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Acknowledgement of Country

ARPANSA proudly acknowledges Australia's Aboriginal and Torres Strait Islander community and their rich culture and pays respect to their Elders past and present. We acknowledge Aboriginal and Torres Strait Islander people as Australia's first peoples and as the Traditional Owners and custodians of the land and water on which we rely.

We recognise and value the ongoing contribution of Aboriginal and Torres Strait Islander people and communities to Australian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice.

Foreword

The concept of diagnostic reference levels (DRLs) were first introduced in ICRP's Publication 73 (ICRP, 1996). In its Publication 103 the idea of DRLs were developed further to form one of the principles of optimisation of protection in diagnostic medical exposures. The most recent relevant ICRP document, 135 (ICRP, 2017), contains a useful summary of the role of DRLs and their application. This summary is paraphrased below.

The principles of justification and optimisation of protection are key and complementary radiological safety tenets. DRLs do not apply to individual patients. They are derived as an arbitrary threshold from radiation metric data obtained locally and collected nationally or regionally. In nuclear medicine the metric that is used to establish a DRL is the administered activity. For computed tomography it can be the Computed tomography dose index (volume) ($CTDI_{vol}$) and/or dose-length product (DLP). A DRL is a supplement to professional judgement and does not provide a dividing line between good and bad medical practice. All individuals who have a role in subjecting a patient to a medical exposure should be familiar with DRLs as a tool for optimisation of protection.

The application of the DRL process is not sufficient, by itself, for optimisation of protection. Optimisation is generally concerned with maintaining the quality of the diagnostic information provided by the examination commensurate with the medical purpose while, at the same time, seeking to reduce patient exposures to radiation to a level as low as reasonably achievable. Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing) must also be evaluated. Methods to achieve optimisation that encompass both the DRL process and image quality evaluation should be implemented. In some cases, optimisation may result in an increase in dose.

A dose below a DRL value does not, by itself, indicate that the procedure is performed at an optimised level with regard to the amount of radiation used. The ICRP recognises that additional improvement can often be obtained by using the median value (the 50th percentile) of the national distribution of values of dose-related quantities to provide additional guidance for further optimisation efforts. If local median values of the DRL quantity are below the national median value, image quality, rather than the amount of radiation used, should be considered as a greater priority in this additional optimisation process. The basis for this recommendation is that if practices at the local facility have already achieved levels of radiation use that are below the national median value, further reduction in the amount of radiation used is not the principal concern. When local practices result in levels of radiation that are below the national median value, ensuring that image quality is adequate should be a priority.

It is important to recognise that DRLs are not intended to be applied to individual patients and should not be used as dose limits. Instead, DRLs are an essential tool in the optimisation process, especially as dose limits are not relevant in the medical exposure of patients. In surveys performed to acquire dose information for different procedures, it is important to identify radiation doses that are too low as well as too high, as both may have consequences for the patient.

Contents

1. Abstract

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) published new Australian diagnostic reference levels (DRLs) for nuclear medicine in 2017. The DRLs are based on data collected via a national survey started in 2014 coordinated by ARPANSA and from two earlier surveys conducted in 1998 and 2008 by the Australian and New Zealand Society of Nuclear Medicine. The Australian nuclear medicine DRLs cover general nuclear medicine, SPECT/CT and PET/CT for adult patients.

Where possible, the DRLs have been set using a methodology analogous to that used for setting the Multi-Detector CT DRLs first issued by ARPANSA in 2012.

2. Introduction

A diagnostic reference level (DRL) is a value - generally a dose surrogate - that an imaging provider can use as a benchmark against which to compare the doses delivered at their facility. If the facility's dose exceeds the DRL for a given procedure, it is an indication that the facility would benefit from optimising their imaging protocol. The International Commission on Radiological Protection (ICRP) recommends that health authorities instigate DRLs as a form of radiation protection (ICRP, 2017). Australian regulations specify, via Radiation Protection Series (RPS) 14 (ARPANSA, 2008) and C-5 (ARPANSA, 2019), that facilities must periodically compare their doses against DRLs for procedures where Australian DRLs have been introduced.

Ideally, DRLs are based on the results of region-wide dose surveys that sample the distribution of doses delivered during similar radiological procedures at different imaging facilities. The ICRP recommends that the DRL for a particular protocol should be based on the 75th percentile of the distribution of median doses reported by survey participants for that protocol. In this context, the median dose delivered at a facility for a given protocol is known as a facility reference level (FRL).

The first Australian DRLs for adult patients were released by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) in 2011 and only covered Multi-Detector CT (MDCT) procedures (Hayton, et al., 2013). These DRLs were based on the 255 surveys submitted in 2011 to the National Diagnostic Reference Levels Service (NDRLS) MDCT survey, encompassing six protocols.

Prior to 2017, rather than DRL, there were tables of most common activities (MCAs) and reference activities (RAs) published on behalf of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM). These tables were based on two surveys conducted in 1998 (Towson, 2000) and 2008 (Botros, et al., 2009) that asked nuclear medicine facilities to report what the prescribed radiopharmaceutical activities were for all of the procedures they provided.

The reference activities published by the ANZSNM were analogous to DRLs – they were the 75th percentile of the distribution of doses reported by the survey participants and the MCAs were the mode of the dose distributions. The dose distributions in question were of the doses prescribed to a hypothetical normal patient as opposed to the median dose actually delivered to a sample of patients that underwent that procedure. While the two values should normally be the same, the ANZSNM survey did not necessarily pick up cases where facilities applied *ad hoc* weight (or similar) correction.

The ANZSNM tables are a valuable resource, however they were never officially recognised for the purposes of regulatory compliance and the tables did not cover the CT component of multimodality imaging. Furthermore, the most recent table released by the ANZSNM was published in 2008, since which time there have been considerable changes to how PET and SPECT is utilised. ARPANSA therefore decided to conduct a new survey from which to derive the Australian nuclear medicine DRLs.

3. Method

ARPANSA convened a liaison panel incorporating members from relevant professional bodies to provide guidance on the development of the nuclear medicine DRLs. Members of the panel represented ARPANSA, ANZSNM, the Australasian Association of Nuclear Medicine Specialists (AANMS), and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM). The initial task of the panel was to oversee the creation of the National Diagnostic Reference Level Service (NDRLS) nuclear medicine survey.

A survey, in the form of a Microsoft Excel workbook, was devised that requested basic information about each radiopharmaceutical administration that occurred within a participating facility over a four week period. The information requested included the patient's age, sex and weight, the date of the administration, the scan category and type, the type and activity of the radiopharmaceutical administered and the reason, site and dose-length product (DLP) of any CT performed on the patient.

For general nuclear medicine, the scan category and types were selectable from drop down lists. The categories were anatomical/physiological (e.g. skeletal, endocrine etc.) and the scan types were more protocol specific (e.g. 3-phase bone scan, Thyroid uptake scan, etc.). In the case of PET, the categories were provided with the survey but the scan type was a free text field. The site of the CT scan was also a free text field where the user could enter any specifier and the reason for the scan was either 'Diagnostic' or 'Attenuation correction/localisation'.

Facilities were asked to make it clear when a single patient was administered multiple doses of radiopharmaceutical for a single study (for example during myocardial perfusion imaging (MPI)). The exception was for ventilation/perfusion lung studies (VQ scans), where facilities were asked to omit the ventilation agent and dose.

Invitations to participate in the NDRLS survey were sent by ARPANSA to 175 imaging facilities throughout the ACT, NSW, the NT, SA, Tasmania, and Victoria. The state regulators for Queensland and WA sent invitations to their licensees on behalf of ARPANSA.

Each survey returned was checked for obvious errors and some fields (particularly in the case of PET and the CT component of multimodality surveys) were reclassified to match either submissions from other participants or the ANZSNM protocols. The CT data in particular often required reclassification due to differences in nomenclature between facilities when describing scan regions. Each participant was sent an interim report that summarised their submission, compared the median administered doses for each reported protocol to the ANZSNM MCA and RAs and provided the participant an opportunity to question any changes ARPANSA made to scan or region classification.

The approach to deciding on a DRL for both the administered activities and the CT doses was, where feasible, to mimic the method used for determining the MDCT DRLs. This approach is as recommended by the ICRP.

Rather than publish just the DRLs, it was decided by the liaison panel that the 25th and 50th percentiles of the FRL distributions should be released. As discussed further in the results section, for protocols where there was an entry in the ANZSNM table but insufficient data was submitted to the NDRLS survey, it was decided that the ANZSNM data should be used for deriving DRLs. To facilitate this, the data used to generate the ANZSNM tables was kindly provided by one of the authors of the ANZSNM tables. This allowed for the 25th and 50th percentiles of the ANZSNM data to be calculated.

Following a set of DRLs being agreed by the liaison panel, the tables were circulated to the AANMS, ANZSNM and ACPSEM for endorsement. Following agreement from these organisations, the DRLs became officially recognised on 1 July 2017.

4. Results

4.1 Community participation

Ninety three facilities registered to participate in the survey from which 78 submitted surveys. Assuming a similar number of facilities per head of population in WA and Queensland to the rest of Australia, ARPANSA estimates that there were a total of 250 nuclear medicine facilities throughout Australia in 2015. This being the case, the 78 responding facilities represent around 30% of all facilities. Figure 1 shows the number of invitations sent, the number of facilities that enrolled and the number of facilities that submitted surveys from each state/territory.

