Diagnostic Reference Levels

Based on Latest Surveys in Japan

—Japan DRLs 2015—

Japan Association on Radiological Protection in Medicine
Japan Association of Radiological Technologists
Japan Network for Research and Information on Medical Exposure
Japan Radiological Society
Japan Society of Medical Physics
Japanese Radiation Research Society
Japanese Society for Oral and Maxillofacial Radiology
Japanese Society of Nuclear Medicine
Japanese Society of Nuclear Medicine Technology
Japanese Society of Pediatric Radiology
Japanese Society of Radiological Technology

In collaboration with

The Japan Medical Imaging and Radiological Systems Industries Association and the National Institute of Radiological Sciences

Preface

In recent years, concern regarding the effects of radiation exposure in medical care has increased with the rapidly expanding use of medical radiation. Patients exposed to radiation in diagnosis or treatment gain clear benefits because the proper use of radiation can help overcome potentially life-threatening diseases; therefore, the application of radiological procedures should be judged on a case-by-case basis rather than by applying uniform standards, such as dose limits. However, in actual practice, the top priority is to solve the health problems of the patient, and it is not always easy to optimally minimise the risks of harmful effects that may occur in the future as a result of radiation exposure.

To cope with the growing issue of medical exposure, international organisations, such as the United Nations Scientific Committee on the Effects of Atomic Radiation, International Commission on Radiological Protection, International Atomic Energy Agency and World Health Organization, have cooperated to achieve evidence-based protection from medical radiation. One such measure is the application of diagnostic reference levels (DRLs) to optimise protection. Currently, the establishment of DRLs is an international requirement for protection from medical radiation.

Japan is facing a unique situation; the use of radiological examinations is rapidly increasing, whereas societal concern regarding the potential adverse radiation effects on human health is extremely high. Accordingly, protective measures should be implemented as rapidly as possible. To this end, cooperation between academic societies and organisations is required to concentrate the professional expertise of many experts, to collect and share information on medical radiation exposure from within and outside of Japan and to establish a framework for protection from medical exposure that fulfils the needs of the Japanese people. To conduct such activities, the Japan Network for Research and Information on Medical Exposures (J-RIME) was established in 2010 with the cooperation of related academic societies.

The purpose of the J-RIME is to collect data related to medical exposure (i.e. radiation dose and risks received by radiological procedures), to address the actual state of medical exposure in Japan and to construct a framework within Japan for appropriate protection from medical exposure based on international trends. As of 2015, the J-RIME has functioned as a nationwide network with the participation of academic organisations of radiological sciences, including learned societies, universities, professional associations and medical facilities along with cooperation from administrative and related industrial organisations.

The J-RIME has established the first DRLs in Japan as a result of discussions with various experts, including physicians, radiological technologists and medical physicists, based on the results of the latest nationwide surveys conducted by liaison organisations of the J-RIME and

the advice from experts belonging to international bodies. This report for DRLs, called Japan DRLs 2015, was approved for publication by the J-RIME and its liaison organisations in June 2015. The J-RIME will promote better understanding, expanded use and deeper permeation of DRLs in medical settings while offering advice regarding expanding target modalities, infrastructure development for the review of DRLs at certain intervals and incorporation into domestic regulation systems.

Finally, I extend my heartfelt gratitude to all related individuals and parties for the time and effort devoted to the dose surveys and preparation of this Report.

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1. Background of Establishment of Diagnostic Reference Levels

International guidelines, such as the recommendations and guidance published by the International Commission on Radiological Protection (ICRP) and International Basic Safety Standards published by the International Atomic Energy Agency (IAEA), state that diagnostic reference levels (DRLs) are important tools for optimisation of image quality and the radiation dose delivered to patients in diagnostic fields. The approach to establish DRLs includes not only setting radiation dose levels but also determining dose quantities and units used to set DRLs, standardising methodology for dose measurements, collecting data and determining the application methods of DRLs. These processes are closely related to quality control of equipment and protocol. Thus, DRLs are important in the optimisation process.

Overseas, the European Union (EU) issued the Council Directive 97/43/Euratom (June 1997), which required all member states to establish DRLs for controlling diagnostic radiation, and DRLs have subsequently been introduced in each country of EU. In the United States, DRLs presented by organisations such as the American College of Radiology (ACR), American Association of Physicists in Medicine (AAPM) and National Council on Radiation Protection and Measurements (NCRP) have been adopted as actual standards.

