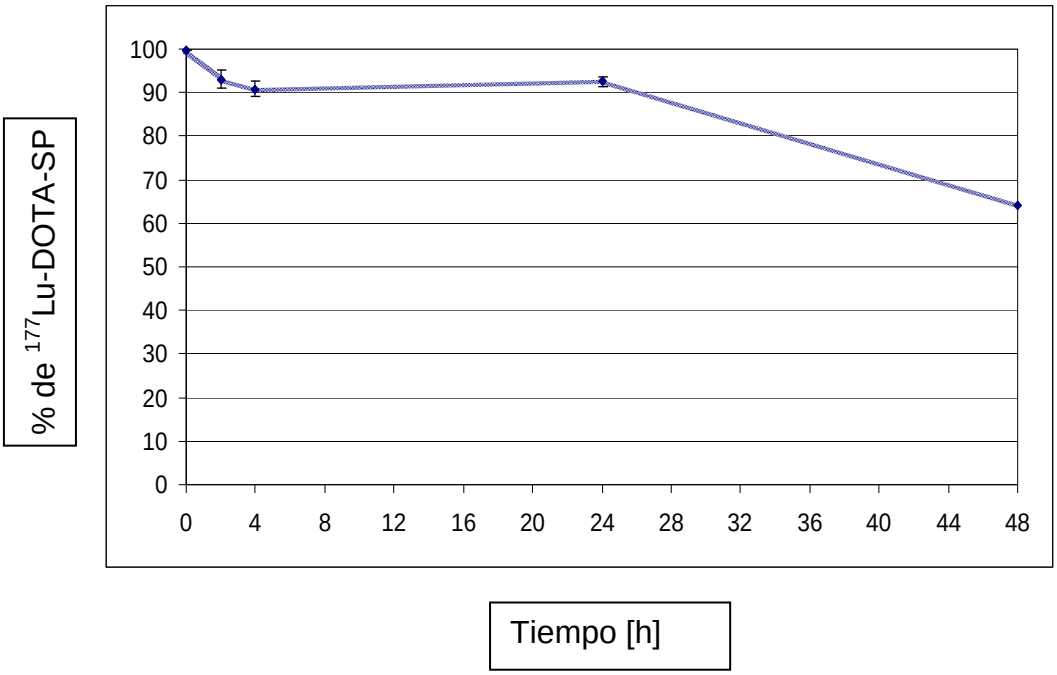


Figura 3. Gráfico de unión a proteínas

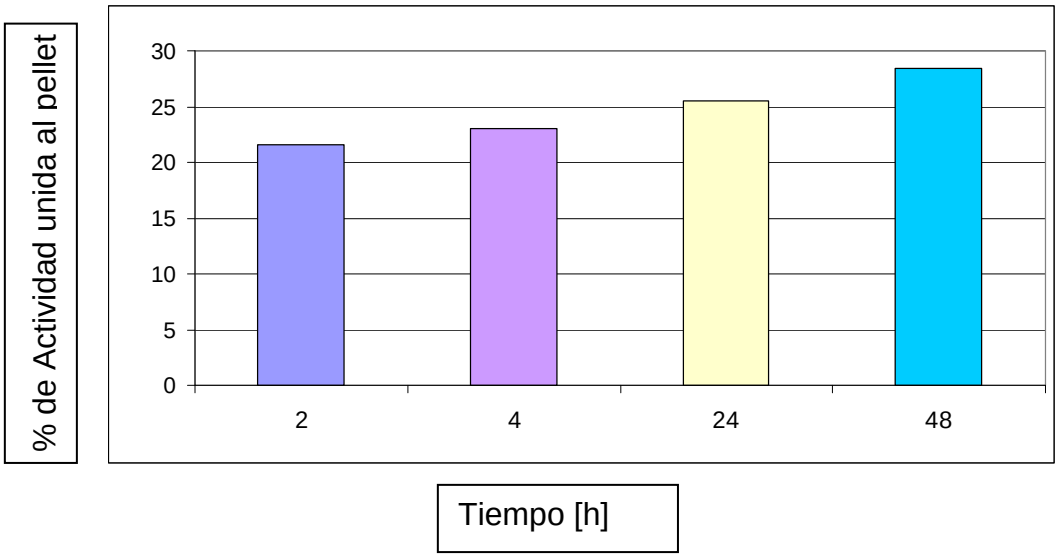


Figura 4. Biodistribuciones de ^{177}Lu-DOTA-SP en ratones normales NIH

