

# Assessment of Occupational Dose Records in a Radiopharmaceutical Facility

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## ABSTRACT

Routine monitoring of occupational radiation exposure is associated with the continuing operations and is intended to demonstrate that the working conditions remain satisfactory and in compliance with dose limits. Statistical analysis of past and present dose records provides a useful tool in the management of institutional radiation safety programs. In this context, the aim of this paper is to carry out a retrospective study of occupational doses from radiopharmaceutical production facility. The trends are analyzed and presented over the 20 years period from 1991 to 2010. A total of 2,455 annual individual dose records were evaluated and the characteristics of dose distribution were estimated on the basis of the average annual effective dose, the annual collective dose, measurable dose and the number of monitored workers for each dose interval. Several doses ranges (mSv), were considered taking into account some flexibility, such as: 0-2.4; >2.4-5; >5-10; >10-15; >15-20; >20 mSv, in order to get information that best conveys the impact of the practices undertaken in a Brazilian radiopharmaceutical production facility. The average annual effective dose of all monitored workers during the period studied ranged from 2.58 to 7.38 mSv. The results showed that there is a wide variation in the average annual effective dose among the workforce. The fraction of the workers monitored with annual effective dose higher than 2.4 mSv represented about 34% although it was observed a significant impact on the total collective dose and its contribution was accounted above 50%. However, the levels of individual dose remained satisfactory and are in compliance with national regulatory authority.

**Key words: personal monitoring; occupational safety; collective dose; statistics**

## INTRODUCTION

Routine monitoring of occupational radiation exposure is associated with the continuing operations and is intended to demonstrate that the working conditions remain satisfactory and in compliance with dose limits [1,2]. Individual dose records are kept and remain stored for many years, as required by regulations, for information and for legal purposes. However, statistical analysis of past and present dose records also provides a useful tool in the management of institutional radiation safety programs. The records are also used to determine long-range dose trends for different occupations in a radiopharmaceutical facility.

In the optimization protection process, the ICRP 75 [3] recommends the establishment of dose constraints to reflect the maximum level of individual exposure that is both acceptable and achievable in a well-designed and managed workplace. Assessment of individual doses and

their distribution is necessary in setting the dose constraint, the value of which should be in the region of the upper end of the dose distribution.

The Instituto de Pesquisas Energéticas e Nucleares, IPEN - CNEN/SP, is the major center, in Brazil and it is responsible for the radioisotope and radiopharmaceutical production as well it's processing labeling and distribution, mainly for medicine uses.

The main source of occupational exposure in radioisotope production and its distribution is external irradiation. Currently, the dosimetry service provides routine monthly monitoring to about 200 workers from radiopharmaceutical production facility.

Internal exposure may be significant in some cases, and arrangements are then made for personal monitoring. In general, all workers have been internally monitored, but the frequency of measurements differs according to the task performed and the operation place. The frequency is monthly in the radioisotope production for Occupationally Exposed Individual, OEI. For those workers that carry out task-correlated, the frequency is by semester. An annual frequency is for administrative persons of facility, fellow and workers contracted for carry out some specific task. In this work, internal exposures have not been included in the dose estimates due the contribution of internal component was not significant for the pathways of occupational exposure.

The aim of this paper is to carry out a retrospective study of occupational doses over the last 20 years (1991-2010) from Brazilian radiopharmaceutical production facility. The data obtained were analyzed in terms of trends through the years, and can be used as indicators of good radiation safety practices. Statistical analyze is expected to generate information useful to the management of the radiation safety program. The conclusions drawn from this study may also be of interest to other institutions of similar practices.

## **MATERIALS AND METHODS**

To attend the objectives of this study, it was used a quantitative analyses. This study has exploratory and descriptive character and it is based on statistical procedures for analysis of the numerical information. The data were derived from examinations of the individual monitoring records and the administrative register of IPEN - CNEN/SP institution [4].

A total data of 2,455 registers (all monitored workers in the period) were evaluated and the dose distribution, within the radiopharmaceutical workforce, was shared in six doses ranges, such as: 0-2.4; >2.4-5; >5-10; >10-15; >15-20; >20 mSv in order to get information that best conveys the impact of the practices undertaken in a radiopharmaceutical production facility. In order to compare the dose distributions and evaluate trends some characteristics were taking accounted: the number of monitored workers, the annual effective dose, average annual effective dose and annual collective effective dose.