In Japan, various societies, researchers and organisations, including the J-RIME liaison organisations, have performed the radiation dose surveys associated with imaging examinations and have independently proposed values as reference dose levels. However, these activities have not been performed with sufficient cooperation among all organisations concerned with the scientific and related aspects of medical radiation protection; thus, no 'Japan DRLs' have been widely recognised or actually implemented in medical care settings in Japan.

In March 2010, the J-RIME was established to enable related organisations to coordinate and share research information related to medical exposure. Among the activities of the J-RIME, a DRL working group (DRL-WG), comprising members recommended by each the J-RIME liaison organisation, was established in August 2014 to first establish Japan DRLs. Following a collaboration of liaison organisations on a single platform and detailed discussions on dose quantities and units used to set DRLs and survey design, some liaison organisations performed large-scale nationwide surveys. Committee members of DRL-WG discussed all survey data available from liaison organisations in consideration of comments from experts within and outside of Japan. All activities for establishing DRLs were performed with transparency and objectivity; this was required for accepting the proposed Japan DRLs 2015 as reasonable standards and supporting their wide use throughout Japan.

2. Purpose of Establishing Diagnostic Reference Levels

2.1 Features of Diagnostic Reference Levels

ICRP defines DRLs as 'a form of investigation level, applied to an easily measured quantity, usually the absorbed dose in air or tissue-equivalent material at the surface of a simple standard phantom or a representative patient'.[1] This definition strongly emphasises that DRLs are not dose limits and do not help distinguish between good and poor medical practice.[2] Although dose limits must not be exceeded, DRLs may be exceeded if clinically necessary.[1] DRLs also differ from dose limits for occupational exposure because they are not used to constrain individual patient exposures; this is because a dose higher than the standard dose may be required depending on the patient's body size and weight. DRLs are a tool for identifying facilities with unusually high doses and for promoting the optimisation process. Separate DRLs have been established for each country and/or region because equipment and procedure protocols can vary between different facilities in countries or regions. DRLs are set for patients with standard sizes or for standard phantoms in easily measurable and highly reproducible dose metrics; they should not be set as effective doses.[2] Image quality is considered when setting DRLs.

When setting DRLs, dose measurements are first performed using a previously standardised method for each type of radiation examination. DRLs are generally set as the 75th percentile of the typical dose distribution for a patient or phantom measurement. However, this does not necessarily apply to examinations with narrower dose distributions because of the effect of optimisation.

DRLs that have been established in certain countries or regions are also periodically reviewed in accordance with changes in clinical practice and equipment. The Japan DRLs 2015 also should be reviewed at certain time intervals in response to changes in the state of radiation-based medical care and to advances in devices or methods. Accordingly, periodical collection of data regarding diagnostic radiology doses throughout Japan will be needed, and technological progress for these dose surveys are being promoted. Currently, the use of DICOM (PS3.16)-standardised Radiation Dose Structured Reports for electronically gathering information related to medical exposure is being investigated using radiation diagnostic equipment.[4-7]

In addition to DRLs, achievable dose (AD) and diagnostic reference range (DRR) are also tools for optimisation of patient protection. ADs are set at approximately 50th percentile of the dose distribution. DRLs will provide incentives for optimisation for the 25% of facilities that use dose over the DRLs for a particular examination. Then, NCRP recommends the use of ADs to encourage optimisation for the 75% of facilities that already use dose within the current DRLs.[3] The use of DRRs has also been proposed as a useful approach for quality improvement. DRR can indicate investigation or action levels ranging from the lower value, below which reduced image quality may not be diagnostic, to the upper values, above which the dose may be in excess.[8]

2.2 Approaches for Use of Diagnostic Reference Levels in Medical Settings

When the typical dose used at a facility exceeds DRLs without clinical needs, a review should be performed to determine whether the dose has been optimised. In general, the equipment performance and protocols (procedures) are investigated, the reason for higher doses is found and optimisation actions are implemented. After implementing such measures, the typical dose at the facility is again evaluated to ensure that it is below DRL. NCRP recommends that protocols and practice be periodically reviewed (e.g. at least annually) to ensure that the protocols and techniques have not inadvertently changed periodically.[3] Protocols for new equipment should be initially assessed before the equipment is used for patient examinations and reassessed after a longer (i.e. at 3–6 months) experience has been obtained.[3] During all these steps, the need for adequate image quality, but not the highest image quality, should be considered.