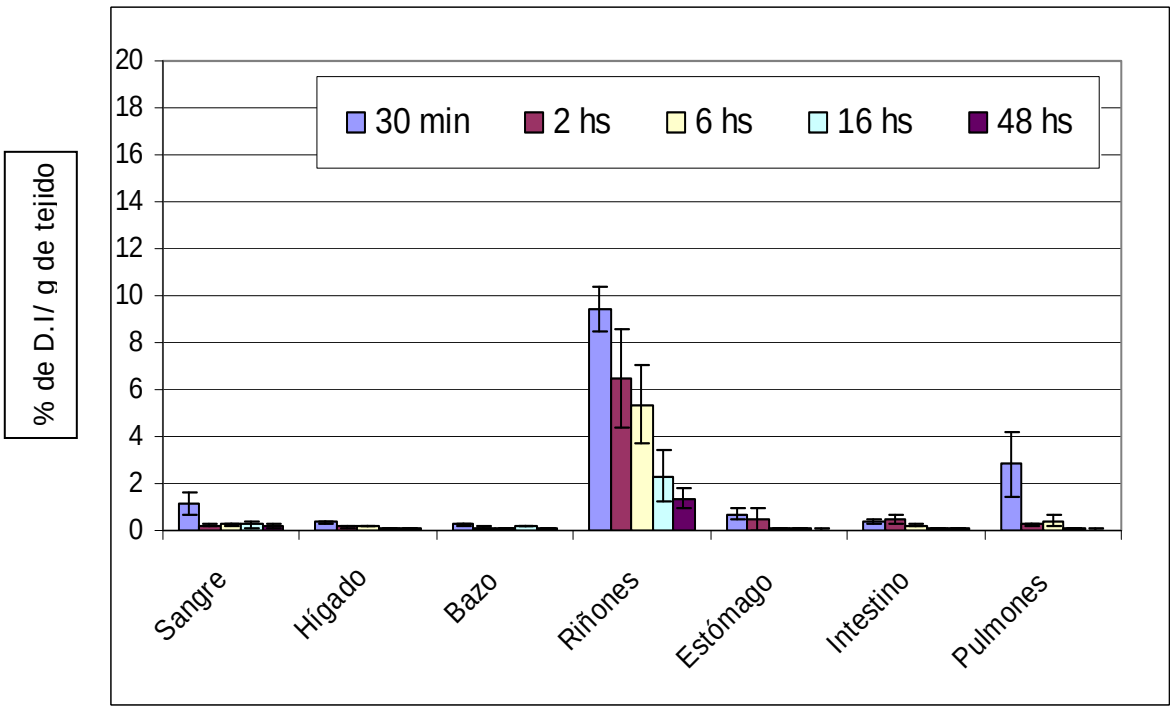
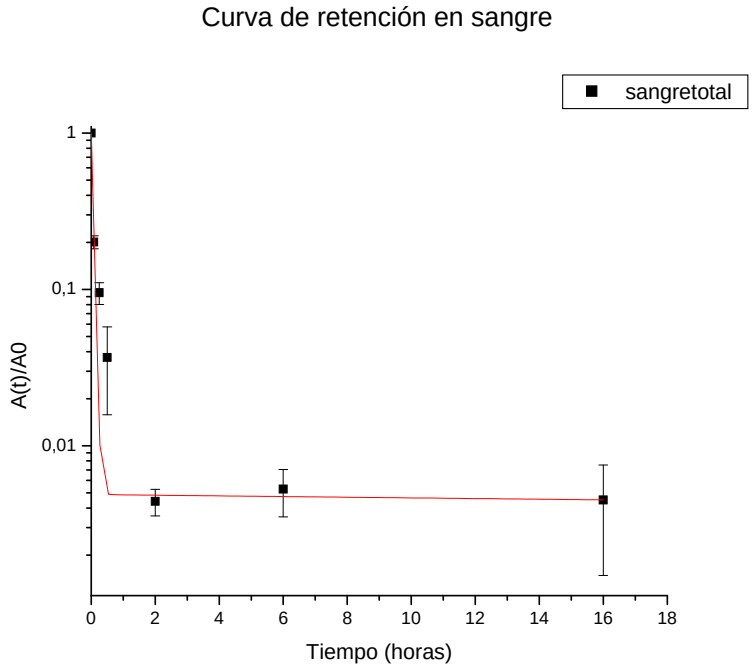
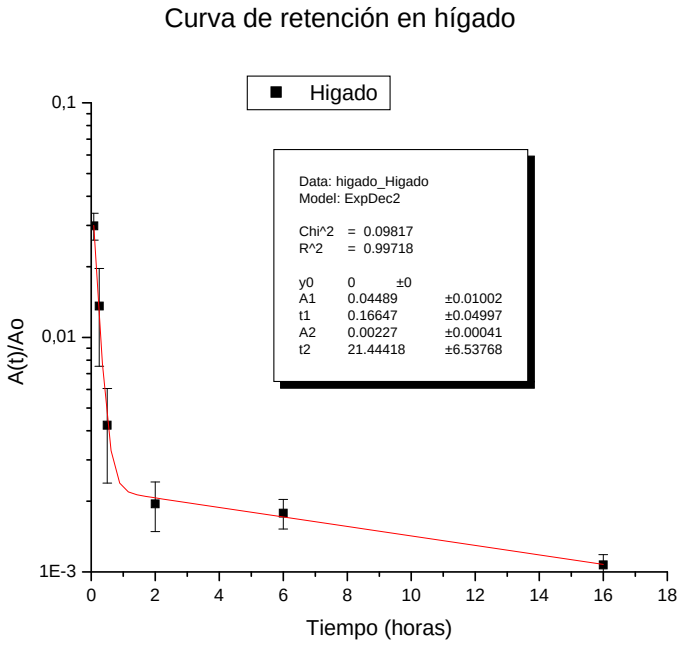
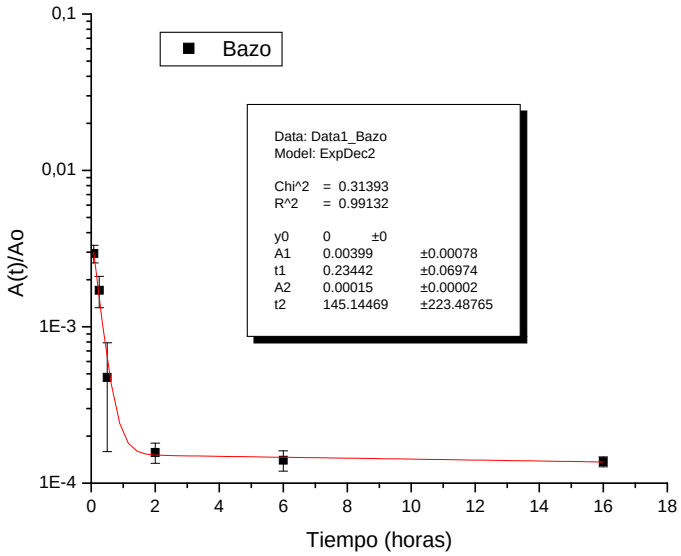


