TRANSPORT OF RADIOPHARMACEUTICALS AND LABELLED COMPOUNDS IN CUBA

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Abstract

The Centre of Isotopes (CENTIS) is the main consignor and carrier of radioactive material in Cuba. The purpose of this paper is to describe the Radiation Protection Programme (RPP) implemented inside a Quality Management System, to achieve and maintain an optimized standard of protection in the accomplishment of these functions. All those areas involving radiation exposures are considered (e.g. design of type A packages, packing, loading, handling, in-transit storage, road transport and inspection and maintenance of packaging). The quality assurance requirements for packaging components were established using a grading process. A material to absorb twice the volume of the liquid contents is tested and its water absorptivity, grammage and capillary rise were estimated. Categories and transport indexes for 69 packages of radiopharmaceuticals incorporating radioiodines, ^{32}P, ^{188}Re and ^{90}Y and technetium generators, are determined. Tests for demonstrating compliance with requirements for type A packages with liquid and solid radioactive content and for air transport are performed and documented. Safety and security of radioactive materials during storage in transit and transport are supervised. Individual Licensing of this staff is conducted by CENTIS and presented to the Cuban Regulatory Authority. The effective annual doses distributions are reported since 1996 to 2010. Occupational exposure is acceptably low and less than 6mSv, which is the dose constrain adopted. It has not been reported any incident in about two and half thousand road shipments carried out. CENTIS' RPP has been under review, detailed appraisals and audits.

Key Words: Transport of radioactive material, consignor, carrier, radiation protection programme, type A packages.

Introduction

CENTIS is located about 30 Km to the southeast of Havana city. Up today there are about seventeen years of experiences in the transport of radioactive materials. There is a prevalence of excepted and type A packages in about 250 shipping by year. A Radiation Protection Programme (RPP) was implemented to cover the functions of CENTIS like designer, manufacturer, consignor and carrier of radioactive packages. This is intended to establish and document in a systematic and structured way the framework of control applied to satisfy the radiation protection requirements and provisions established in the transport regulations [1÷5].

Scope of the RPP

The CENTIS' RPP covers the transport and storage of radiopharmaceuticals and labeled compounds incorporating radioiodines and technetium generators during normal and accident conditions. Packages design and the reuse of packaging also are considered. CENTIS supplies typically about 2000 packages per year to users all over the country. About 68% of the packages designed are category III-YELLOW, 20% of the packages are category II-YELLOW, 9% of the packages are category I-WHITE and 3% are excepted packages. The maximum transport index (TI) number encountered is 3.1, and the packages with this TI would be a small fraction of those of category III-YELLOW. The centre has two delivery vans to transport the packages to consignees.

Roles and Responsibilities

The roles and responsibilities for practice are established [6]. Prime responsibility for implementing and supervising RPP lies with the CENTIS' Director. The administrative personnel are directly responsible for vehicles' maintaining. The sales manager has responsibility for the acquisition of approved packaging components, delivery to authorized consignees and implementation of the required documentation for the dispatch staff. The personnel of the radiation protection department and quality assurance department play the role of controller, because this performs audits and inspections. There is a relationship between these areas, since they should integrally develop, implement and maintain the RPP. However, the first also elaborates the necessary documentation for to request of the competent authority approval, performs the radiological surveillance, complete the shipper's declaration, training of staff and participate in the maintenance of capacities for response to radiological emergencies. The duties and rights of workers are related in [6] too. It is established the Individual Operation Certificate like authorization to grant by Director of centre and an Individual Licensee by the competent authority [7].

Dose Assessment and Optimization

The annual effective doses in 15 y period covering 1996÷2011 are measured using a credited individual dosimetry. Film dosimetry was used only for the five first years in this period. Since 2001 workers has been monitored with TLD and Hp(10) is an estimate of the effective dose (E) [8]. Dosemeters were issued on a thirdly or monthly basis and the recording levels considered were 0.20 and 0.10 mSv, respectively. The overall uncertainty reported is lower than 20 %. In order to take into account the distribution of the occupational exposure for transport related operations, mean effective doses, maximum and minimum values of E were calculated.