In most circumstances, the doses due to external radiation can be readily assessed by the systematic individual monitoring of workers. In this case, all workers of radiopharmaceutical production facility use a passive dosimeter, type Thermoluminescent Dosimeters, TLD. It is worn on the surface of the body for a month period, and at the end of this period it is read and the doses recorded. The dosimeter consists of the three-element TLD (CaSO<sub>4</sub>:Dy) card and holder with filters for measurements of personal dose equivalents at depths of 10 mm [*Hp*(10)] and 0.07 mm [*Hp*(0.07)]. Calibration of the TLD system is done in the standard dosimetry laboratory (SDL) using a reference <sup>137</sup>Cs source following the procedures of ICRU 47 [5].

The record level is set to 0.2 mSv/monthly; the calculated doses below this value are entered as “M” (minimal). For calculation purposes, “M” represents the value 0.2 mSv [1].

A dose level of 10 mSv is chosen since this is the mid-value of the annual dose limit and only a small fraction of workers were exposed to this level. For the purposes of this study, annual dose levels < 10 mSv are considered low to moderate exposures, while those ≥10 mSv are considered dose values high, under investigation.

Only the *Hp*(10), which estimates the effective dose, was included in the analysis. The *Hp*(0.07) and the extremity dose were excluded from this study. Although all radiopharmaceutical production staff has been internally monitored the results have shown that its contribution to the effective dose was not significant.

The correlation coefficients between the annual collective dose and the following variables were calculated to investigate the existence of linear association:

- Number of monitored workers;
- Number of measurably exposed workers;
- Number of workers with annual dose <10 mSv;
- Number of workers with annual dose ≥10 mSv;
- Collective dose of workers with annual <10 mSv; and
- Collective dose of workers with annual dose ≥10 mSv.

## RESULTS

The effective dose range distribution reported in six intervals, during 1991-2010, is showed in Table 1. In this Table, is also presented the number of monitored workers annually, over the four periods evaluated (1991-1995), (1996-2000), (2001-2005) and (2006- 2010).

On the basis of all reported data indicate a progressive increase in the number of monitored workers over time. According to the distribution data, 65.66% of the workforce monitored received doses lower than 2.4 mSv per year (the value 2.4 mSv is the record level in accordance with the national regulatory authority); approximately 26.52% of monitored individuals received a measurable dose in the range greater than 2,4 mSv and less than 10 mSv per year and 7.80% received doses higher than 10.0 mSv per year.

**Table 1. Effective dose range distribution, per year, over the period 1991-2010**

Dose range	Monitoring period (Year)									
	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
0 < E ≤ 2.40 mSv	35	29	24	30	53	51	68	76	77	88
2.40 < E ≤ 5.0 mSv	10	13	22	19	08	08	17	07	11	15
5.0 < E ≤ 10.0 mSv	05	07	10	03	09	07	06	12	14	17
10.0 < E ≤ 15.0 mSv	01	06	02	04	04	05	07	10	09	07
15.0 < E ≤ 20.0 mSv	01	01	04	01	03	03	03	06	03	01
E > 20 mSv	01	02	02	02	02	10	04	01	01	03
Number of monitored workers	53	58	64	59	79	84	105	112	115	131
Dose range	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
0 < E ≤ 2.40 mSv	100	118	100	73	81	88	102	133	127	159
2.40 < E ≤ 5.0 mSv	22	22	46	12	12	26	29	24	39	30
5.0 < E ≤ 10.0 mSv	20	17	21	13	16	16	18	16	16	16
10.0 < E ≤ 15.0 mSv	06	03	04	11	09	12	05	04	08	02
15.0 < E ≤ 20.0 mSv	00	00	00	02	02	00	03	07	00	02
E > 20 mSv	01	00	00	00	00	00	01	00	01	00
Number of monitored workers	149	160	171	111	120	142	158	184	191	209

Table 2 presents the dose distribution arising in radiopharmaceutical production facility during the years 1991 to 2010. For each year, was identified the total number of monitored workers and the number of measurably exposed workers.