Figura 5. Curvas de retención

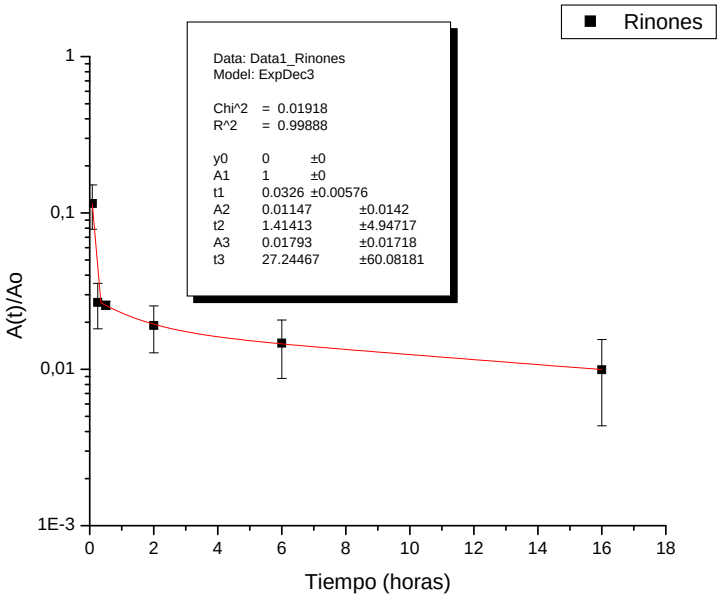




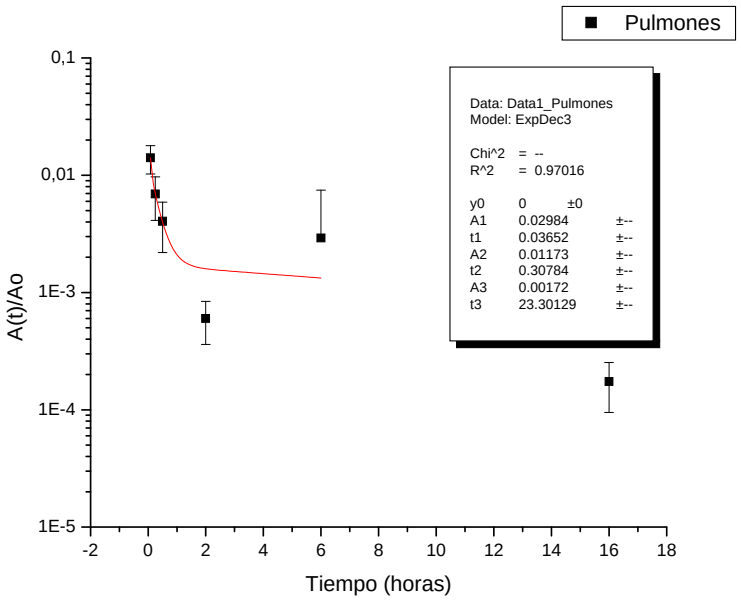
Curva de retención en bazo



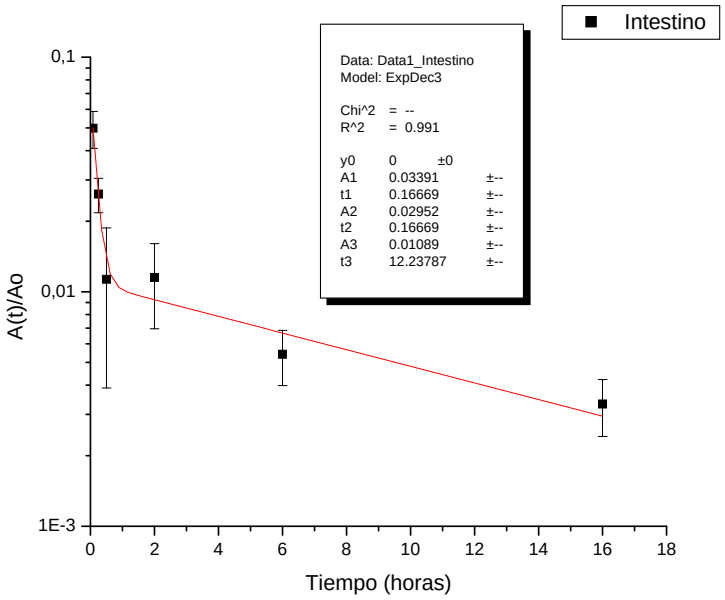
Curva de retención en riñones



Curva de retención en pulmones



Curva de retención en intestino



Estudio biocinético y dosimétrico de un kit de producción local de ^{177}Lu-EDTMP para su uso como agente paliativo del dolor

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Estudio biocinético y dosimétrico de un kit de producción local de ^{177}Lu-EDTMP para su uso como agente paliativo del dolor.

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Resumen

Los radiofármacos con afinidad por el tejido óseo como el ácido etilen-diamino-tetrametilen-fosfónico (EDTMP) marcado con radioisótopos emisores β^- han demostrado su eficacia en el tratamiento paliativo de las metástasis óseas. Se realizó un estudio biocinético y dosimétrico del ^{177}Lu-EDTMP en ratones NIH. Los resultados obtenidos fueron extrapolados a humanos. Se estimó la dosis absorbida en órganos para dos modelos: un hombre adulto y una mujer adulta.

El ^{177}Lu-EDTMP posee una selectiva captación en hueso, una rápida eliminación en sangre e insignificante captación en tejidos no óseos. La dosis en hueso estimada para el hombre se encuentra entre 14,7-15,3 cGy/mCi y entre 19,6-20,4 cGy/mCi para la mujer. La toxicidad en médula ósea representa el factor limitante de este tipo de terapia, y para evitar superar la dosis máxima que ésta puede tolerar (200 cGy), se encontró que la actividad máxima segura de ^{177}Lu-EDTMP que puede ser inyectada al hombre (73,9Kg), corresponde a un valor de 1,01 mCi/kg y a un valor de 1,25 mCi/Kg para la mujer (56,9Kg).

Palabras claves: Radiofármacos con afinidad por el tejido óseo, EDTMP, ^{177}Lu, tratamiento paliativo, metástasis óseas, médula ósea.

Biokinetic and dosimetric study of a kit of ^{177}Lu-EDTMP produced locally for use as a pain palliation agent

Abstract

Bone-seeking radiopharmaceuticals like the ethylenediaminetetramethylene phosphonic acid (EDTMP) labeled with β^--emitting radioisotopes have demonstrated their efficacy in the palliative treatment of skeletal metastasis.

A biokinetic and dosimetric study of ^{177}Lu-EDTMP in NIH mice was performed. The results obtained were extrapolated to human. We estimate the absorbed doses in organs for two models: an adult male and an adult female.

^{177}Lu-EDTMP has a selective uptake in bone, a rapid elimination from blood and negligible uptake in non-skeletal tissues. The estimated dose in bone is between 14.7-15.3 cGy/mCi for men and between 19.6-20.4 cGy/mCi for women.

Bone marrow toxicity represents the limiting factor in this kind of therapy, and to avoid exceed the maximum dose it can tolerate (200 cGy), it was found that the maximum safe activity of ^{177}Lu-EDTMP to be injected to male (73.9 kg), corresponds to a value of 1.01 mCi/kg and a value of 1.25 mCi/kg for female (56.9 kg).

Keywords: Bone-seeking radiopharmaceuticals, EDTMP, ^{177}Lu, palliative treatment, skeletal metastasis, bone marrow.

Introducción

Las metástasis óseas son una de las principales complicaciones de una gran variedad de cánceres, siendo frecuentes en los cánceres osteofílicos como son: el cáncer de próstata, seno y pulmones. Cuando las metástasis óseas son localizadas pueden ser tratadas con éxito mediante procedimientos quirúrgicos y radioterapia externa. Cuando éstas son múltiples y menos localizadas, la modalidad más eficaz para su tratamiento es el tratamiento paliativo con radiofármacos que presenten afinidad por el tejido óseo [1, 2]. Estos radiofármacos son complejos que usualmente están formados por una molécula que presenta afinidad por el hueso mineral y un radionucleído emisor β^-. Estas características les confiere la capacidad de irradiar selectivamente las metástasis óseas con una mínima radiación a los tejidos normales. Sin embargo, la elevada radiosensibilidad de las células hematopoyéticas ubicadas en la médula ósea roja hacen que este órgano sea, en general, el factor limitante en este tipo de terapia [3].

Actualmente el radiofármaco empleado para el tratamiento paliativo de las metástasis óseas, es el ácido etilen-diamino-tetrametilen-fosfónico (EDTMP) marcado con ^{153}Sm, demostrando ser seguro y efectivo [4]. Sin embargo, la disponibilidad de ^{153}Sm en la mayoría de países sigue siendo limitada como consecuencia de su corto período de semidesintegración y su alto costo de producción, por lo que otros radionucleídos emisores beta negativos, como el ^{177}Lu, están recibiendo una atención significativa. En este sentido el Organismo Internacional de Energía Atómica (OIEA) está impulsando el estudio de más de 30

aplicaciones clínicas del ^{177}Lu en el marco de un Proyecto de Investigación Coordinado "CRP for the development of Therapeutic Radiopharmaceuticals based on ^{177}Lu" (2006-2010) en el que Argentina está participando activamente [5].

El EDTMP marcado con ^{177}Lu parece ofrecer una eficacia clínica similar al ^{153}Sm-EDTMP, y presenta la ventaja adicional de que puede ser producido a bajo costo, con alta pureza, y mayor disponibilidad en más países [6]. Además, su máxima energía β^- (497 keV) es adecuadamente baja comparada con la del ^{153}Sm (810 keV), razón por la cual se espera que se minimicen efectos adversos que pueden ser provocados por este tipo de tratamiento, como la mielosupresión [6,7].