The purpose of DRLs is not dose reduction but optimisation. If a justified examination does not provide the necessary clinical information because of too low dose resulting in an inadequate image quality, then the patient has been exposed needlessly to radiation. In practice, it is assumed that the necessary dosage, including to the margins, will be used.

In medical settings, it is necessary to first compare an institution's doses with DRLs in the optimisation process. However, in medical settings where a dosimeter is not available, the dose comparison may be difficult. A possible countermeasure for this problem is the use of values calculated using Non Dosimeter Dosimetry[9] or conventional software for calculating radiation exposure dose or values displayed on equipment as a substitute. In addition, systems should be constructed in which dosimeters or phantoms owned by the affiliated organisation or other facility can be used.

DRLs may also be used for international comparisons.[10] DRLs based on standard phantoms can be compared with those of other countries. However, when considering DRLs based on 'standard' patients, caution is necessary, because the sizes of Western and Japanese patients clearly differ.

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3. National Diagnostic Reference Levels Established in 2015 (Japan DRLs 2015)

The following are recommended as national DRLs in Japan.

3.1 Japan DRLs 2015 for Computed Tomography

3.1.1 Japan DRLs 2015 for Adult Computed Tomography

	$CTDI_{vol}$ (mGy)	DLP (mGy·cm)
Routine brain	85	1350
Routine chest	15	550
Chest to pelvis	18	1300
Abdomen to pelvis CT	20	1000
Liver, multi-phase	15	1800
Coronary CTA	90	1400

1) Standard patient weight: 50–60 kg or 50–70 kg for coronary CTA.
2) Liver, multiphase does not include the chest region or pelvis.

3.1.2 Japan DRLs 2015 for Paediatric Computed Tomography

	Younger than 1 year		1–5 years		6–10 years	
	$CTDI_{vol}$ (mGy)	DLP (mGy·cm)	$CTDI_{vol}$ (mGy)	DLP (mGy·cm)	$CTDI_{vol}$ (mGy)	DLP (mGy·cm)
Head CT	38	500	47	660	60	850
Chest CT	11 (5.5)	210 (105)	14 (7)	300 (150)	15 (7.5)	410 (205)
Abdomen CT	11 (5.5)	220 (110)	16 (8)	400 (200)	17 (8.5)	530 (265)

1) Values for a 16-cm diameter phantom along with values for a 32-cm diameter phantom in parentheses.

3.2 Japan DRLs 2015 for General Radiography

Examinations	Entrance surface dose (mGy)	Examinations	Entrance surface dose (mGy)
Skull	3.0	Pelvis	3.0
Lateral of the skull	2.0	Femur	2.0
Cervical spine	0.9	Ankle joint	0.2
Thoracic spine	3.0	Forearm	0.2
Lateral of the thoracic spine	6.0	Guthmann[a]	6.0
Chest P→A	0.3	Martius[b]	7.0
Abdomen	3.0	Infant chest	0.2
Lumbar spine	4.0	Child chest	0.2
Lateral of the lumbar spine	11.0	Infant hip joint	0.2

a) Lateral pelviography for pregnant women
b) Superior–interior pelviography for pregnant women

3.3 Japan DRL 2015 for Mammography

- Mean glandular dose: 2.4 mGy (95th percentiles)

3.4 Japan DRLs 2015 for Dental Intraoral Radiography

*Standard intraoral radiography using the bisecting or paralleling technique was subject to this survey. Bitewing radiography, occlusal radiography (bisecting technique and axial projection technique) and others were not included.

Examination site	PED (mGy)[a]	
	Adult[b]	Child[c]
Maxilla		
Incisor	1.3	0.9
Canine	1.6	1.0
Premolar	1.7	1.1
Molar	2.3	1.3
Mandible		
Incisor	1.1	0.7
Canine	1.1	0.9
Premolar	1.2	0.9
Molar	1.8	1.1

a) Patient entrance dose (PED) is the air kerma in cone-tip free air not including the patient's backscattering.
b) Adult patient with standard size
c) Ten-year-old paediatric patient

3.5 Japan DRL 2015 for Fluoroscopically Guided Interventional Procedures

- Fluoroscopic radiation dose rate: 20 mGy/min (interventional reference point dose rate)