The collective effective dose (collective dose) was also determined, following the expressions mentioned in ICRP Publication 103 [9] and [10]. For the purposes of this work, monitored workers are people to whom a dosemeter was issued. The maximum and minimum values of E per year are shown in Table 1. Maximum dose is about 5.71 mSv (2003) and minimum dose is 0 mSv.

Collective doses (S) are presented in Table 2. In the Figs. 1 and 2 is showed its relation with the number of monitored workers (MW) and the maximum effective dose (Emax). The increase of personnel implies the same behavior of S, but reduces E. In spite of this, in 2003 the increment of individual radiation doses contributed to the biggest value of S (about 10E-03 man-Sv). It should be observed in the Fig. 1 that an appreciable reduction of individual exposures determines the decreasing of E after this year.

Fig. 3 shows the annual averaged values of E. The largest values registered in 1998, 2000, 2002÷2003 and 2010 are due to the increase of the number of packages with category III-YELLOW in consignments. In the other hand, the annual effective dose constraint adopted for the practice is 6 mSv. With the exception of one case, workers have not received a dose bigger than 50% of this.

Table 1. Maximum and minimum annual individual effective dose for monitored workers

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Maximum [mSv]	0.86	0.55	1.37	1.06	1.88	1.57	2.88	5.71	0.82	0.49	0.00	0.28	0.53	1.04	2.7
Minimum [mSv]	0.00	0.00	0.00	0.00	0.10	0.24	0.00	0.11	0.00	0.00	0.00	0.00	0.00	0.00	0.39

Table 2. Annual collective doses derived for transport related operations

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
1E-03 [Man-Sv]	1.06	0.97	2.54	3.2	6.53	7.05	7.98	10.06	1.26	1.42	0.00	0.48	0.99	1.76	10.41

It can see in the table 3 the maximum and minimum values of Transport index (TI) of received packages with ^{131}I y de ^{99}Mo, and their total activity by year. The biggest registered TI is 7 and belongs to a package with ^{131}I that has been received in 1999. Nevertheless, there are packages with ^{99}Mo with the larger IT. Mean annual activities of ^{131}I and ^{99}Mo are 4.89 TBq and 15.7 TBq, respectively.

Maximum activities are registered in 20011 and 2009, respectively. The annual increase of activity of ^{131}I is presented in 1998, 2001, 2004, 2007 and 2009÷2011. The beginning of the generator of Technetium production in 2003, determine the increase of transported activity of ^{99}Mo. Its annual variations since 2003 show the biggest increase (17 TBq) in 2009. During 2000÷2003 increase transported activity of ^{99}Mo which is seen in figure 4. This is reflected in the values of TI and its maximum was registered in 2002.

Segregation Measures

Consignments are segregated by the dispatch staff during when loading the packages on to the vehicle. This segregation is commensurate with the type and category of packages [6]. This means all packages, especially the high TI packages, are placed at the rear of the goods compartment. The storage area is about 10 m from an on-site workshop. The personnel of this workshop are regarded by CENTIS as members of the public.