Para poder implementar el ^{177}Lu-EDTMP como radiofármaco en el tratamiento paliativo del dolor por metástasis óseas, es necesario conformar un conjunto de estudios preclínicos, generalmente realizados en animales, que permitan valorar su eficacia y seguridad antes de realizar los ensayos clínicos en humanos. Para contribuir con tal fin, en este trabajo se propone estudiar la biodistribución y metabolismo de un kit de producción local de ^{177}Lu-EDTMP en un modelo experimental animal, estimar la dosis absorbida en los órganos de interés, identificar los órganos críticos y extrapolar los resultados obtenidos a humanos, con el propósito de evaluar los riesgos de radiotoxicidad en los órganos de éste.

Materiales y Métodos

Se produjo ^{177}Lu, en el reactor nuclear RA-3 del Centro Atómico Ezeiza (Argentina), por activación neutrónica de un blanco natural Lu_2O_3 con un flujo de

7×10^{13} n cm^{-2} s^{-1}. Se reconstituyó el ^{177}Lu con 0,1 M de HCl. Seguidamente, el kit liofilizado compuesto por 25 mg de EDTMP y 2,5 mg de ácido gentísico, se marcó con 1 ml de $^{177}LuCl_3$ (36 mCi, relación molar EDTMP:^{177}Lu; 42:1), y se determinó la pureza radioquímica utilizando ITLC empleando Metanol: NH_3: H_20 como eluyente.

Se realizaron biodistribuciones en un total de 24 ratones adultos NIH normales, con un peso promedio de 25 g, a 30 min, 2, 4, 24, 48 h y 7 días post-inyección. Para esto, se inyectó inicialmente en la vena de la cola alrededor de 50 µCi de ^{177}Lu-EDTMP y se evaluaron 4 ratones por cada tiempo de medición. Luego de sacrificarlos, se extrajeron órganos y tejidos de interés (fémur, hígado, bazo, pulmones, sangre, riñones, estómago e intestino) y se midió directamente su actividad empleando un contador gamma automático, aprovechando la emisión gamma del ^{177}Lu de 208 keV.

Se realizaron mediciones de actividad retenida en cuerpo entero, en 4 ratones adultos NIH normales. Para esto se inyectó en la vena de su cola alrededor de 50 µCi de ^{177}Lu-EDTMP y para los mismos tiempos de medición en los que se evaluó la biodistribución, se midió la actividad en cuerpo entero con un activímetro [5, 8]. Con el fin de obtener la actividad que quedó retenida en los órganos no seleccionados para la medición de su actividad, se sustrajo de la actividad de cuerpo entero, la actividad de todos los órganos medidos para los mismos tiempos de medición. Esta actividad correspondió al valor de actividad retenida en el resto del cuerpo.

La principal vía de excreción del EDTMP, según estudios experimentales reportados en la literatura, es a través de orina [9, 10, 11]. Como se espera que el radiofármaco ^{177}Lu-EDTMP siga el metabolismo propio del EDTMP, se estimó la actividad en orina empleando la ecuación 1, la cual se recomienda utilizar cuando se establece que la única forma de excreción del radionucleido es vía urinaria [9, 12].

$$\widetilde{A_U}(t) = A_0 - A_{WB}(t) \quad (1)$$

Donde $\widetilde{A_U}(t)$ representa la actividad acumulada en orina en el tiempo t, A_0 el valor de la actividad inicial en el cuerpo entero y $A_{WB}(t)$ la actividad del cuerpo entero en el momento t.

Los datos experimentales de actividad en cada órgano o tejido en conjunto con los datos inferidos de orina y resto del cuerpo, fueron usados para establecer el modelo compartimental que simula el metabolismo seguido por el ^{177}Lu-EDTMP en el ratón NIH con la ayuda del software SAMM II [13]. Este programa permite resolver un modelo compartimental, representado por un sistema de ecuaciones lineales, y ajustarlo a los datos experimentales empleando técnicas matemáticas y estadísticas. Para producir el mejor ajuste, el programa SAMM II minimiza una función objetivo que mide la bondad del ajuste con respecto al conjunto de datos experimentales [13]. Se eligió el modelo que, luego de iterar, optimizó el valor de la función objetivo y el valor de los criterios de información Akaike (AIC) y el Schwarz-Bayesian (BIC) [13]. El programa SAMM II aporta los valores de las

tasas de transferencia entre compartimentos (k) óptimas, sus desviaciones estándar, coeficientes de variación e intervalos del 95% de confianza para cada una de ellas.

Del mismo modo, haciendo uso del software SAMM II, se calculó el área bajo las curvas de actividad en función del tiempo generadas por el modelo compartimental (actividad acumulada), las cuales normalizadas a la actividad inicial inyectada corresponden al valor de los tiempos de residencia τ.

La dosis absorbida en los distintos órganos blanco del ratón NIH fue calculada siguiendo el formalismo MIRD (Medical Internal Radiation Dose), donde la dosis en cada órgano blanco del ratón por unidad de actividad inyectada, se determinó como el producto entre el tiempo de residencia de cada órgano fuente y los factores S para todas las combinaciones órganos fuentes-blanco posibles [14, 15]. Los valores de los factores S para los órganos del ratón NIH, fueron calculados mediante a una corrección por masa de los factores calculados por Larsson *et al.* [16] para un modelo animal que simula al ratón[8].

Se extrapolaron los resultados obtenidos del modelo animal a un modelo humano empleando el método directo. Este método de extrapolación considera que los tiempos de residencia determinados para los diferentes órganos del ratón, son iguales a los tiempos de residencia de los órganos equivalentes en humanos [8, 17]. Se determinó la dosis en los diferentes órganos de un modelo humano (hombre y mujer adulta) mediante el empleo del programa OLINDA [18], el cual permitió este cálculo al introducir los valores de los tiempos de residencia y al seleccionar adecuadamente los modelos humanos a utilizar y el radionucleído de

interés (^{177}Lu). Como la dosis en médula ósea roja se ve influenciada por la distribución heterogénea del radiofármaco en el hueso, se evaluó la dosis en ella suponiendo diferentes relaciones de actividad acumulada entre el hueso trabecular y el cortical (entre 1 y 2).

Finalmente, se calculó la actividad máxima de ^{177}Lu-EDTMP que puede administrarse a un paciente (los dos modelos humanos empleados) sin exceder el máximo de tolerancia del órgano sano de mayor riesgo. Se identificó a la médula ósea roja como el órgano sano limitante. La dosis en este órgano no debe superar un valor de 200 cGy, según datos reportados en la literatura [19], y por ello se calculó la actividad "máxima" segura que puede ser inyectada a los dos modelos humanos empleados según la expresión 2. Para este cálculo se supuso el caso particular de una relación de actividad acumulada entre el hueso trabecular y el cortical de 1,75, la cual es sugerida en la literatura para el caso del ^{153}Sm-EDTMP [9, 20].

$$Actividad\ max\left(\frac{mCi}{Kg}\right) = \frac{200\ cGy}{coeficiente\ de\ dosis\ M.O. * masa} \qquad (2)$$

El coeficiente de dosis M.O. representa la dosis en médula ósea por unidad de actividad incorporada. La masa toma los valores de la masa de los modelos usados: 73,7 Kg para el hombre y 56,9 Kg para la mujer.