**Table 2. Dose distribution at Radiopharmaceutical Facility workers during 1991–2010 periods**

Dose	Monitoring period (Year)									
	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Number of monitored workers	53	58	64	59	79	84	105	112	115	131
Total collective dose (S= person.mSv)	203,33	282,24	341,45	295,60	378,70	619,90	483,4	542,35	512,03	543,33
Average effective dose ( $\bar{E} = mSv$ )	3,84± 6,04	4,87± 6,51	5,34± 6,03	5,01± 6,98	4,79± 5,64	7,38± 10,23	4,60± 6,38	4,84± 4,74	4,45± 3,95	4,15± 6,68
Mensurable collective dose (S=person.mSv)	144,93	238,40	300,85	226,60	254,00	519,60	362,6	359,95	327,23	374,74
Number of measurably exposed workers	18	29	40	29	26	33	37	36	38	43
Average mensurable effective dose ( $\bar{E} = mSv$ )	8,05± 9,09	8,22± 7,90	7,52± 6,74	7,81± 9,21	9,77± 7,80	15,74± 12,34	9,80± 8,59	10,00± 5,58	8,61± 4,64	8,71± 10,30
Year	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Number of monitored workers	149	160	171	111	120	142	158	184	191	209
Total collective dose (S= person.mSv)	556,13	451,84	519,90	442,13	411,16	490,81	542,06	586,12	600,21	539,24
Average effective dose ( $\bar{E} = mSv$ )	3,73± 2,98	2,82± 2,21	3,04± 2,14	3,98± 3,73	3,43± 3,67	3,45± 3,19	3,43± 3,49	3,18± 3,71	3,14± 2,86	2,58± 2,59
Mensurable collective dose (S=person.mSv)	316,13	229,38	329,39	302,35	292,57	341,35	358,7	371,48	355,79	285,99
Number of measurably exposed workers	49	42	71	38	39	54	56	51	64	50
Average mensurable effective dose ( $\bar{E} = mSv$ )	6,45± 4,01	5,46± 2,86	4,64± 2,46	7,96± 4,06	7,50± 4,03	6,32± 3,58	6,40± 4,47	7,28± 5,07	5,56± 3,85	5,72± 3,66

The number of monitored workers increasing over the four periods as shown in Tables 1 and 2. The total collective dose varied between the periods evaluated. An increasing in the first period (1991-1995) from 1.50 person.Sv to 2.70 person.Sv, (1996-2000) second period; for the third period (2001-2005) decreasing to 2.38 person.Sv followed by an increase to 2.76 person.Sv in the last period (2006- 2010).

The average effective dose had a slight increase over the first two five-year periods: from (4.77±0.50) mSv in 1991-1995 to (5.08±1.17) mSv in 1996-2000 and decreasing for the last two periods from (3.40±0.43) mSv in 2001-2005 to (3.16±0.31) mSv in 2006-2010.

The percentage of measurably exposed workers for the four periods was evaluated also in Table 2, being 34.33% of the total number of monitored workers. Measurably exposed workers are those workers who have an annual dose > 2.4 mSv.

The trends in occupational exposure from a radiopharmaceutical production facility are summarized in Table 3 (a,b,c).

**Table 3. Trends in occupational exposure from a radiopharmaceutical production facility during 1991–2010 periods**

(a) Administrative, quality control, trainees, contractors and researchers groups

Year	Total Annual collective dose (person-mSv)	Number of Worker / Effective dose range				
		E≤ 2,4mSv	%	Average Effective Dose (mSv)	Collective Effective Dose (person.mSv)	%
1991	203,33	35	66,03	1,67	58,40	28,72
1992	282,24	29	50,00	1,51	43,84	15,53
1993	341,45	24	37,50	1,69	40,60	11,89
1994	296,60	30	50,84	2,33	70,00	23,60
1995	378,70	53	67,08	2,35	124,70	32,93
<b>1991-1995</b>	<b>1502,32</b>	<b>171</b>	<b>54,63</b>	<b>1,97</b>	<b>337,54</b>	<b>22,46</b>
1996	619,90	51	60,71	1,96	100,30	16,18
1997	483,40	68	64,76	1,77	120,80	24,99
1998	542,35	76	66,08	2,40	182,40	33,63
1999	512,03	77	66,95	2,40	184,80	36,09
2000	543,33	88	67,17	1,91	168,59	31,03
<b>1996-2000</b>	<b>2701,01</b>	<b>360</b>	<b>65,81</b>	<b>2,10</b>	<b>756,89</b>	<b>28,02</b>
2001	556,13	100	67,11	2,40	240,00	43,15
2002	451,84	118	73,75	1,88	222,46	49,23
2003	519,90	100	58,48	1,90	190,51	36,64
2004	442,13	73	65,76	1,91	139,78	31,61
2005	411,16	81	67,50	1,46	118,59	28,84
<b>2001-2005</b>	<b>2381,16</b>	<b>472</b>	<b>66,38</b>	<b>1,93</b>	<b>911,34</b>	<b>38,27</b>
<b>2006</b>	490,81	88	61,97	1,69	149,46	30,45
<b>2007</b>	542,06	102	64,55	1,79	183,36	33,82
<b>2008</b>	586,12	133	72,28	1,61	214,64	36,62
<b>2009</b>	600,21	127	66,49	1,92	244,42	40,72
<b>2010</b>	539,24	159	76,07	1,59	253,25	46,96
<b>2006-2010</b>	<b>2758,44</b>	<b>609</b>	<b>68,89</b>	<b>1,71</b>	<b>1045,13</b>	<b>37,89</b>
<b>1991-2010</b>	<b>9,342,93</b>	<b>1612</b>	<b>65,66</b>	<b>1,89</b>	<b>3050,90</b>	<b>32,65</b>