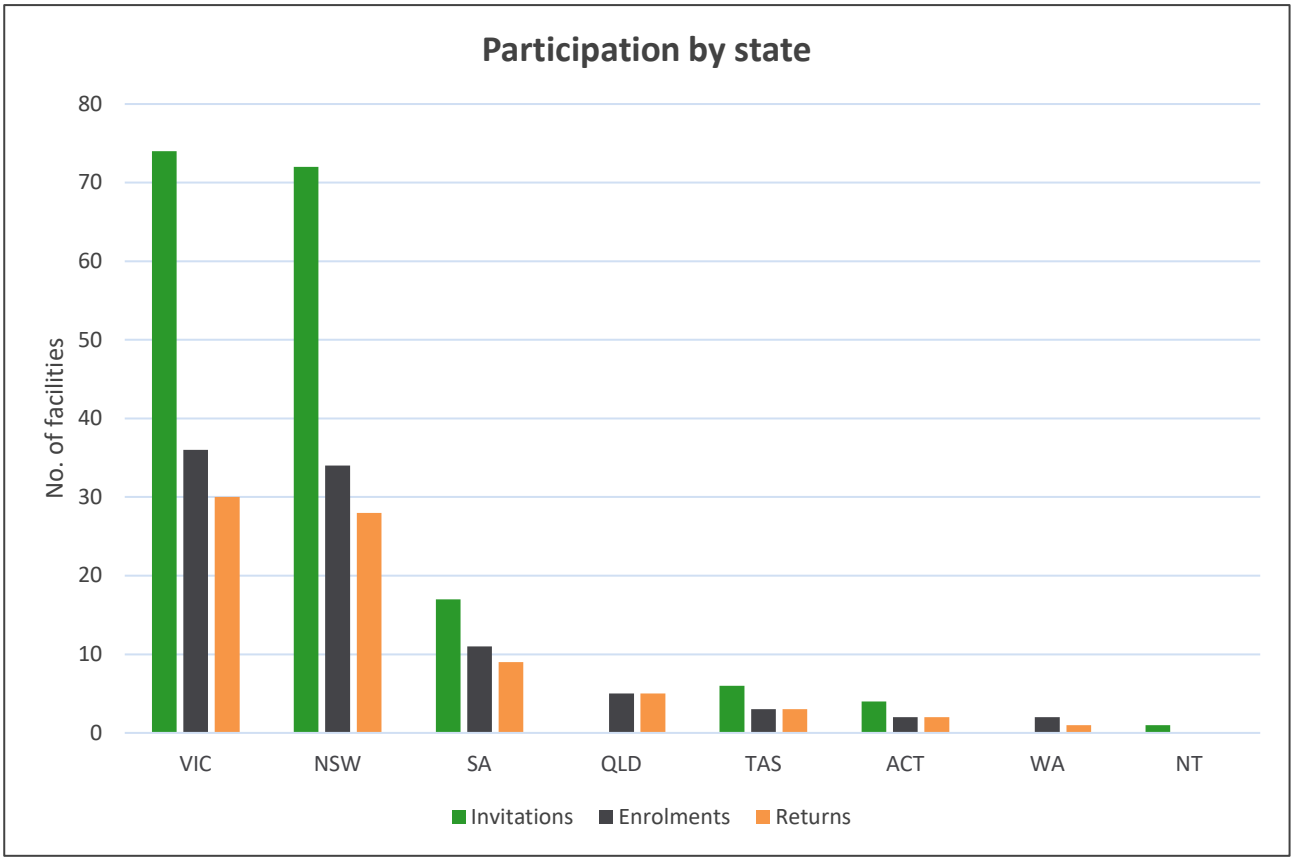

Figure 1: Number of facilities sent invitations, and the number of facilities that enrolled and participated in the NDRLS survey classified by state.

4.2 Submitted data

In total there were 17393 rows of data submitted, 12913 of which related to general nuclear medicine (including SPECT/CT) and 4480 related to PET (or PET/CT).

For the Australian MDCT DRLs, an age of 15 years is used to define the boundary between paediatric and adult patients (Hayton, et al., 2013). Using the same definition, Table 1 lists the number of administrations/scans reported to the survey for adult and paediatric patients.

Table 1: Number of facilities that participated in the NDRLS survey and the number of scans conducted as a function of modality.

	Adult		Paediatric	
	No. facilities	No. scans	No. facilities	No. scans
General NM	76	11815	38	414
CT with NM	62	5835	15	49
PET	19	3743	7	64
CT with PET	19	4108	7	65

While a number of facilities conducted scans on paediatric patients, not many of those facilities could be considered specialist paediatric facilities; only five facilities reported conducting more than ten paediatric NM scans during their four week collection period. Three facilities reported conducting more than ten paediatric PET scans. The paediatric data was considered to be insufficient for DRLs to be determined and was consequently discarded from the dataset.

The combination of the scan category, scan type and administered radiopharmaceutical was used to define a protocol. Eighty-six unique general nuclear medicine protocols and 24 PET protocols were reported by survey respondents. However, the majority of protocols were either conducted by relatively few facilities or were conducted at a number of facilities but only rarely at each one. As a consequence, for many protocols it was either not possible or not appropriate to derive a DRL on the basis of the distribution of FRLs.

An FRL for a given protocol was only calculated for a facility if that facility reported four or more instances of that protocol having occurred. If fewer than four instances of a given protocol were reported at a facility then that facility's data was discarded from that protocol's dataset. A DRL was only calculated for a protocol if its dataset contained four or more FRLs.

In instances where there was an entry in the 2008 ANZSNM table for a protocol that was not present in the (truncated) NDRLS dataset, it was decided that the ANZSNM data would be used for creating a DRL. This decision was made because the ANZSNM data often had more respondents, a result of not requiring a site to actually perform the scan within a given time period.

4.3 General nuclear medicine

Seventeen general nuclear medicine protocols met the condition of having four or more FRLs. Five facilities met the condition for an FRL to be issued for DTPA glomerular filtration rate (GFR), however two of these facilities were referring to non-imaging GFRs while the rest appeared to be referring to imaging studies, so

the set was discarded. Four facilities also reported conducting whole body scans for thyroid cancer using ^{131}I, however in (at least) one case this was done by imaging the therapeutic dose and therefore fell outside the scope of DRLs.

Table 2 lists the remaining 15 protocols and a summary of the individual doses administered to patients. There was a large variation between individual doses administered, as evidenced through the large standard deviations (σ) of Table 2. The distributions of activity are neither normal nor log-normal and vary considerably from protocol to protocol. As an example, the dose distributions from the four most reported scan types are shown in Figure 2.

Table 2: General nuclear medicine protocols that met the condition for a DRL to be calculated from the NDRLS dataset. The FRLs column is a surrogate for the number of facilities, Admins. is the number of administrations recorded. The mean activity is the mean of the individual patient doses, not the FRLs. Similarly, σ is the standard deviation of all the reported doses.

Category	Scan type	Radiopharmaceutical	FRLs	Admins.	Mean activity (MBq)	σ (MBq)
Cardiac	Gated blood pool scan	Tc_99m RBCs	37	443	886	207
	MPI - 1 day rest + stress	Tc_99m MIBI	56	1709	1327	270
	MPI - Single phase	Tc_99m MIBI	22	583	618	284
Endocrine	Parathyroid	Tc_99m MIBI	24	150	829	121
	Parathyroid subtraction	Tc_99m $TcO4^-$	13	79	125	131
	Thyroid	Tc_99m $TcO4^-$	60	670	209	43
Gastrointestinal	Gastric emptying	Tc_99m Colloid, DTPA	11	70	42	10
Genitourinary	Renal scan	Tc_99m DTPA	8	45	444	119
		Tc_99m MAG3	15	137	260	56
Hepatobiliary	Hepatobiliary	Tc_99m HIDA/DISIDA	15	97	193	28
Infection	Infection	Ga_67 Citrate	9	65	196	66
Lymphatic	Sentinel node	Tc_99m Colloid	37	449	58	44
Nervous System	Brain	Tc_99m HMPAO/ECD	9	110	718	86
Pulmonary	Lung perfusion	Tc_99m MAA	57	829	209	49
Skeletal	Bone scan	Tc_99m MDP/HDP	73	5244	863	94