Resultados

La pureza radioquímica del kit ^{177}Lu-EDTMP fue superior a 98%.

Los estudios de biodistribución llevados a cabo en ratones NIH normales (n= 4) a los 30 minutos, 2 h, 4 h, 24 h, 48 h y 7 días post-inyección de 50 µCi de ^{177}Lu-EDTMP se muestran en la tabla 1. Los resultados son expresados como el cociente de actividad por dosis inyectada.

De los datos experimentales se observa que menos del 1% de la actividad inyectada de ^{177}Lu-EDTMP permanece en sangre a partir de los 30 min p.i. El resto se depura rápidamente y principalmente es retenido en hueso.

El modelo óptimo que describe el metabolismo del ^{177}Lu-EDTMP en el modelo animal propuesto, se esquematiza en la figura 1. El modelo mamilar obtenido está compuesto por un compartimento central que representa la sangre y 9 compartimentos periféricos que rodean al compartimento sangre e intercambian material (^{177}Lu-EDTMP) exclusivamente con él. Estos nueve compartimentos representan los órganos y tejidos medidos, la orina acumulada estimada y el resto del cuerpo.

En la figura 2 se muestran las curvas resueltas por el modelo para la actividad acumulada en orina y para la retención de actividad en hueso, sangre y resto del cuerpo, todas normalizadas al valor de actividad inyectada. El resto del cuerpo no incluye los órganos medidos. Las curvas de retención de actividad en los órganos no óseos medidos son ilustradas en la figura 3. Según las curvas, se observa que a las 5 horas p.i. se elimina a través de orina, alrededor del 45% del porcentaje de actividad inyectada de ^{177}Lu-EDTMP. El hueso presenta su máximo porcentaje de actividad de ^{177}Lu-EDTMP entre las 2 y 4 horas, y equivale casi a un 50 % de la actividad inyectada. La retención del ^{177}Lu-EDTMP en los órganos medidos diferentes al hueso fue insignificante, menor del 1 % para todos los tiempos.

Los tiempos de residencia hallados para el ^{177}Lu-EDTMP en los diferentes órganos del ratón se muestran en la tabla 2.

Las dosis absorbidas para los diferentes órganos del ratón NIH y para los diferentes órganos humanos (hombre y mujer adulta) por unidad de actividad inyectada de ^{177}Lu-EDTMP, se presentan en la tabla 3. Se puede observar que, la dosis depositada en las células osteogénicas tanto del ratón (61,97±13,63 cGy/µCi), como la estimada en los modelos humanos (entre 14,7-15,3 cGy/mCi para el hombre y entre 19,6-20,4 cGy/mCi para la mujer), es significativamente más grande que para el resto de los órganos.

La actividad de ^{177}Lu-EDTMP retenida en médula ósea roja podría ser inferida a partir de la actividad en sangre, sin embargo, al ser este radiofármaco tan rápidamente eliminado de sangre, se encontró despreciable su retención en médula. En consecuencia, la dosis depositada en la médula ósea por el ^{177}Lu-EDTMP se debe, casi exclusivamente, al depósito del radiofármaco en el hueso.

El rango de dosis en médula ósea encontrado para los dos modelos humanos, suponiendo diferentes relaciones de actividad acumulada entre el hueso trabecular y el cortical, se presenta en la tabla 3. Se encontró que el valor superior del rango corresponde al caso en que el radiofármaco se acumula más selectivamente en el hueso trabecular que en el cortical, es decir, al caso en que la relación de actividad acumulada entre el hueso trabecular y el cortical es 2.

La dosis en médula, en el caso particular de suponer una relación de actividad acumulada entre el hueso trabecular y el cortical de 1,75, tiene un valor de 2,68 cGy/mCi para el hombre y 2,80 cGy/mCi para la mujer. Por lo tanto, tomando como válida esta suposición, se encontró que la actividad máxima de ^{177}Lu-

EDTMP que puede ser inyectada, sin exceder el máximo de tolerancia de la médula, corresponde a un valor de 1,01 mCi/Kg para el hombre, y un valor de 1,25 mCi/Kg para la mujer.

Discusión

El kit de ^{177}Lu-EDTMP mostró una alta pureza radioquímica, lo que demuestra la capacidad de producir este radiofármaco de forma local.

El estudio de biodistribución realizado para el ^{177}Lu-EDTMP, evidenció que el metabolismo del complejo está dirigido prácticamente por la molécula EDTMP, ya que los patrones de biodistribución del ^{177}Lu-EDTMP muestran una captación y una eliminación en tejido similar a los reportados en estudios con ^{153}Sm-EDTMP [10]. De la misma forma se registró que el radiofármaco ^{177}Lu-EDTMP muestra una biodistribución diferente de la obtenida con ^{177}Lu libre [8], lo que claramente demuestra la gran estabilidad *in vivo* del complejo.

El estudio de biodistribución, biocinética y dosimetría del ^{177}Lu-EDTMP realizado en ratones NIH y extrapolado a humanos, permitió revelar el potencial que posee el radiofármaco para ser implementado con éxito en el tratamiento paliativo de metástasis óseas. Es un radiofármaco que posee una rápida y selectiva captación en hueso, una rápida eliminación en sangre e insignificante captación en tejidos no óseos.

El factor limitante que puede presentar el tratamiento con ^{177}Lu-EDTMP es la toxicidad en médula ósea, esto como consecuencia de su gran retención en hueso. La estimación de la dosis en el modelo humano facilitó identificar los

riesgos a priori de alcanzar la mielotoxicidad. La estimación precisa de la dosis en médula, como se observó, requiere conocer la distribución real del radiofármaco en el hueso, por esto se sugiere implementar un método basado en imágenes que permitan conocer la distribución específica del radiofármaco. Sin embargo, tomando en cuenta que la contribución a la dosis en médula por la actividad acumulada en el hueso trabecular es más grande que el aporte por la actividad acumulada en el hueso cortical, la suposición que considera que 1,75 es la relación de actividad acumulada entre el hueso trabecular y el cortical, es bastante conservativa, además de estar reportada experimentalmente en el caso de ^{153}Sm-EDTMP [9, 20].

Se encontró que el valor de la actividad máxima que puede ser inyectada al hombre (1,01 mCi/Kg) y a la mujer (1,25 mCi/Kg) es razonable, pues es consistente con estudios clínicos reportados para el ^{153}Sm-EDTMP, donde se establece que una actividad de 1 mCi/Kg es segura y efectiva para el tratamiento paliativo de las metástasis óseas [9, 10, 21, 22, 23], a pesar de que este último deposita una dosis en médula mayor que la que se estima entrega el ^{177}Lu-EDTMP.

Este estudio contribuye con la parte dosimétrica de la etapa preclínica, indicando que el kit de ^{177}Lu-EDTMP producido localmente es probable que sea seguro y eficaz en las personas.