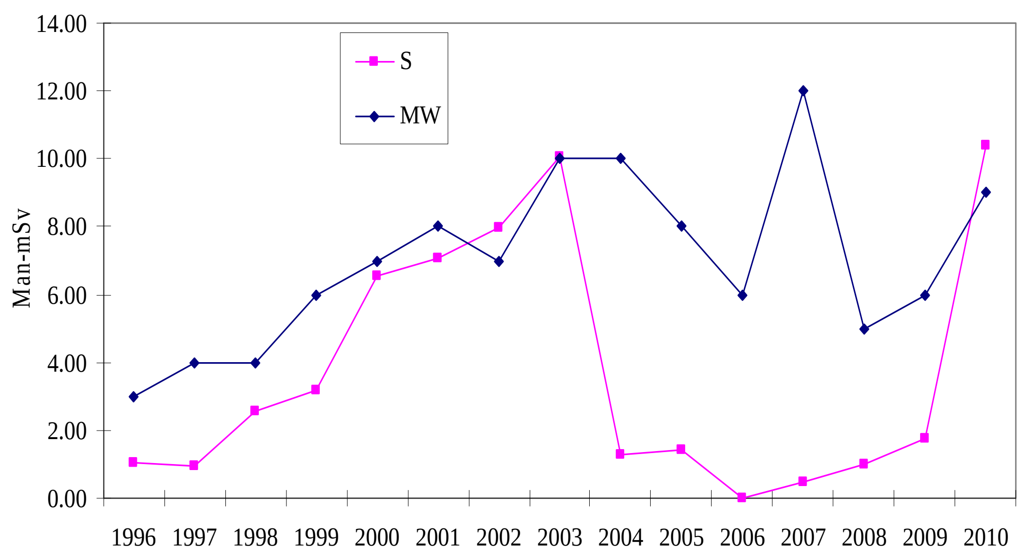

Figure 1. Collective dose (S) vs. number of monitored workers (MW) by year

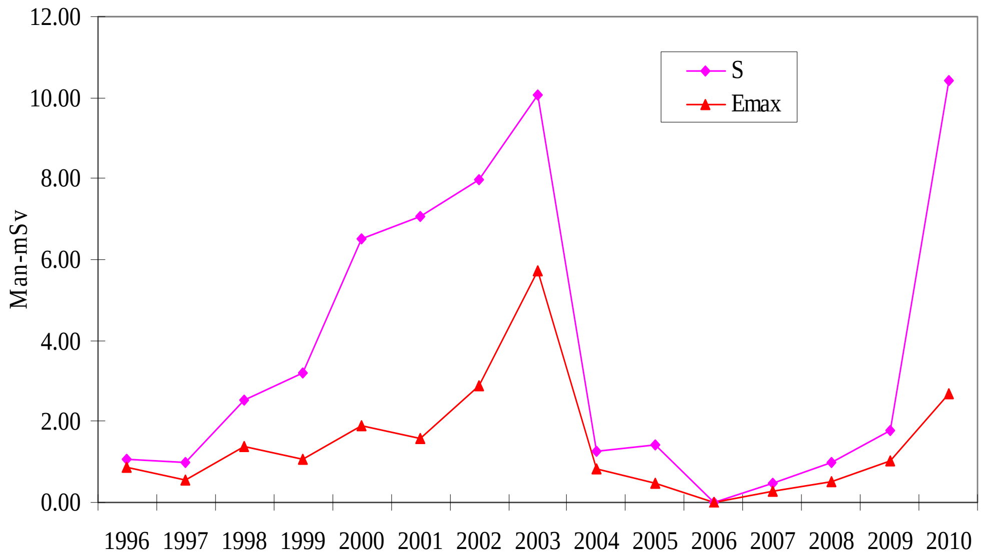

Figure 2. Collective dose (S) vs. maximum Effective Dose (Emax) by year

There is a maximum of 2 h of exposure for these by week due to the stored packages. This represents an exposure of 100 h per year. Therefore, the maximum total TI number at this distance would be limited to 100, corresponding to an annual dose of 1 mSv. This is the maximum total TI anticipated for present operations. However, the concrete storeroom walls, which are 25 cm thick, provide a dose rate reduction factor of 100 [4], and therefore annual doses are anticipated to be of the order of 10 μSv.