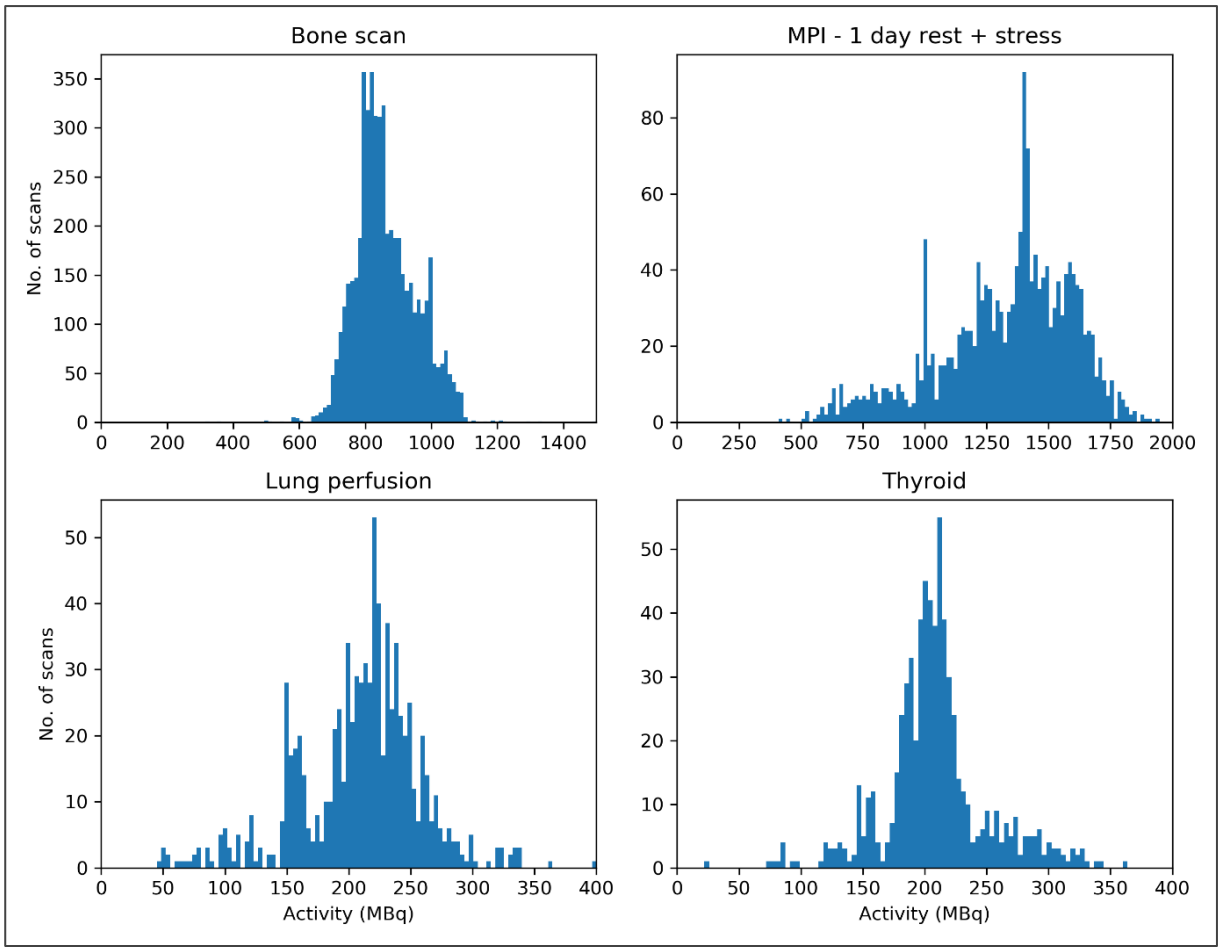

Figure 2: Histograms of the dose distributions for the four most often reported general nuclear medicine protocols.

All of the protocols listed in Table 2 had an associated MCA and RA in the ANZSNM tables. However, the ANZSNM tables had additional classifications with regards to MPIs, where the order of the rest and stress components were specified. The NDRLS survey did not contain this level of detail and instead the protocol was classified as only either a one day study or as a single phase study (the assumption being that a two day study is essentially the same as two single phase studies). The result is that there are only two protocols for MIBI MPIs in Table 2 as opposed to six entries in the ANZSNM tables.

The entries for sentinel node studies is quoted for the entire procedure rather than on a per-injection basis. The survey did ask participants to specify whether the study was for breast cancer, melanoma or other lesion, however all three types yielded similar results and the results have been collated in Table 2. Similarly, participants specified whether VQ scans were planar or SPECT acquisitions but, as the median FRLs for both acquisition types were quite similar, the two have been combined throughout this analysis.

For all protocols, the activity administered for each patient was plotted against patient weight to ascertain whether weight correction was being conducted. The only scans where it was clear that a portion of the respondents moderated their doses based on patient weight (or some other related characteristic such as BMI or surface area) was for MPIs. The dose versus patient weight for single day MPI studies is shown in Figure 3. At least five of the 56 facilities that submitted MPI data conduct dose correction based on weight, however the overall effect on the median dose as a function of weight was negligible and the DRL for MPIs is treated the same as the protocols where weight correction is rare.

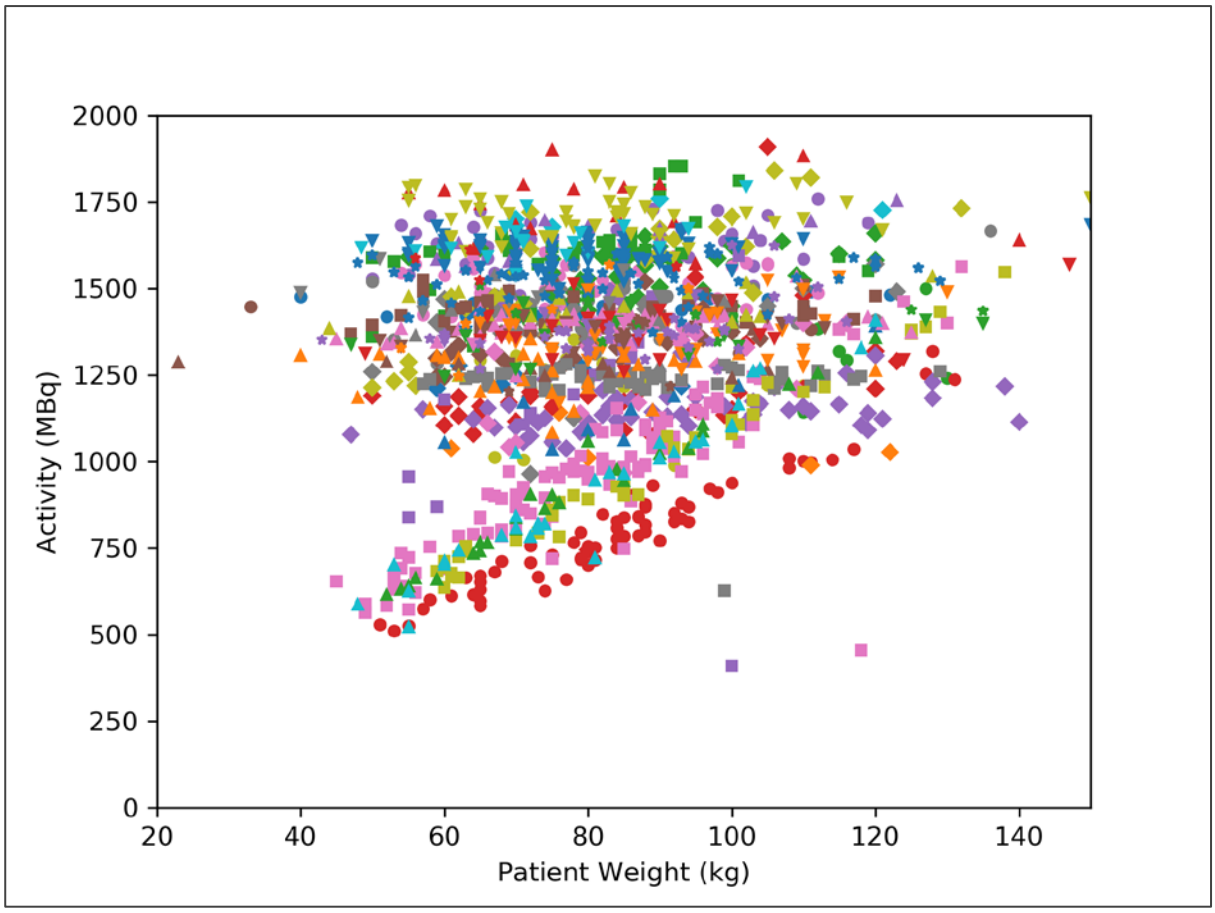

Figure 3: Doses reported as a function of patient weight for one day MPI scans. Each set of coloured circles, triangles and diamonds represents a different facility, some of which show a clear positive correlation with patient weight.

There were additional instances where it appeared facilities would increase the dose to some heavier patients, but again, the overall effect on the dose distribution was negligible. One site reported using the principle of 'compassionate ALARA' (where ALARA refers to the principle of keeping doses as low as reasonably achievable), whereby patients that were identified as being at risk of discomfort lying still for the normal bone scan duration were given considerably higher doses than other patients. In this case the respondent specified when compassionate ALARA was being employed and these data were excluded from the analysis of bone scans.

The 75th percentiles of the FRL distributions for the 15 included protocols are displayed in Table 3 along with the MCA and RA of the corresponding protocols in the ANZSNM tables. The median of the FRLs generally matches the MCA within 10%, meaning the mode of the dose distribution of the ANZSNM surveys of 2008 generally matches the median of this survey. There are three exceptions where the difference exceeds 10%. The first was parathyroid subtraction scans (MCA of 150 MBq, FRL median of 74 MBq), where the MCA also happened to be the highest dose reported to the ANZSNM. The second exception is for sentinel node scans (MCA of 20 MBq, FRL median of 40 MBq), where the ANZSNM had asked for the dose per injection whereas ARPANSA asked for the total dose. The final exception, MPI single phase studies (MCA of 600 MBq, FRL median of 500 MBq) suggests that there has been some change in how MPIs are conducted between 2008 and 2015.