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Tablas

Tabla 1. Biodistribución del ^{177}Lu-EDTMP en ratón NIH

	0,5 hr	2 hr	4 hr	24 hr	48 hr	7 d
Sangre	1,11E-02±3,02E-3	5,44E-03±2,63E-3	4,39E-03±1,73E-3	4,96E-03±2,14E-3	5,54E-03±1,80E-3	2,07E-03±4,16E-4
Hueso	3,64E-01±1,01E-1	4,87E-01±8,69E-2	…	4,24E-01±6,95E-2	2,70E-01±9,34E-2	1,75E-01±2,49E-2
Hígado	2,60E-03±3,03E-4	2,88E-03±2,72E-3	…	2,40E-03±1,54E-3	1,84E-03±3,50E-4	1,09E-03±1,69E-4
Bazo	1,92E-04±3,04E-5	1,26E-04±3,77E-5	…	1,18E-04±1,85E-5	1,44E-04±2,87E-5	8,61E-05±1,31E-5
Estómago	2,57E-03±1,65E-3	1,08E-03±4,81E-4	4,44E-04±2,06E-4	2,02E-04±5,56E-5	2,90E-04±2,86E-5	1,45E-04±3,67E-5
Intestino	2,62E-03±4,13E-4	1,86E-03±1,17E-3	1,58E-03±1,02E-3	8,77E-04±3,06E-4	5,36E-04±1,94E-4	2,56E-04±3,50E-5
Pulmones	5,94E-04±2,17E-4	1,65E-04±4,63E-5	1,25E-04±4,38E-5	1,07E-04±2,58E-5	1,19E-04±2,61E-5	1,05E-04±5,78E-5
Riñones	3,60E-03±6,89E-4	2,05E-03±1,68E-4	1,55E-03±8,01E-4	1,21E-03±4,90E-5	1,08E-03±1,87E-4	4,22E-04±3,96E-5
Resto del cuerpo	5,28E-01±1,00E-1	2,62E-01±5,00E-2	…	1,35E-08±2,00E-2	7,43E-02±1,00E-1	1,45E-02±1,00E-2

Estos valores corresponden al cociente de actividad por dosis inyectada.

Tabla 2. Tiempos de residencia (horas) para los órganos y tejidos del ratón NIH.

Órganos y Tejidos	τ(horas)
Sangre	3,30E-01 ± 9,63E-04
Hueso	7,27E+01 ± 1,30E+01
Resto del cuerpo	1,51E+00 ± 1,73E-01
Orina acumulada	5,63E+02 ± 1,63E+00
Hígado	4,33E-01 ± 7,90E-02
Bazo	3,60E-02 ± 1,25E-02
Estómago	9,13E-03 ± 4,01E-03
Intestino	9,13E-02 ± 2,22E-02
Pulmones	1,76E-03 ± 9,05E-04
Riñones	2,01E-01 ± 4,80E-02

Tabla 3. Dosis absorbida por unidad de actividad inyectada de ^{177}Lu-EDTMP en órganos y tejidos del ratón NIH, y del hombre y la mujer adulta.

Órganos y Tejidos	Dosis Absorbida		
	Ratón (cGy/µCi)	Hombre (cGy/mCi)	Mujer (cGy/mCi)
Células Osteogénicas	6,20E+01 ± 1,36E+01	1,47E+01 – 1,53 E+01	1,96E+01 – 2,04 E+01
Médula	2,04E+01 ± 4,48E+00	2,12E+00 – 2,81E+00	2,22E+00 – 2,94E+00
Riñones	1,3E-01 ± 3,00E-02	2,33E-01	2,57E-01
Intestino	1,00E-02 ± 8,00E-04	1,03E-01	1,61E-01
Hígado	1,20E-01 ± 2,00E-02	8,81E-02	1,19E-01
Bazo	1,10E-01 ± 4,00E-02	7,75E-02	9,59E-02
Estómago	3,00E-02 ± 1,00E-02	2,41E-02	3,08E-02
Pulmones	4,10E-01 ± 9,00E-02	1,99E-02	2,57E-02

Figuras

Figura 1. Modelo metabólico compartimental del ^{177}Lu-EDTMP.

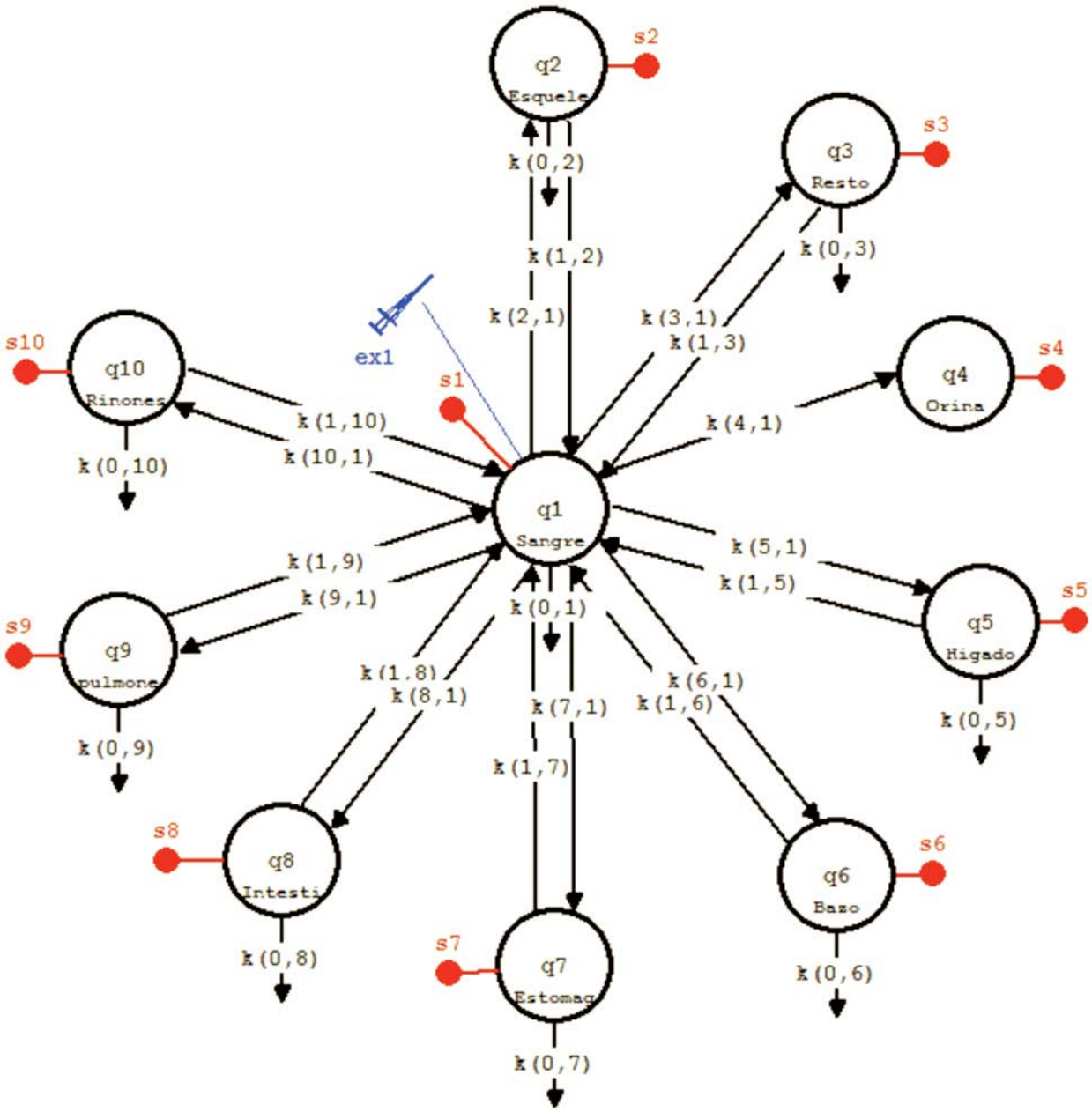


Figura 2. Biocinética del ^{117}Lu-EDTMP en orina acumulada, hueso, resto del cuerpo y sangre en ratón NIH. El resto del cuerpo no incluye los órganos medidos.