3.6 Japan DRLs 2015 for Nuclear Medicine

Diagnostic Nuclear Medicine	DRLs (MBq)[a]
Bone: ^{99m}Tc-MDP	950
Bone: ^{99m}Tc-HMDP	950
Bone marrow: ^{111}In-Cl	120
Cerebral blood flow: ^{99m}Tc-HM-PAO (rest or stress)	800
Cerebral blood flow: ^{99m}Tc-HM-PAO (rest and stress)	1200
Cerebral blood flow: ^{99m}Tc-ECD (rest or stress)	800
Cerebral blood flow: ^{99m}Tc-ECD (rest and stress)	1100
Cerebral blood flow: ^{123}I-IMP (rest or stress)	200
Cerebral blood flow: ^{123}I-IMP (rest and stress)	300
Cerebral blood flow: Iomazenil (^{123}I)	200
Dopamine transporter: Ioflupane (^{123}I)	190
Cisternography: ^{111}In-DTPA	70
Thyroid imaging: ^{123}I-NaI	10
Thyroid imaging: ^{99m}Tc-pertechnetate	300
Parathyroid : ^{201}Tl-Cl	120
Parathyroid : ^{99m}Tc-pertechnetate	300
Parathyroid : ^{99m}Tc-MIBI	800
Lung ventilation: ^{81m}Kr-gas	200
Lung ventilation: ^{133}Xe-gas	480
Lung perfusion: ^{99m}Tc-MAA	260
Venography: ^{99m}Tc-MAA	500
Liver and spleen: ^{99m}Tc-phytate	200
Liver function: ^{99m}Tc-GSA	260
Hepatobiliary: ^{99m}Tc-PMT	260
Liver and spleen: ^{99m}Tc-Sn colloid	180
Myocardial perfusion: ^{201}Tl-Cl	180
Myocardial perfusion ^{99m}Tc-tetrofosmin (rest or stress)	900
Myocardial perfusion: ^{99m}Tc-tetrofosmin (rest and stress)	1200
Myocardial perfusion: ^{99m}Tc-MIBI (rest or stress)	900
Myocardial perfusion: ^{99m}Tc-MIBI (rest and stress)	1200
Myocardial fatty acid metabolism: ^{123}I-BMIPP	130
Cardiac sympathetic nerve imaging: ^{123}I-MIBG	130
Cardiac blood pool: ^{99m}Tc-HSA	1000
Cardiac blood pool: ^{99m}Tc-HSA-D	1000

Myocardial infarction: ^{99m}Tc-PYP	800
Salivary gland: ^{99m}Tc-pertechnetate	370
Meckel's diverticulum: ^{99m}Tc-pertechnetate	500
Gastrointestinal bleeding: ^{99m}Tc-HSA-D	1040
Renal imaging (static): ^{99m}Tc-DMSA	210
Renal imaging (dynamic): ^{99m}Tc-MAG3	400
Renal imaging (dynamic): ^{99m}Tc-DTPA	400
Adrenal cortex: ^{131}I-Adosterol	44
Adrenal medulla: ^{131}I-MIBG	45
Adrenal medulla ^{123}I-MIBG	130
Tumour: ^{201}Tl-Cl	180
Tumour and inflammation: ^{67}Ga-citrate	200
Lymphatic system: ^{99m}Tc-HSA-D (not covered with health insurance)	950
Sentinel lymph node: ^{99m}Tc-Sn colloid	120
Sentinel lymph node: ^{99m}Tc-phytate	120
RI angiography: ^{99m}Tc-HSA-D	1000
Tumour: ^{18}F-FDG (in-house-produced)	240
Tumour : ^{18}F-FDG (delivery)	240
Brain : ^{18}F-FDG (in-house-produced)	240
Brain: ^{18}F-FDG (delivery)	240
^{15}O-CO$_2$ gas: 2D	8000
^{15}O-O$_2$ gas: 2D	6000
^{15}O-CO gas: 2D	3000
^{15}O-CO$_2$ gas: 3D	2900
^{15}O-O$_2$ gas: 3D	7000
^{15}O-CO gas: 3D	7500
Myocardiac metabolism: ^{18}F-FDG (in-house-produced)	240
Myocardiac metabolism: ^{18}F-FDG (delivery)	240
Myocardiac perfusion: ^{13}N-NH3	720

a) Adult dosage (MBq)