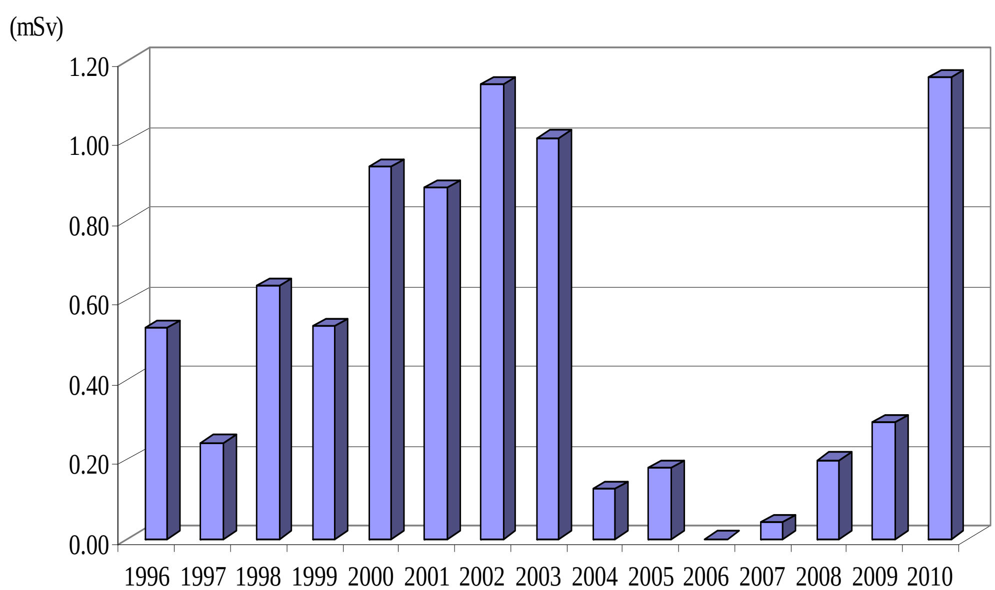

Figure 3. Mean effective doses for monitored workers

Table 3. Maximum and minimum TI and total received activity by year of radioisotopes with larger contribution to E.

Year	Maximum TI ^{131}I	Minimum TI ^{131}I	Activity ^{131}I (Bq y^{-1})	Maximum TI ^{99}Mo	Minimum TI ^{99}Mo	Activity ^{99}Mo (Bq y^{-1})
1996	--	--	--	2.5	--	3.20E+11
1997	1.7	0.5	7.33E+11	2.5	--	5.92E+11
1998	0.9	0.1	4.90E+12	2.5	1.3	5.39E+11
1999	7.0	0.4	4.87E+12	3.1	0.6	6.60E+11
2000	4.0	0.3	4.84E+12	3.1	0.6	5.35E+11
2001	1.0	0.2	4.88E+12	3.1	0.2	1.38E+12
2002	2.4	0.2	4.60E+12	4.1	1.9	1.59E+12
2003	2.9	0.6	3.94E+12	3.5	0.9	1.49E+13
2004	1.7	0.1	4.71E+12	3.3	0.2	2.73E+13
2005	1.4	0.1	4.08E+12	3.3	0.2	2.77E+13
2006	1.7	0.1	3.28E+12	3.6	1.5	2.29E+13
2007	1.3	0.1	4.91E+12	3.4	1.4	2.52E+13
2008	2.1	0.1	4.33E+12	3.4	0.1	2.32E+13
2009	2.9	0.1	5.76E+12	3.1	0.1	4.01E+13
2010	1.5	0.1	7.09E+12	3.0	1.6	3.19E+13
2011	3.0	0.1	1.05E+13	3.2	1.8	3.19E+13

Emergency Response Arrangements

The planning and preparing for response to radiological transport emergencies are included in the CENTIS' Emergency Plan [11]. The postulated radiological occurrences are the collision of the vehicle without fire with damage to packages, the collision of the vehicle with fire and severe damage to type A packages and the loss or robbery of radioactive material. A scale is adopted for the classification of the radiological accidents, including transport, and this is based on approaches exposed in [12]. Experience shows that there have not been radiological transport occurrences during the studied period.

CENTIS has four approved vehicles for transport of radioactive materials, which have a fire extinguisher, an emergency kit, a copy of [6] and a placard with the center's telephones. Two of these vehicles are maintaining as reserve. The personnel have individual communication means and a portable area dosimeter (model Supermini 3510, with Geiger probe to measure superficial contamination) that is annually verified in the Secondary Calibration Laboratory of Cuba. In written procedures for the emergency response organization are established responsibilities and step-by-step actions, according to [6, 11]. Director should guarantee necessary logistics during emergency and for maintenance of response capabilities. In the case of accident he notifies authorities. When accident is reported the radiation protection team should travel to the site, with necessary equipment, in an expeditious manner. This evaluates the radiological hazard and performs protective and recovery actions coordinating with all those present authorities. Saving lives and fighting fires have priority over anything else.