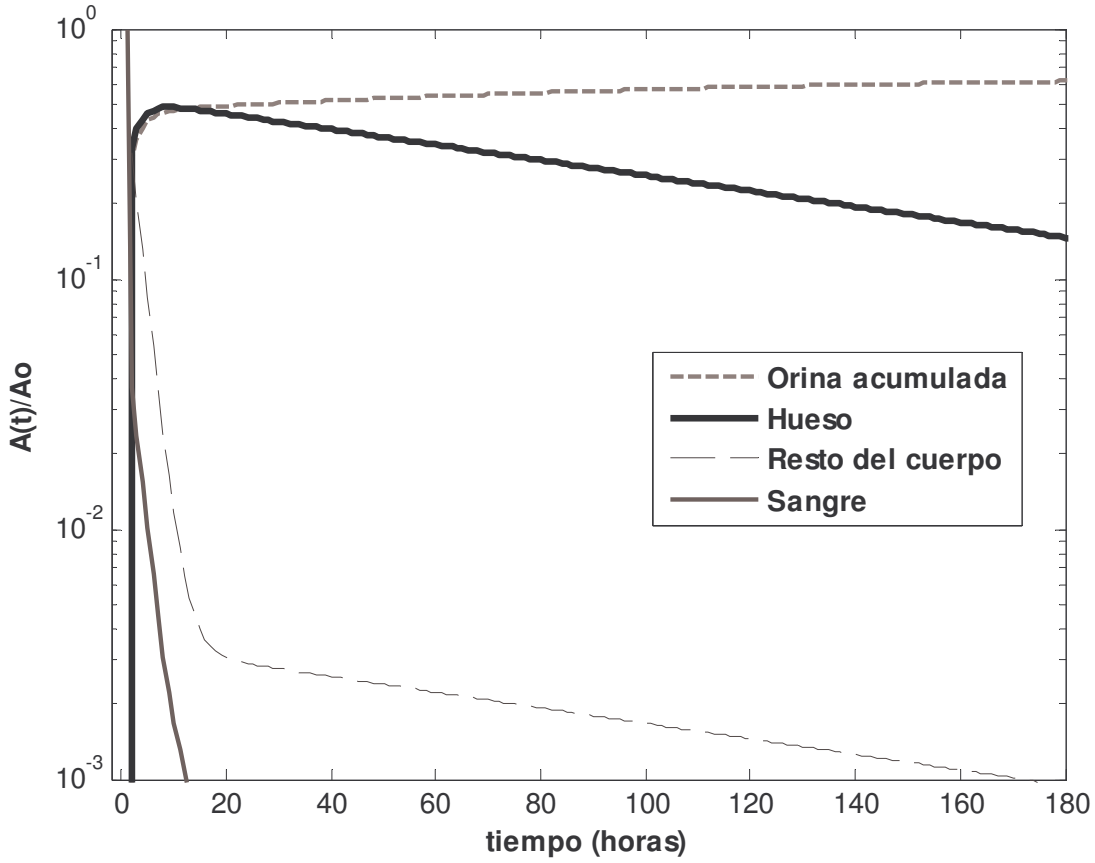
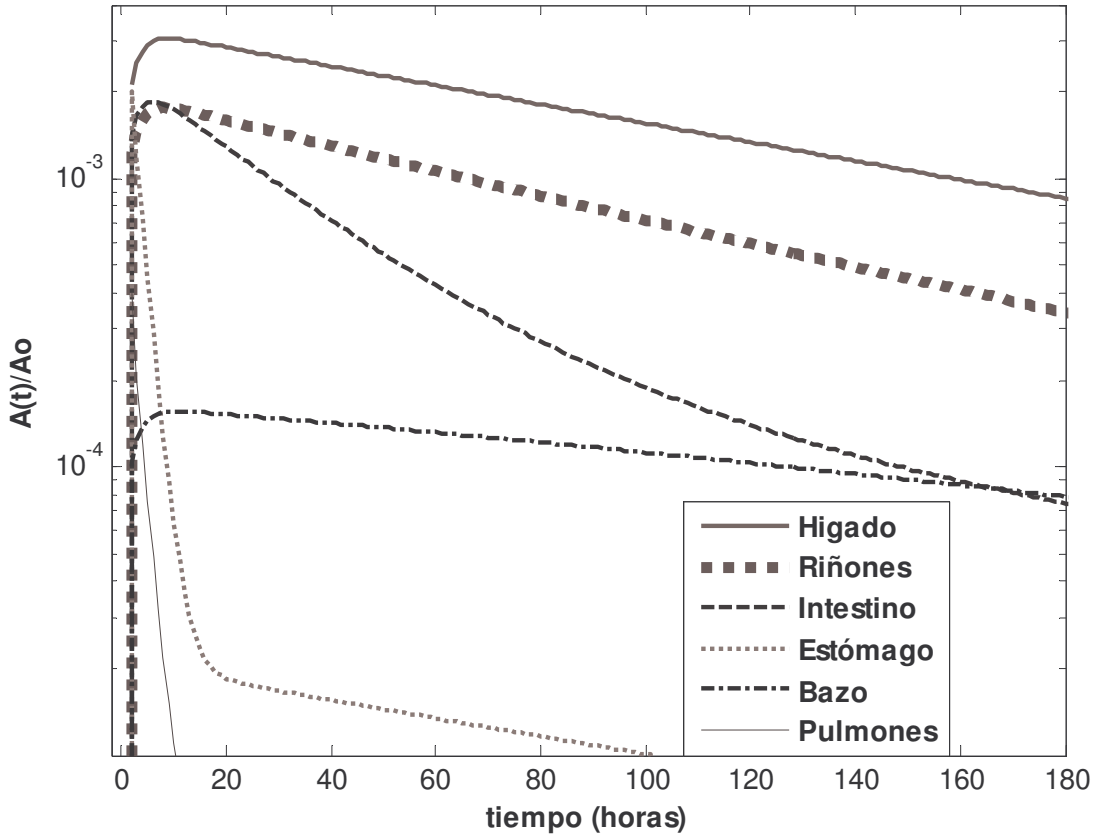


Figura 3. Biocinética del ^{117}Lu-EDTMP en hígado, riñones, intestino, estómago, bazo y pulmones en ratón NIH.