Table 3: The median and 75th percentile of the FRL distributions for the included NDRLS protocols. The 75th percentiles listed are the basis of the issued DRLs. The NDRLS data is compared with the ANZSNM data gathered during their 2008 survey. *These values are the average of the relevant MCAs and RAs specified in the ANZSNM tables.

Category	Scan	Radiopharmaceutical	MCA (MBq)	Median FRL (MBq)	RA (MBq)	75th FRL (MBq)
Cardiovascular	Gated heart pool	Tc-99m RBCs	1000	987.5	1000	1033
	Rest/Stress MPI	Tc-99m MIBI	1350*	1398.5	1515*	1521
	Single phase MPI	Tc-99m MIBI	600*	500	870*	620
Endocrine	Parathyroid	Tc-99m MIBI	800	820	900	902
		Tc-99m $TcO4^-$	150	73.5	150	219
	Thyroid	Tc-99m $TcO4^-$	200	211	200	215
Gastrointestinal	Gastric emptying	Tc-99m Colloid	40	43	40	44
Genitourinary	DTPA renal	Tc-99m DTPA	400	398	600	501
	MAG3 renal	Tc-99m MAG3	300	270	350	304
Hepatobiliary	Hepatobiliary	Tc-99m HIDA	200	205	200	210
Infection	Gallium scan	Ga-67 Citrate	200	198.5	250	218
Lymphatic	Sentinel node	Tc-99m Colloid	20	40.8	40	52
Nervous System	Cerebral perfusion	Tc-99m HMPAO	800	720	900	752
Pulmonary	VQ	Tc-99m MAA	200	218.5	220	238
Skeletal	Bone scan	Tc-99m MDP	800	836	900	921

There is more variation between the RAs reported in 2008 and the 75th percentiles of the FRLs in this survey. Five of the 15 protocols have a 75th percentile of FRLs that is more than 10% lower the ANZSNM RA. Two protocols have a 75th percentile of FRLs that are higher than the corresponding RAs: the aforementioned sentinel node scans and parathyroid subtraction scans.

The results presented in Table 3 were used as the basis of the DRLs that were published. A further 45 general nuclear medicine imaging DRLs were generated using the 75th percentiles from the dose distributions recorded during the 2008 ANZSNM survey. The full list of general nuclear medicine DRLs is presented in Table 4

Table 4

Category	Procedure name	Nuclide	Chemical form	Route of Admin.	25th percentile	Median	DRL
Cardiac	Cardiac first pass	Tc-99m	Pertechnetate, Red cells	IV	590	875	930
	Cardiac L/R shunt	Tc-99m	Pertechnetate	IV bolus	400	550	900
	Cardiac R/L shunt	Tc-99m	MAA	IV	100	150	185
	Gated blood pool scan	Tc-99m	Red cells	IV	900	990	1030
	Myocardial hot spot	Tc-99m	PYP	IV	720	800	800
	MPI – Rest	Tl-201	Chloride	IV	80	120	120
	MPI – Stress	Tl-201	Chloride	IV	100	120	120
	MPI – Reinjection	Tl-201	Chloride	IV	30	40	40
	MPI - Single phase	Tc-99m	Tetrofosmin, MIBI	IV	350	500	620
	MPI - 1 day rest + stress	Tc-99m	Tetrofosmin, MIBI	IV	1250	1400	1520
				Note: dose is for both studies combined			
	MPI - 1 day rest (^{201}Tl)/stress (^{99m}Tc)	Tl-201	Chloride	IV	100	110	120
		Tc-99m	Tetrofosmin, MIBI	IV	900	1000	1075
Endocrine	Parathyroid	Tc-99m	Tetrofosmin, MIBI	IV	765	820	900
	Parathyroid subtraction	Tc-99m	Pertechnetate	IV	45	75	220
	Thyroid	I-123	Iodide	IV	180	185	345
	Thyroid	Tc-99m	Pertechnetate	IV	200	210	215

Category	Procedure name	Nuclide	Chemical form	Route of Admin.	25th percentile	Median	DRL
Gastrointestinal	Blood loss	Tc-99m	Red cells	IV	800	1000	1000
	Colonic transit	Ga-67	Citrate	Oral	6	10	20
	Gastric emptying	Ga-67	Citrate	Oral	10	15	20
	Gastric emptying	Tc-99m	Colloid, DTPA	Oral	39	43	44
	Oesophageal reflux	Tc-99m	Colloid, DTPA	Oral	40	40	40
	Oesophageal transit	Tc-99m	Colloid, DTPA	Oral	20	40	40
	Small bowel transit	Tc-99m	Colloid, DTPA	Oral	20	40	40
	Meckel's diverticulum	Tc-99m	Pertechnetate	IV	225	400	400
	Salivary glands	Tc-99m	Pertechnetate	IV	150	185	200
Genitourinary	Renal cystogram	Tc-99m	Pertechnetate	Bladder	40	50	94
	Renal scan	Tc-99m	DMSA	IV	120	150	200
	Renal scan	Tc-99m	DTPA	IV	380	400	500
	Renal scan	Tc-99m	MAG3	IV	235	270	305
	Renal transplant	Tc-99m	DTPA, MAG3	IV	210	325	400
	Testicular scan	Tc-99m	Pertechnetate	IV	200	400	600
Haematological	Arterial infusion	Tc-99m	MAA	Intra-arterial	100	135	190
	Le Veen shunt	Tc-99m	Colloid	Intra-peritoneal	95	185	200
	Venogram	Tc-99m	Pertechnetate	IV	700	770	800
Hepatobiliary	Hepatobiliary	Tc-99m	HIDA, DISIDA, DIDA	IV	185	205	210
	Liver blood flow	Tc-99m	Red cells	IV	800	900	1000

Category	Procedure name	Nuclide	Chemical form	Route of Admin.	25th percentile	Median	DRL
	Liver/spleen	Tc-99m	Colloid	IV	150	200	200
	Liver transplant	Tc-99m	HIDA, DISIDA	IV	155	185	200
Infection	Infection	Ga-67	Citrate	IV	185	200	220
	Infection	Tc-99m	WBC-colloid, WBC-HMPAO	IV	500	700	800
Lacrimal	Lacrimal drainage	Tc-99m	Pertechnetate	Eye drops	7	10	18
				Note: dose is expressed in terms of drops per eye			
Lymphatic	Lymphoscintigraphy	Tc-99m	Nanocolloid	Perilesional	32	40	52
				Note: dose is for entire procedure, not per injection			
Nervous System	Brain	Tc-99m	DTPA	IV	800	800	900
	Brain	Tc-99m	HMPAO, ECD	IV	640	720	750
	CSF leak	In-111	DTPA	Intrathecal	15	22.5	38
	CSF leak	Tc-99m	DTPA	Intrathecal	77	300	370
	CSF shunt patency	Tc-99m	Pertechnetate, DTPA	Cisternal	40	40	80
Oncology	Somatostatin receptors	In-111	Octreotide	IV	200	200	235
	Thyroid - wb scan for Ca	I-123	Iodide	Oral	190	370	450
	Thyroid - wb scan for Ca	I-131	Iodide	Oral	100	150	200
	Tumour	Ga-67	Citrate	IV	300	400	400
	Tumour	I-123	MIBG	IV infusion	200	290	400
	Tumour	I-131	MIBG	IV infusion	24	31	38
	Tumour	Tc-99m	MIBI	IV	740	800	800

Category	Procedure name	Nuclide	Chemical form	Route of Admin.	25th percentile	Median	DRL
	Tumour	Tc-99m	[V]-DMSA	IV	370	400	440
	Tumour	Tl-201	Chloride	IV	115	125	185
Pulmonary	Lung perfusion	Tc-99m	MAA	IV	200	220	240
Skeletal	Bone marrow	Tc-99m	Colloid, nanocolloid	IV	150	400	550
	Bone scan	Tc-99m	MDP, HDP	IV	810	840	920
Splenic	Liver/spleen – see Hepatobiliary						
	Spleen	Tc-99m	Denatured RBCs	IV	200	300	670
Non-imaging	Breath test	C-14	Urea	Oral	0.037	0.037	0.037
	GIT blood loss	Cr-51	Red cells	IV	4	4	5.5
	Plasma volume	I-125	HSA	IV	0.2	0.25	0.5
	Red cell survival	Cr-51	Red cells	IV	4	6	7
	Red cell volume	Cr-51	Red cells	IV	1	1.5	4
	Renal GFR	Tc-99m	DTPA	IV	57.5	85	100
	Renal GFR	Cr-51	EDTA	IV	3	4	4

4.4 CT component of SPECT/CT

For each nuclear medicine scan conducted, NDRLS survey participants were asked for the site, DLP and reason for any CT conducted. Only data relating to CTs that were conducted for the purposes of attenuation correction and/or localisation were included in the DRL analysis.