(b) Production, distribution and labeling groups

Year	Total Annual collective dose (person-mSv)	Number of Worker / Effective dose range				
		2,4 mSv < E < 10 mSv	%	Average Effective Dose (mSv)	Collective Effective Dose (person.mSv)	%
1991	203,33	15	28,30	4,75	71,25	35,04
1992	282,24	20	34,48	4,27	85,41	30,26
1993	341,45	32	50,00	4,70	150,37	43,94
1994	296,60	22	37,28	3,84	84,50	28,49
1995	378,70	17	21,52	5,34	90,90	24,00
<b>1991-1995</b>	<b>1502,32</b>	<b>106</b>	<b>33,86</b>	<b>4,55</b>	<b>482,43</b>	<b>32,11</b>
1996	619,90	15	17,85	5,38	80,70	13,01
1997	483,40	23	21,90	4,70	108,10	22,36
1998	542,35	19	16,96	5,34	101,52	18,72
1999	512,03	25	21,74	5,87	146,79	28,67
2000	543,33	32	24,42	5,04	161,51	29,72
<b>1996-2000</b>	<b>2701,01</b>	<b>114</b>	<b>20,84</b>	<b>5,25</b>	<b>598,62</b>	<b>22,16</b>
2001	556,13	42	28,18	5,17	217,29	39,07
2002	451,84	39	24,37	4,90	191,07	42,28
2003	519,90	67	39,18	4,23	283,60	54,54
2004	442,13	25	22,52	5,57	139,31	31,50
2005	411,16	28	23,33	5,44	152,49	37,08
<b>2001-2005</b>	<b>2381,16</b>	<b>201</b>	<b>28,27</b>	<b>4,89</b>	<b>983,76</b>	<b>41,31</b>
2006	490,81	42	29,57	4,73	198,81	40,50
2007	542,06	47	29,74	4,70	220,91	40,75
2008	586,12	40	21,74	4,93	197,47	33,69
2009	600,21	55	28,79	4,27	234,88	39,13
2010	539,24	46	22,01	4,86	223,74	41,49
<b>2006-2010</b>	<b>2758,44</b>	<b>230</b>	<b>26,02</b>	<b>4,67</b>	<b>1075,81</b>	<b>39,00</b>
<b>1991-2010</b>	<b>9,342,93</b>	<b>651</b>	<b>26,51</b>	<b>4,82</b>	<b>3140,62</b>	<b>33,61</b>