PARTE II

Resúmenes de publicaciones en revistas

IONIZING RADIATION MODULATES THE SURFACE EXPRESSION OF HUMAN LEUKOCYTE ANTIGEN-G IN A HUMAN MELANOMA CELL LINE[1]

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ABSTRACT:

Human leukocyte antigen G (HLA-G) is a nonclassical HLA class I molecule involved in fetus protection from the maternal immune system, transplant tolerance, and viral and tumoral immune escape. Tumor-specific HLA- G expression has been described for a wide variety of malignancies, including melanomas. The aim of this study was to evaluate whether ionizing radiation (IR) could modulate the surface expression of HLA-G1 in a human melanoma cell line that expresses endogenously membrane-bound HLA-G1. For this purpose, cells were exposed to increasing doses of γ-irradiation (0–20Gy) and HLA-G1 levels at the plasma membrane were analyzed at different times post irradiation by flow cytometry. HLA-G total expression and the presence of the soluble form of HLA-G1 (sHLA-G1) in the culture medium of irradiated cells were also evaluated. IR was capable of down regulating cell surface and total HLA-G levels, with a concomitant increase of sHLA-G1 in the medium. These results could indicate that γ-irradiation decreases HLA-G1 surface levels by enhancing the proteolytic cleavage of this molecule.

Keywords: γ-Radiation; HLA-G; Melanoma; Immune system; Immunotolerance

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INTERNATIONAL APPROACHES TO REMEDIATION OF TERRITORIAL RADIOACTIVE CONTAMINATION[2]

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The so-called remediation of territories[3] experiencing contamination with radioactive substances has been one of the more elusive issues for the radiation protection community to tackle and regulate. Following the presence of radioactive residues[4] over a territory, radiation protection experts have generally been unable to respond to a simple and straightforward question from anxious members of the general public: Is it safe for me and my family to live here? Providing non-conclusive and consistent answers to such a simple enquiry was most unhelpful. Experts tried to explain that, while the territory was in fact contaminated, remediation had to be 'optimised', and depending on many factors (generally incomprehensible for the common public), they might or might not remain there. Moreover, some experts, dishonouring their professional responsibilities, implicitly advised members of the public that it was ultimately their decision to leave or to remain in a 'contaminated' territory (this was often done in reaction during so-called 'stakeholders involvement' meetings).

The terms remediation and contamination are purposely italicised in this introductory chapter because their meaning is vague and ambiguity in understanding has been part of the problem in solving this controversial issue. Practical solutions for the conundrum of whether a contaminated territory needs remediation have been unconvincing for a growingly skeptical public, inter alia because the arguments were unimpressive and puzzling. There have been common misunderstandings on the basic concepts, not only by the public but also among the 'experts' themselves. While this book will mainly address the technical aspects of the problem, this initial chapter is intended to present some conceptual misapprehensions and to describe the radiation protection paradigm that is internationally recommended for tackling the issues and the regulatory approaches.

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[2] González, A.J. "International Approaches to Remediation of Territorial Radioactive Contamination". - Voigt, G.; Fesenko, S. "Remediation of Contaminated Environments". 2009. ISBN 978-0-08-044862-6 - Radioactivity in the Environment; vol. 14, p. 1-40, 2009.

[3] The term territory, from Latin territorium, from terra 'land', and its derivatives, is used to mean just an area of ground or land rather than its usual connotation of an area under the jurisdiction of a ruler or state.

[4] The term (radioactive) residues is used for radioactive materials that have remained in the environment from early operations and accidents involving the use of radioactive substances. The term could also, in principle, be used to describe the presence on land of primordial radioactive materials that have accumulated over time as a result of natural processes, such as the territorial deposits of radium caused by the drying of underground water released from natural springs.

THE 12th CONGRESS OF THE INTERNATIONAL RADIATION PROTECTION ASSOCIATION: STRENGTHENING RADIATION PROTECTION WORLDWIDE[5]

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Nuclear Regulatory Authority
Argentina

The AIM of this commentary is to describe concisely the 12th Congress of the International Radiation Protection Association (IRPA), which has held in Buenos Aires, Argentina, on 19-24 October 2008 Termed IRPA 12, the Congress was organized by the Sociedad Argentina de Radioprotección (Argentine Radiation Protection Society), SAR, under the motto "Strengthening Radiation Protection Worldwide." It was declared of "national interest" by the relevant governmental offices, notably buy the Argentine´s Ministry of Foreing Affairs, International Trade and Worship and Nuclear Regulatory Authority (ARN). The Congress was inaugurated by the Argentine Governor to the International Atomic Energy Agency (IAEA) and Permanent Representative to the International Organizations in Vienna, Ambassador Eugenio María Curia, and the President of Board of the Directors of ARN, Raúl Racana, and formally opened by IRPA President, Phil Metcalf.

This initial introductory chapter will summarily portray the essential organizational features and objectives of IRPA 12. The subsequent chapters will resume the proceedings of the three fields covered by the Congress´s unusually comprehensive program: the epistemological basis of essential radiation science, the paradigmatic models used to protect people against radiation exposure, and the practical implementation and achievements of radiation safety. An epilogue will summarize the author´s personal views on the outcome.

IRPA 12 was a real mammoth endeavor involving more than 1,700 participants and 1,500 papers, including 88 chairmen and co-chairmen, 36 rapporteurs, 36 thechnical secretaries, 30 conferences speakers, 36 keynote speakers, and 250 presenters. All its activities were planned and coordinated by the Congress´s Organizing Committee and SAR authorities, over four years of intensive work. The Congress program was developed by the IRPA 12 Programme Committee, chaired by Eduardo Gallego (Spain), in consultation with the Congress´s President.

The extraordinary professional ensemble making possible IRPA 12 will remain in records for their magnificent work. The outcome of all their activities was recorded and compiled by the IRPA 12 secretariat and is being incorporated into the IRPA 12 Web site (http://www.irpa12.org.ar).

It would be presumptuous to try to recap again the magnificent work of those who summarized the findings and conclusions in each scientific area. The reader´s indulgence is therefore requested for the summary presentation of the outcomes of the various Topical Sessions. The summaries are necessarily inhomogeneous reflecting different attitudes of the authorities of the different sessions. Sometimes they are simply incomplete; sometimes not. For further detail the reader is referred to the various session officers whose names and e-mail addresses are recorded.

Notwithstanding the above caveats, the following summary points aim at squeezing the various outcomes into a concentrate of the main findings. These are as follows:

- The epistemological basis of the sciences of radiation exposure and its effects, which provides the foundation for radiation protection, was generally corroborated and found to be sound, reliable and sensible;
- The globally accepted radiation protection paradigm, which has been developed by the International Commission on Radiological Protection (ICRP) over the years and

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currently provides the foundations for most national and international radiation protection standards, was generally re-endorsed while recognizing that is being reviewed and will be adjourned; and

- The radiation protection practitioners in nuclear, medical and other activities making use of radiation, who massively attended the Congress, showed satisfaction with the developments and contentment with the progress reached by the fast growing global radiation safety regime being build up by relevant national and intergovernmental organizations.

ÍNDICE DE AUTORES