As previously mentioned, no guidance was provided regarding scan region nomenclature; as a result, there was a large variety of scan regions submitted (in excess of 200). In cases where the scan region location and size was constrained by the diagnostic task (for example, a chest CT for a cardiac NM scan), this lack of uniformity in nomenclature did not present an issue.

There were five such protocols that met the inclusion criteria of having four or more FRLs. These protocols are listed in Table 5. In the case of cardiac CT, only CTs associated with MPIs were included. It was necessary to contact a number of sites to ascertain whether they had submitted the DLP for a single scan or if the DLP of multiple scans had been submitted. The dose distributions for the four most common CT types are shown in Figure 4. The DLP distributions appear qualitatively more log-normal than the activity plots of Figure 2 which is in keeping with the diagnostic CT data collected by ARPANSA for the NDRLS MDCT survey.

Table 5: General nuclear medicine CT protocols that met the condition for a DRL to be calculated from the NDRLS dataset. The FRLs column is a surrogate for the number of facilities. The mean and 75th percentiles listed are of the individual patient doses, not the FRLs. Similarly, σ is the standard deviation of all the reported doses.

Category	Region	FRLs	Scans	Mean (mGy.cm)	75th (mGy.cm)	σ (mGy.cm)
Cardiac	Chest	28	1303	44	55	32
Lymphatic	Chest (breast ca.)	16	137	148	195	81
Neurological	Brain	7	62	112	234	154
Parathyroid	Neck/chest	20	121	217	255	130
Pulmonary	Chest	16	173	96	117	51

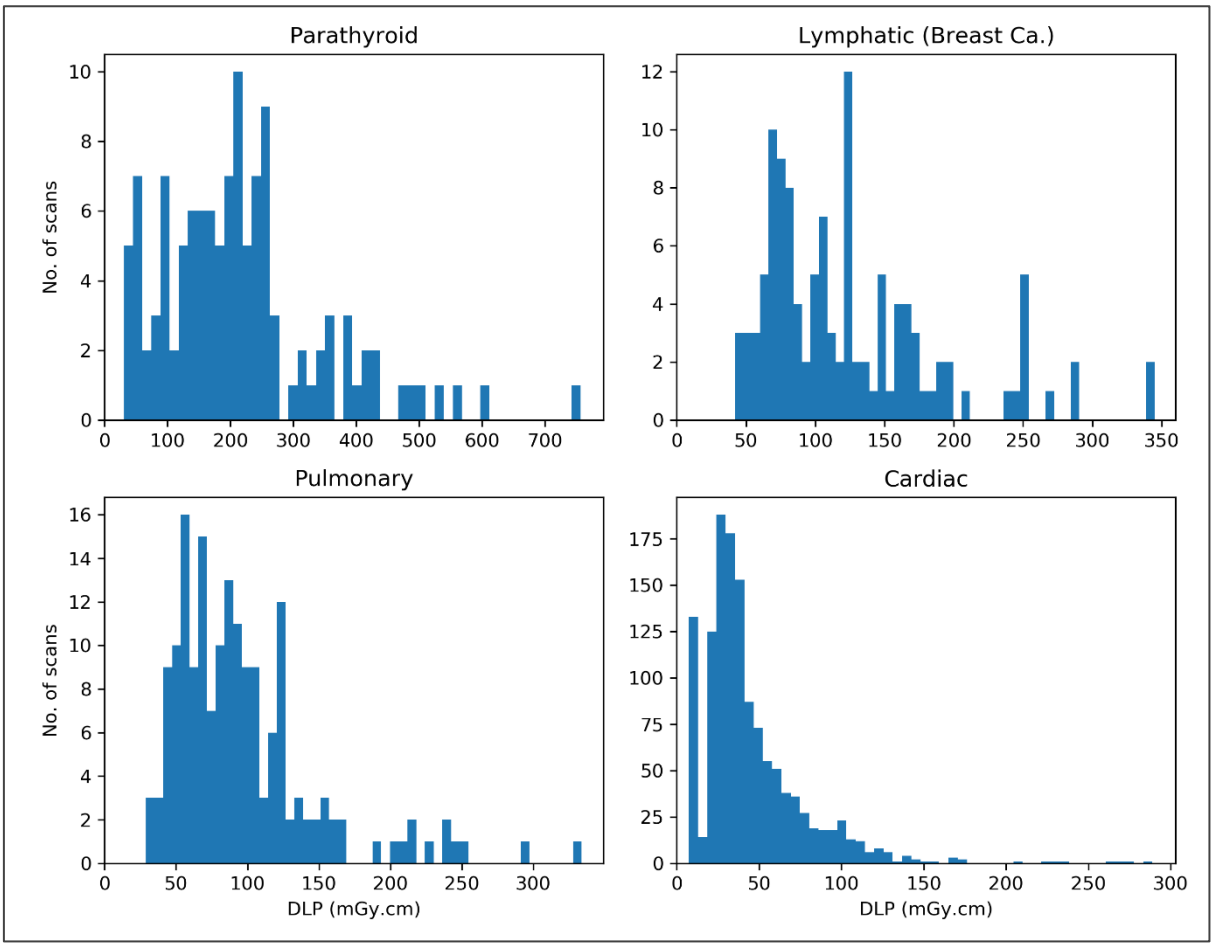

Figure 4: Histograms of the dose distributions for the four most often reported CT scans conducted as part of a SPECT/CT study.

Where the CT accompanied a more general nuclear medicine scan (for example a bone scan), correctly classifying the various scans into logical groups required more processing. An additional complication was that the scan length (or volumetric CT Dose Index - $CTDI_{vol}$) was not requested from participants, it was therefore difficult to differentiate scans conducted over a large Field of View (FoV) using low dose parameters from scans conducted over a small FoV using higher dose parameters.

The only such protocol that received enough submissions to warrant a DRL was CT conducted as part of a bone scan. For skeletal CTs, the various scan regions reported were re-classified into six regions, encompassing the skull, cervical/thoracic spine, thoracic/lumbar spine, pelvis/lumbar spine, chest/abdomen/pelvis (CAP) and extremities. The skull dataset did not meet the number of FRLs required and was discarded. A summary of the remaining regions is shown in Table 6.

Table 6: CT scans conducted as part of an MDP/HDP bone SPECT/CT.

Region	Facilities	Scans	Mean DLP (mGy.cm)	75th DLP (mGy.cm)	σ (mGy.cm)
Cervical/Thoracic	39	386	138	190	94
Thoracic/Lumbar	12	104	207	261	153
Lumbar/Pelvis	55	1113	187	245	109
Extremities	48	673	160	154	194
CAP	17	194	313	414	183

For the sake of simplicity, it was decided to combine the cervical/thoracic, thoracic/lumbar and lumbar/pelvis scans into a single "Axial" category. The resulting DLP distribution is shown in Figure 5 with the contributions made by the three sub categories shown.