(c) Packaging and maintenance groups

Year	Total Annual collective dose (person-mSv)	Number of Worker / Effective dose range				
		E ≥ 10 mSv	%	Average Effective Dose (mSv)	Collective Effective Dose (person.mSv)	%
1991	203,33	3	5,66	24,56	73,68	36,23
1992	282,24	9	15,51	17,00	152,99	54,20
1993	341,45	8	12,50	18,81	150,48	44,07
1994	296,60	7	11,86	20,30	142,10	47,91
1995	378,70	9	11,39	18,12	163,10	43,06
<b>1991-1995</b>	<b>1502,32</b>	<b>36</b>	<b>11,50</b>	<b>18,95</b>	<b>682,35</b>	<b>45,42</b>
1996	619,90	18	21,42	24,38	438,90	70,80
1997	483,40	14	13,33	18,17	254,50	52,64
1998	542,35	17	15,17	15,20	258,43	47,65
1999	512,03	13	11,30	13,88	180,44	35,24
2000	543,33	11	8,39	19,38	213,23	39,24
<b>1996-2000</b>	<b>2701,01</b>	<b>73</b>	<b>13,34</b>	<b>18,43</b>	<b>1345,50</b>	<b>49,81</b>
2001	556,13	7	4,69	14,12	98,84	17,77
2002	451,84	3	1,87	12,77	38,31	8,47
2003	519,90	4	2,34	11,44	45,79	8,80
2004	442,13	13	11,71	12,54	163,04	36,87
2005	411,16	11	9,16	12,73	140,05	34,06
<b>2001-2005</b>	<b>2381,16</b>	<b>38</b>	<b>5,34</b>	<b>12,79</b>	<b>486,03</b>	<b>20,41</b>
2006	490,81	12	8,45	11,87	142,54	29,04
2007	542,06	9	5,69	15,31	137,79	25,42
2008	586,12	11	5,97	15,82	174,01	29,68
2009	600,21	9	4,71	13,43	120,91	20,14
2010	539,24	4	1,91	15,56	62,25	11,54
<b>2006-2010</b>	<b>2758,44</b>	<b>45</b>	<b>5,09</b>	<b>14,16</b>	<b>637,50</b>	<b>23,11</b>
<b>1991-2010</b>	<b>9,342,93</b>	<b>192</b>	<b>7,82</b>	<b>16,41</b>	<b>3151,70</b>	<b>33,73</b>

## DISCUSSION

The dose limit for radiation workers is currently 20 mSv per year averaged over defined period of 5 years, with the further provision that the effective dose should not exceed 50 mSv in any single year (CNEN). The dose distribution during the period studied (1991-2010) indicated about 92% of workers received an annual effective dose less than 10 mSv. In fact, more than half of the annual effective dose records analyzed is below the record level (2.4 mSv per year), while approximately 8% received doses equal or higher than 10 mSv. The highest recorded annual effective dose was 66.94 mSv, received by a technologist involved in the hot cell maintenance task, occurred in 2000.

The average annual effective dose of all monitored workers ranged from 2.58-7.38 mSv over a 20-y period (Table 2) with an mean value of 3.80 mSv. However, a majority of the monitored workers did not receive measurable doses; the average annual effective dose of measurably exposed workers was also calculated and is in the range 4.64-15.74 mSv.

The ratio of collective effective dose between first year (1991) and the last year (2010) increased about a factor 2.6. UNSCEAR 2000 reports that the worldwide average annual effective dose for radioisotope production is 2.95 mSv [6].

The Table 3 (a,b,c) provides more detailed information on occupational exposure related to radiopharmaceutical practices, as well as presents the contribution of external dose to the effective dose. The percentages are related to the total worker force and total collective dose.

The increasing in the number of workers who received measurable dose in the packing task group, was attributed to increasing the handling of radioactive materials mainly due to Iodine 131 and Molybdenum 99.

## CONCLUSION

External radiation exposure is more important than internal radiation exposure but workers may be exposed to internal radiation, particularly during the maintenance work or in the event on leaks.

The evaluation of trends in occupational exposure arising from radiopharmaceutical production facility showed that 92% of workers receiving an annual dose of less than 10.0 mSv.

Only a small fraction of workers (about 8%) have annual doses  $\geq 10$  mSv. Although the fraction of the highly exposed workers is small, there was a significant impact on the collective dose and its contribution was high about 30%. Highly exposed workers tended to concentrate in a few identified occupational groups related with maintenance and packing jobs ( $\geq 10$  mSv).

According to the results there is a large variation in the average annual effective dose among the different occupational groups, for example job functions: 1.89mSv/a (research, quality control

procedures, administrative staff), 4.82mSv/a (production, labeling and distribution) and 16.41mSv/a (maintenance and packing tasks).

Results of this study also showed that the number of exposed workers, the annual effective dose  $\geq 10$  mSv, and the corresponding collective effective dose is a good indicator of institutional radiation safety practices, since they are strongly correlated to the total collective effective dose. Furthermore, if a dose constraint of 10 mSv is imposed on highly exposed occupational groups, the average collective effective dose is estimated to be about 157.0 person.mSv.

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