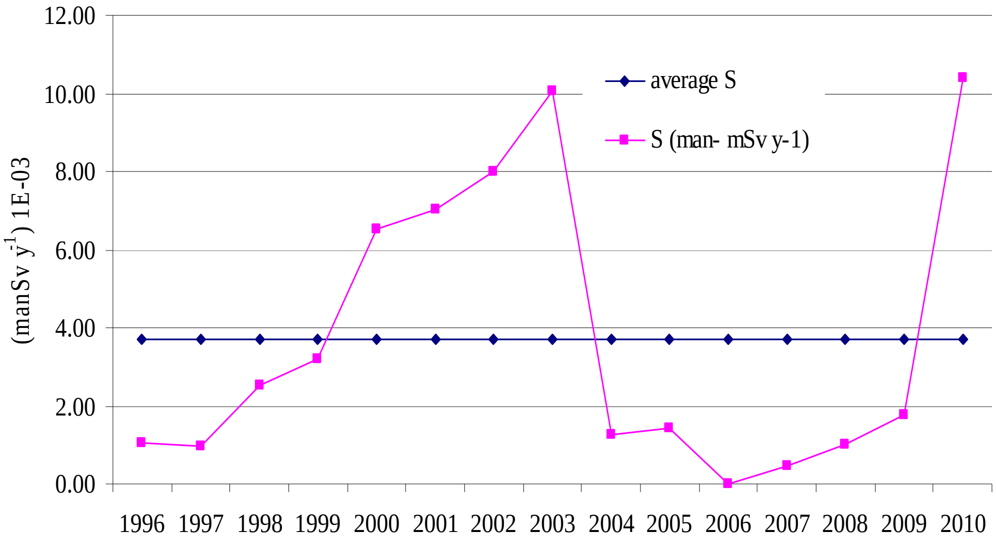

Fig. 4. Annual collective dose (S) vs. average S for the studied period

Training

The training of workers for the transport of radioactive material is oriented towards his or her specific or potential job functions and work environment. That is, a graded approach is adopted, in which the amount, type and complexity of training is commensurate with the nature and degree of the hazards and the type and complexity of the duties in the transport of radioactive material. The training fulfils the applicable requirements of the competent authority [7] and the policies of CENTIS [6]. Training is seen as a continuous commitment throughout employment, and involves initial training and refresher courses every two years.

There are 9 courses with theory and practical test. The effectiveness of the training is periodically evaluated [11]. Records are kept of relevant training. Up to day six refresher courses are executed with theory and practical tests. Two emergency full-scale exercises are made with simulation of fires and communications checks with offsite response organizations. The administrative staff has participated in 3 regional courses of IAEA and one of these included the security in the transport of radioactive materials and [13].

Design and Test o Type A Packages

Type A package components of six manufacturers are studied and absolute frequencies of their use of are obtained. Considering [1-4] and ALARA principle, a qualitative method of optimization is applied to select the second containment system. The test methods for demonstrating their ability to withstand normal conditions of transport for liquid and solid contents [1-3] are carried out in the CENTIS' facilities.

For to simulate the radioactive contents it is used a Permanganate of Potassium dissolution. In designing the containment, the effect of ambient temperature extremes on resultant surface temperatures, contents, thermal stresses and pressure variations were considered to ensure containment of the radioactive material. This means that air transport conditions is also considered. A material to absorb twice the volume of the liquid contents is tested in correspondence with [14-16] due to it is considered as the second containment system. The results of these tests following are: water absorptivity: 581,9 ±0.01 g/m^2; grammage: 911 g/m^2;

capillary rise in the longitudinal direction: 8.36 cm and capillary rise in the across direction: 7.72 cm.

Dose rate in contact and the TI for each package are calculated using the software Microshield Version 5.0.3 [17] for the date of dispatch. In these assessments are taking into account the radioactive decay; cylindrical source in contact with packaging; point source for 1m from this; materials of shielding; maximum activity by product for the date of manufacturing and reference distances for all external surfaces of package. Table 3 presents the radiological issues for all designed packages. Their radioactive content determines a total of 69 packages. These results are in compliance with the scope mentioned for CENTIS' RPP and are presented in table 4.