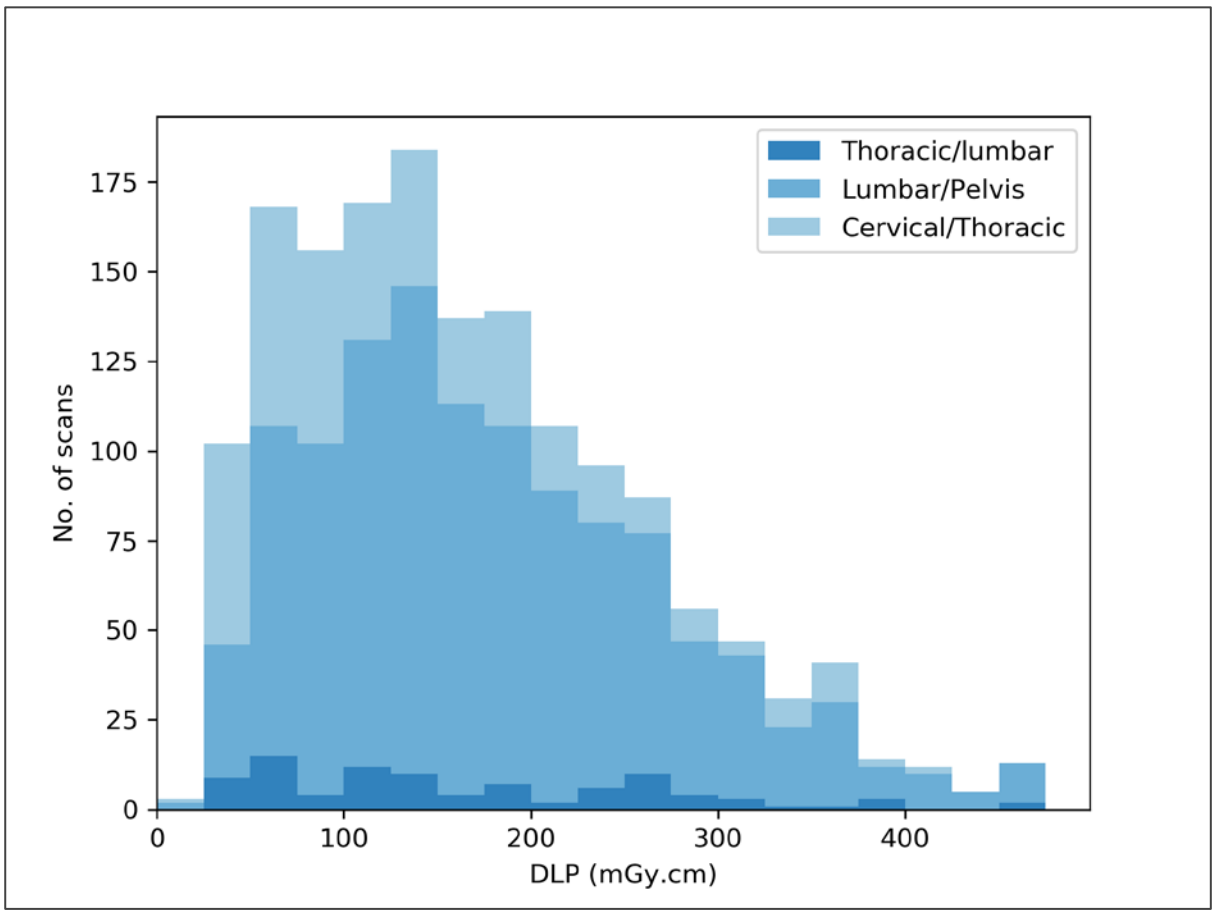

Figure 5: Histogram of the doses delivered during axial CTs, with the contribution of the three subcategories illustrated. Note that the subcategory histograms are stacked on each other (i.e. there are considerably fewer cervical/thoracic scans than lumbar/pelvis scans)

While any definition of the axial skeleton encompasses the chest, abdomen and pelvis, the CAP category was kept separate due to the higher doses involved. Presumably, most SPECT acquisitions of the CAP require multiple bed positions, so for clarity the CAP category was relabelled Axial (2 bed).

Because of the minimal dose burden resulting from attenuation/localisation CT scans, it was decided to not issue a DRL for CTs of the extremities. The DRLs for the CT component of SPECT/CT imaging are listed in

Table 7. As previously stated, these DRLs are only applicable to CT scans conducted for attenuation/localisation purposes.

Table 7 The Australian DRLs issued for the CT component of SPECT/CT scans.

Category	Region	25th percentile (mGy.cm)	Median (mGy.cm)	DRL (mGy.cm)
Cardiac	Chest	25	40	45
Lymphatic (Breast Ca.)	Chest	80	115	170
Neurological	Brain	45	225	255
Parathyroid	Neck/Chest	140	205	255
Pulmonary	Chest	70	95	120
Skeletal	Axial	115	170	240
	Axial (2 bed)	195	340	415

4.5 PET

The vast majority of data submitted to the PET portion of the NDRLS survey related to scans conducted with ^{18}F (specifically FDG, which accounted for 92 % of all scans) and ^{68}Ga (PSMA and dotatate, which together accounted for a further 7 %). The remaining 1 % of scans were conducted with ^{124}I and ^{90}Y as well as several additional ^{18}F labelled pharmaceuticals. Applying the criteria that at least four sites must have conducted a particular protocol to be included in the dataset resulted in all but four protocols being discarded: non-neurological ^{18}F FDG scans, neurological ^{18}F FDG scans, ^{68}Ga PSMA scans and ^{68}Ga dotatate scans.

The liaison panel advised that the main factor in the doses used for ^{68}Ga scans was generally the amount of activity available from the ^{68}Ge/^{68}Ga generator rather than any medical indications or imaging considerations. Consequently, the panel suggested that a DRL should not be issued for these scans.

Figure 6 is a plot of the median dose delivered as a function of weight at each facility during non-neurological PET ^{18}F FDG scans. The black line is the median of the weight specific FRLs, displaying a clear increase in median dose with increasing patient weight.

Non-neurological FDG protocols appear to be the only protocol where weight correction is used routinely at the majority of Australian imaging facilities. Nineteen facilities submitted whole body PET FDG data, thirteen of which clearly weight corrected on a case by case basis, although some applied an upper dose threshold for heavy patients. Of the remaining facilities, two didn't weight correct, two may have been weight correcting but the positive correlation was so small as to be ambiguous and the final facility administered one of two doses depending on whether the patient weighed above or below 90 kg.

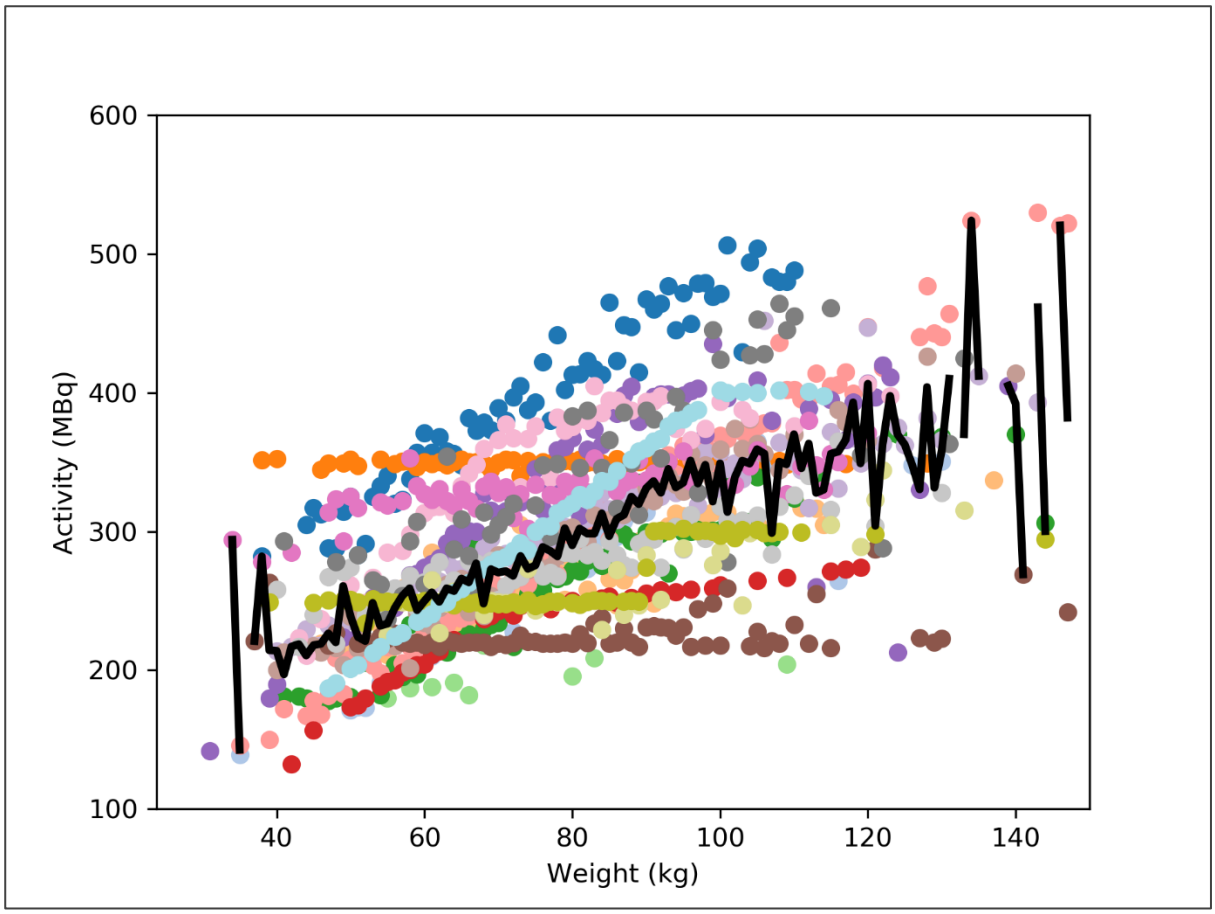

Figure 6: FRLs as a function of weight for non-neurological PET scans. Each different colour represents a different facility. The black line represents the medians of the FRLs for a given weight.

The liaison panel decided that two DRLs should be issued for whole body FDG scans: one for facilities that weight correct and one for facilities that do not. In the former case, the 25th, 50th and 75th percentiles of the weight specific FRLs from the 13 facilities that conducted weight correction were calculated and fitted with lines via a least squares fit. The coefficients of the resulting fits when considering patients in the weight range 40 to 120 kg is shown in Table 8.

Table 8: The coefficients resulting from a linear least squares fit of the 25th, 50th and 75th percentiles of the distribution as of FRLs as a function of weight for non-neurological PET FDG scans conducted at facilities where a continuous weight correction was applied.

Percentile	Gradient	y-intercept
25th	2.26	92
50th	2.32	106
75th	2.45	121

Rather than use the values of the least square fit for the DRL table, it was decided to use equations that would be easier for users to remember and apply. The gradient of each line was set at 2.5 MBq/kg and the y intercept was set at 75 MBq, 100 MBq and 125 MBq for the 25th, 50th and 75th percentile respectively. Figure 7 shows the simplified fits against the 25th, 50th and 75th percentiles of the weight specific FRL distributions. *The 75th percentile line appears to slightly overestimate the data at lower weights (< 60 kg).*

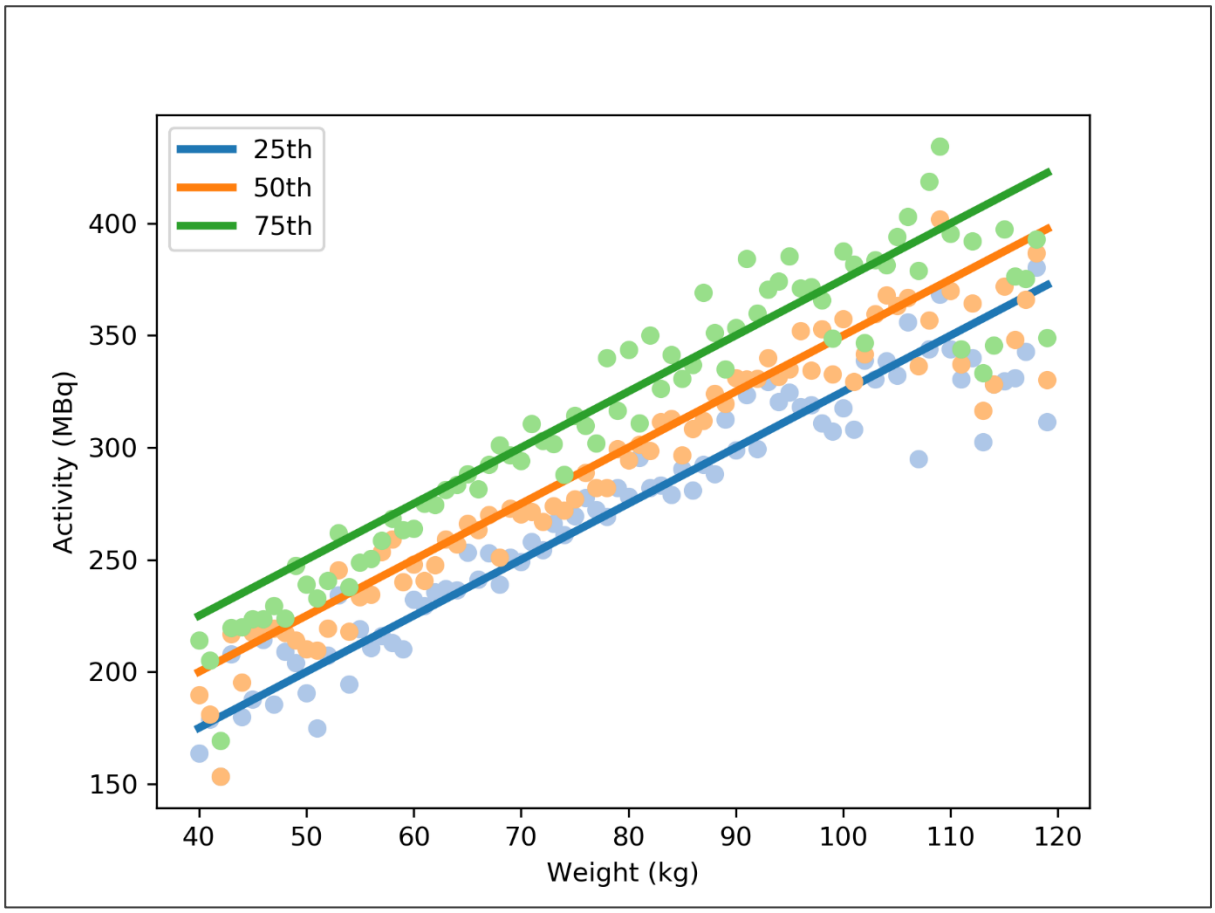

Figure 7: Plot of the simplified 25th, 50th and 75th percentile fits (the coloured lines) and the data being fitted (the coloured dots).

As a sanity check of the simplified fits, the percentage of scans in the dataset that fall below the three lines were calculated. The results are shown in Table 9 and suggest that the simplified fits provide a good approximation of the true percentiles.

Table 9: Percentage of non-neurological FDG weight dependent FRLs from weight-correcting facilities that fall below the simplified percentile fits.

Percentile fit	Equation	% FRLs below fit
25th	2.5 x kg + 75	26
50th	2.5 x kg + 100	48
75th (DRL)	2.5 x kg + 125	72

For whole body protocols that don't use weight correction, and for the brain FDG scans, the same technique was used to calculate the DRLs as was used for the general nuclear medicine DRLs, i.e. the 75th percentile of the distribution of FRLs. However, unlike the general nuclear medicine DRLs, the requirement that a facility must conduct four such scans to be included in the dataset was removed. Figure 8 shows the distribution of doses administered for brain 18F FDG scans and for non-corrected whole body FDG scans.

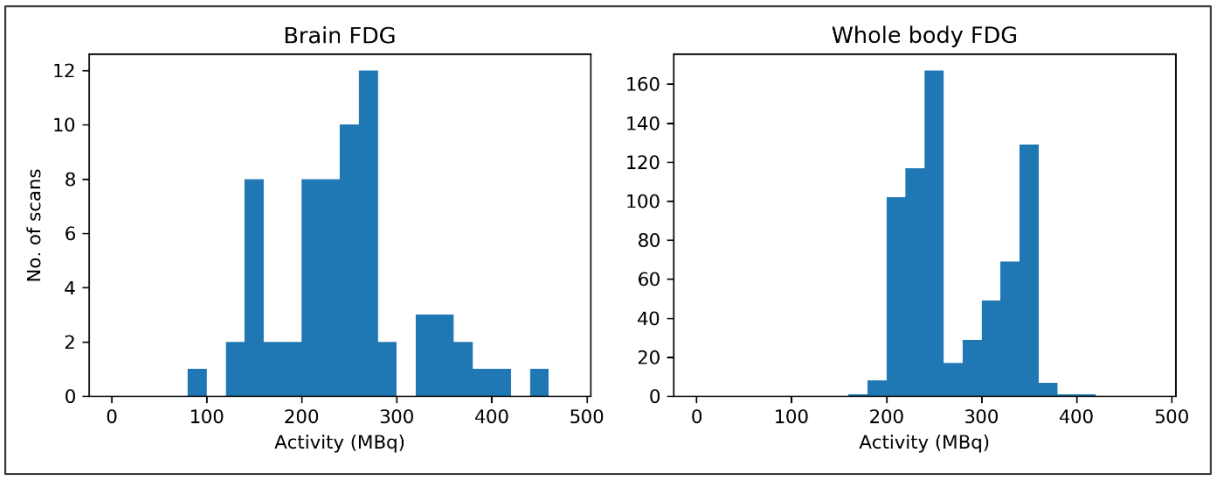

Figure 8: Histograms of the dose distributions for the two non-weight specific PET protocols.

There were three PET procedures included in the 2008 ANZSNM MCA table. These were FDG scans of the brain, myocardial viability scans and tumour imaging. The MCA in each case was 370 MBq.

The brain and tumour MCAs have been superseded with the NDRL survey results, while myocardial viability studies were only reported by one survey participant. Rather than use the existing ANZSNM data to update the DRL for myocardial viability scans (which would replicate the approach taken for general nuclear medicine), no DRL has been issued for these scan types. The reason for this proposal is that the activities reported to the NDRL survey for tumour and brain imaging scans are quite different from the MCAs found by the ANZSNM, so it does not seem prudent to assume that the MCA for myocardial scans is a good indication of current Australian practice. The DRLs for PET procedures are listed in Table 10.

Table 10: The Australian DRLs issued for PET administrations.

Category	Pharmaceutical	25th percentile (MBq)	Median (MBq)	DRL (MBq)
Body	F-18 FDG	225	250	310
Body (weight corrected)	F-18 FDG	2.5 x kg + 75	2.5 x kg + 100	2.5 x kg + 125
Brain	F-18 FDG	200	220	250

4.6 CT Component of PET/CT

The same issues encountered with nomenclature regarding CT scan margins in SPECT/CT were experienced with the PET/CT survey returns. As with the SPECT/CT analysis, all diagnostic CT scans were removed from the dataset. Unlike SPECT/CT, the majority` of PET/CT scans encompassed a large portion of the trunk and some portion of the head/neck and legs for all PET scans except for brain scans.

A similar approach of reclassifying and consolidating scan regions to that used for SPECT/CT was undertaken, with the primary difference being that the PET scan category was not considered. The three final scan categories, conducted by four or more facilities, were: head/brain, eyes-to-thighs and vertex-to-toes. The DLP distributions for these categories are shown in Figure 9 and described in Table 11. The DRLs for the CT component of PET/CT scans are shown in Table 12.

Table 11 PET/CT CT protocols that met the condition for a DRL to be calculated from the NDRLS dataset. The FRLs column is a surrogate for the number of facilities. The mean and 75th percentiles listed are of the individual patient doses, not the FRLs. Similarly, σ is the standard deviation of all the reported doses.