Figure 3. Components of the type A package identified as A13

Management System

The RPP for related transport operations is part of the Quality Management System of CENTIS and is subject to all the requirements of this system for procedures and practices, such as document and version control, document review, issuing and review of instructions and procedures, and follow-up of non-conformances [18]. A graded approach is adopted for quality requirements of packaging components [19-21]. For the component of Grade 1 it is necessary to make the suppliers' evaluation, the design with the approved standards, design verification with the test of specimens, approval of their use and performing audits and inspections by approved personnel.

The last two previous conditions are not considered for the components of Grade 2 and for those of Grade 3. For components of Grade 3 neither the design verification is prescribed. It have been evaluated 3 national cardboard boxes suppliers and 2 from others countries. Four of them have been selected and used. The manufacture of lead shielding of packages was performed in a controlled foundry process.

By economic reasons, the reuse of lead container is implemented. Therefore, the RPP covers the maintenance of empty packages. The traceability of each package is setting through a registered consignee code, which is marked in the packaging as a unique identification number. The management of undeliverable packages is included in the CENTIS' radioactive wastes management. On site there is a temporal storage facility with this purpose. The management system should be designed to enable the organization's objectives to be achieved in a safe, efficient and effective manner. The organization should develop a management system that is appropriate to the stage in the lifetime and the maturity of the facility or activity.

Table 4. Radioactive packages' issues designed at CENTIS

Name of the packaging design	Radionuclide	Activity (Bq)	Category	Maximum TI
A01/A02, A06/ A07	^{131}I	1.85E+09	III	0.7
A01/A06	^{131}I	3.70E+09	III	0.9
		5.55E+09		1.4
		7.40E+09		1.8
		9.25E+09		2.4
A03/A08	^{131}I	7.40E+07	II	0.2
		1.48E+08		0.5
		2.22E+08		0.7
		2.96E+08		1
		3.70E+08		1.2
A10	^{131}I	7.40E+09	III	2.1
A12/A13	^{131}I	3.70E+09	III	0.3
		5.55E+09		0.4
		7.40E+09		0.6
		9.25E+09		0.7
		1.11E+10		0.9
		1.48E+10		1.2
Excepted	^{125}I	3.70E+05	---	---
Excepted	^{32}P	2.00E+07	---	---
A03/A08	^{32}P	3.70E+08	I	0
		7.40E+08		
A03/A08	^{90}Y	1.11E+09	I	0
A02/A07	^{188}Re	1.11E+09	II	0.2
GBTec02	$^{99}Mo/ ^{99m}Tc$	5.99E+09	II	0.3
		7.99E+09	III	0.4
		2.00E+10	III	1.1
		3.00E+10	III	1.6
		3.70E+10	III	2.1
		7.40E+10	III	3.8
MET01/ MET02	^{131}I	7.40E+08	III	1
A02/A07	^{131}I	7.40E+08	III	0.5
MET01/ MET02	^{32}P	7.40E+08	I	0
A03/A08	^{32}P	7.40E+08	I	0
MET01/ MET02	^{99m}Tc	7.40E+09	II	0
A05/A09	^{99m}Tc	7.40E+09	I	0
MET01/ MET02	^{188}Re	1.85E+09	III	1.8
A02/A07	^{188}Re	7.40E+09	III	1.1
MET01/ MET02	^{125}I	3.70E+08	II	0.5
A03/A08	^{125}I	3.70E+08	I	0

Conclusions

The results of the implemented RPP at CENTIS for the transport of radioactive materials in the 1996÷2010 period are analyzed in this paper. It is demonstrated that this RPP covers transport and handling operations that have the potential to result in radiation exposures or contamination of people, property and the environment. The information collected allows verifying this RPP shows a good agreement with the applicable regulations.

In spite of the increased activity by expedition and the amount of these, there are no registered radiological occurrences. The use of a qualitative method of optimization for selection of components of packaging is another useful experience. There are 69 packages which are designed, tested and assessment for our products. The training of staff and maintaining of capacity for responding to emergencies and the adoption of a quality management system have contributed to safe of transport of radioactive material in Cuba.

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