Region	FRLs	Scans	Mean DLP (mGy.cm)	75th DLP (mGy.cm)	σ (mGy.cm)
Head/Brain	12	440	207	144	310
Whole body (Eyes - Thighs)	19	3099	574	746	291
Whole body (Vertex - Toes)	13	291	802	1018	329

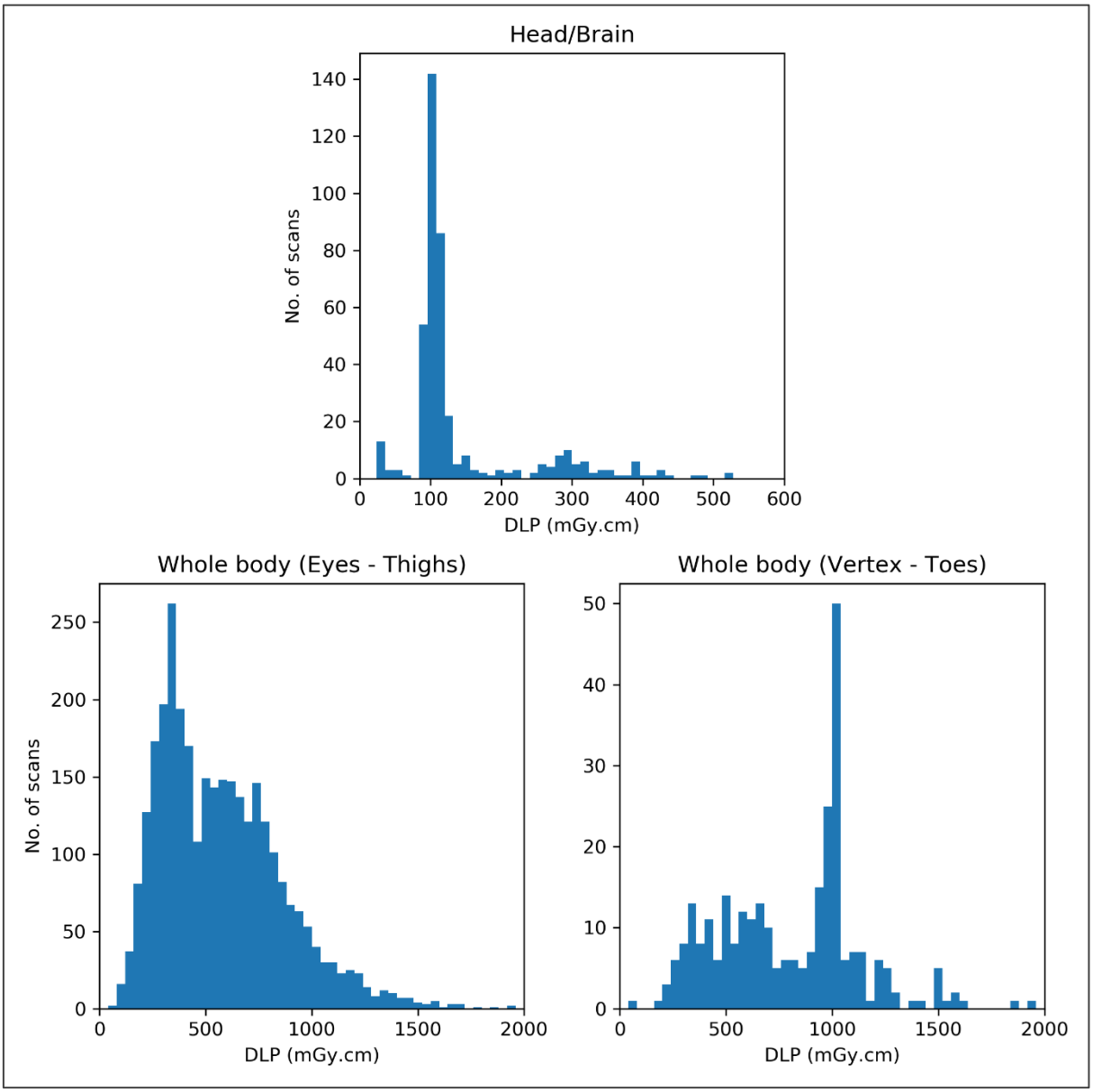

Figure 9: Histograms of the dose distributions for the three included CT types conducted as part of PET/CT protocols.

Table 12: The Australian DRLs issued for the CT component of PET/CT scans.

Protocol	25th percentile (mGy.cm)	50th percentile (mGy.cm)	DRL (mGy.cm)
Head/Brain	75	125	325
Whole body (Eyes - Thighs)	325	430	540
Whole body (Vertex - Toes)	495	655	985

5. Discussion

As previously mentioned, the formulation of the Australian DRLs for nuclear medicine have followed the recommendations of the ICRP via a method analogous to that used for the Australian MDCT DRLs. In some other jurisdictions, the DRLs for administered activity are seen quite differently; rather than being just an indication of current practice, the DRLs are seen as recommended doses.

The guidance document released by the European Commission (European Commission, 1999) is particularly forthright in stating DRLs for nuclear medicine should be seen as recommended doses, stating that the DRL should be an 'optimal dose' and 'approached as closely as possible'. This is at odds with the interpretation of DRLs within diagnostic radiology, whereby the DRL is seen as an action level for triggering a review of imaging protocols.

The difference in application of DRLs is related to the different level of control operators have over the relevant DRL quantities – a nuclear medicine technician makes a conscious decision on what activity to administer to a patient, whereas a radiographer cannot directly chose the $CTDI_{vol}$ or DLP a patient receives. The use of a recommended activity is arguably of greater benefit to the nuclear medicine community than the diagnostic radiology style DRLs, however determining optimal doses is beyond the remit of a radiation protection regulator and would need to be issued by an appropriately skilled and authoritative group of expert physicians.

Given the potential different interpretations of DRLs, it is important that the Australian nuclear medicine community recognises that the Australian nuclear medicine DRLs are not recommended doses. This was one of the reasons why the 25th and 50th percentiles were published along with the DRL –to illustrate that there were a range of doses and the DRL only corresponds to a certain level within that range.

Providing the 25th and 50th percentiles in the DRL table should also highlight to facilities when they are administering an unusually low dose. Furthermore, the 50th percentile, while not a recommended dose, could be used as a reasonable starting point for facilities introducing new protocols or reviewing their existing protocols.

A further attempt to aid the community to understand the context of the DRLs was to provide histograms of the underlying dose distributions used to set the DRLs. All of the distributions are available on the ARPANSA website, allowing facilities undertaking a DRL comparison the ability to determine how they compare with the full survey cohort.

As previously stated, it is a regulatory requirement that facilities must periodically compare their doses to the DRLs. It is also a requirement of the Diagnostic Imaging Accreditation Scheme (DIAS), which is responsible for accrediting facilities for Medicare funding, that a comparison with the DRLs must be

conducted annually (Department of Health, 2016). DIAS first started including the nuclear medicine DRLs in their accreditation audits on 1 July 2018.

Given the large number of DRLs for nuclear medicine, it would be quite onerous to conduct an annual survey of every protocol. After consultation between ARPANSA and DIAS, it was decided that instead, for protocols where the prescribed dose is independent of patient weight, facilities can meet the requirement by simply including the DRL in their written protocol (along with a justification if their prescribed dose is above the DRL). For the CT portion of multimodality scans, and for cases where the dose is varied in a continuous fashion based on patient characteristics, a full survey similar to those used for MDCT DRL comparisons, is required. A guidance document to this effect has been published by DIAS (Department of Health, n.d.) and ARPANSA has advised that meeting the DIAS requirements would also satisfy RPS 14/C-5 (ARPANSA, 2018).

6. Future work

It was decided that the submitted data relating to paediatric patients was insufficient for DRLs to be issued. Rather than conduct more data collection from all nuclear medicine sites, it may be more appropriate to identify the techniques used by only the nuclear medicine facilities that specialise in paediatric imaging.

For DRLs to be useful benchmarks, it is important that the surveyed data is representative of common practice within the region and, consequently, DRLs must be updated over time to reflect changes to the prevalent imaging technology and visualisation techniques. Advances in imaging techniques, particularly in the field of PET and more generally theranostics, continues apace and new DRLs for nuclear medicine will be required in the not too distant future.

With respect to the CT component of multimodality imaging, any future survey would benefit from requesting the $CTDI_{vol}$ in addition to the DLP of the scans conducted. $CTDI_{vol}$ was originally omitted because it was thought that the DLP, being a measure of the total dose delivered during a CT, was a more relevant quantity and removing $CTDI_{vol}$ would make the surveys easier to complete. In retrospect, having the $CTDI_{vol}$ would have allowed easier reclassification of scans and would also allow comparison of scans of different lengths.

At present, ARPANSA is not undertaking an ongoing data collection program for nuclear medicine. This leaves facilities to their own devices when proving regulatory compliance with RPS 14. The NDRLS MDCT survey has been operating online since 2011, and it would be beneficial to the nuclear medicine community for there to be a similar system for nuclear medicine DRLs. Having an ongoing collection program would also allow for trends in nuclear medicine to be tracked and would offer the ability to assess the suitability of the current DRLs. This would be particularly useful for the CT component, as there has been no verification that the reclassification of scans has not had unintended consequences.

7. Conclusion

Australian DRLs have been issued for nuclear medicine, incorporating general nuclear medicine, PET, SPECT/CT and PET/CT. All reference levels have been set based on the response to wide scale surveys, either the NDRLS nuclear medicine survey conducted in 2014/15 or the ANZSNM survey of 2008.

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