



# National Patient Radiation Dose Registry

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- Diagnostic Reference Levels
- U.S. approaches to DRLs
- Radiation dose registries
- Existing registries
- FDA's role and goals



# Diagnostic Reference Levels



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# ICRP

## Annals of the ICRP

ICRP Publication 103

The 2007 Recommendations of the International  
Commission on Radiological Protection



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# ICRP

## Annals of the ICRP

ICRP Publication 105

Radiological Protection in Medicine





# Principles of Radiation Protection

- Justification
- Optimization of protection
- Dose limits



## **DIAGNOSTIC REFERENCE LEVELS IN MEDICAL IMAGING: REVIEW AND ADDITIONAL ADVICE**

*A web module produced by Committee 3 of the  
International Commission on Radiological Protection (ICRP)*

ICRP, 2003. Diagnostic reference levels in medical imaging: review and additional advice. ICRP online educational reference.

[http://www.icrp.org/docs/DRL\\_for\\_web.pdf](http://www.icrp.org/docs/DRL_for_web.pdf)

# Diagnostic Reference Levels (DRLs)

- A form of investigation level for medical imaging
- Objective: to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task

ICRP, 2003. Diagnostic reference levels in medical imaging: review and additional advice. ICRP online educational reference.

[http://www.icrp.org/docs/DRL\\_for\\_web.pdf](http://www.icrp.org/docs/DRL_for_web.pdf)

# DRL Values

- Tied to defined clinical and technical requirements for the medical imaging task
- Usually derived from distributions of dosimetric quantities *observed in practice* in the relevant region or country
- Benchmark—indicator of radiation dose for an average-sized patient; what is achievable with good practice
- Applicable to *groups* of patients





## **DIAGNOSTIC REFERENCE LEVELS IN MEDICAL IMAGING: REVIEW AND ADDITIONAL ADVICE**

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### **Key Points**

- **Diagnostic reference levels (DRLs) should be used by regional, national and local authorized bodies. The numerical values of DRLs are advisory, however, implementation of the DRL concept may be required by an authorized body.**

ICRP, 2003. Diagnostic reference levels in medical imaging: review and additional advice. ICRP online educational reference.

[http://www.icrp.org/docs/DRL\\_for\\_web.pdf](http://www.icrp.org/docs/DRL_for_web.pdf)

# DRL Values

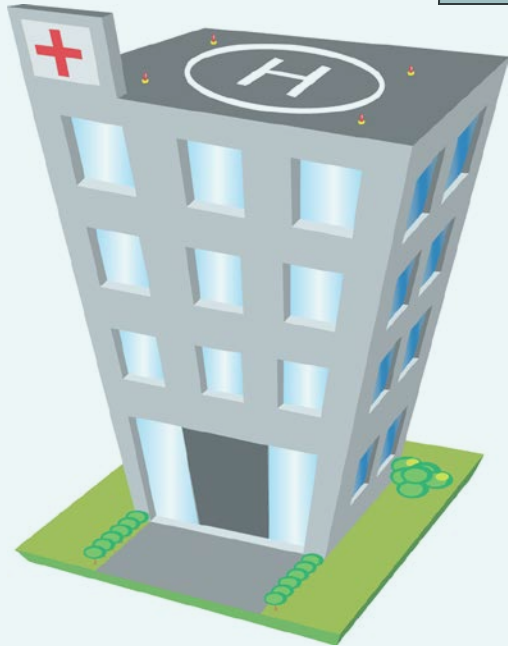
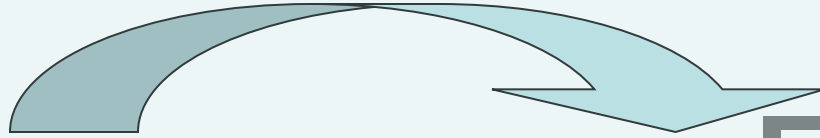
- Not applicable to individual patients
- Not dose constraints or dose limits
- Not regulatory
- Not sufficient by themselves
- *Optimizing radiation dose includes maintaining adequate image quality!*

# Diagnostic Reference Level

- 75<sup>th</sup> percentile of the dose data collected from a number of facilities for a specific examination
- Individual facilities review their mean dose
  - If  $>$  DRL, investigate equipment, protocols, operators
  - If  $<$  DRL, practice acceptable, not necessarily optimized
  - If  $\ll$  DRL, check image quality



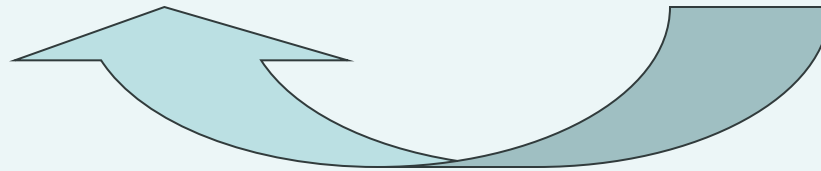
# Local Data



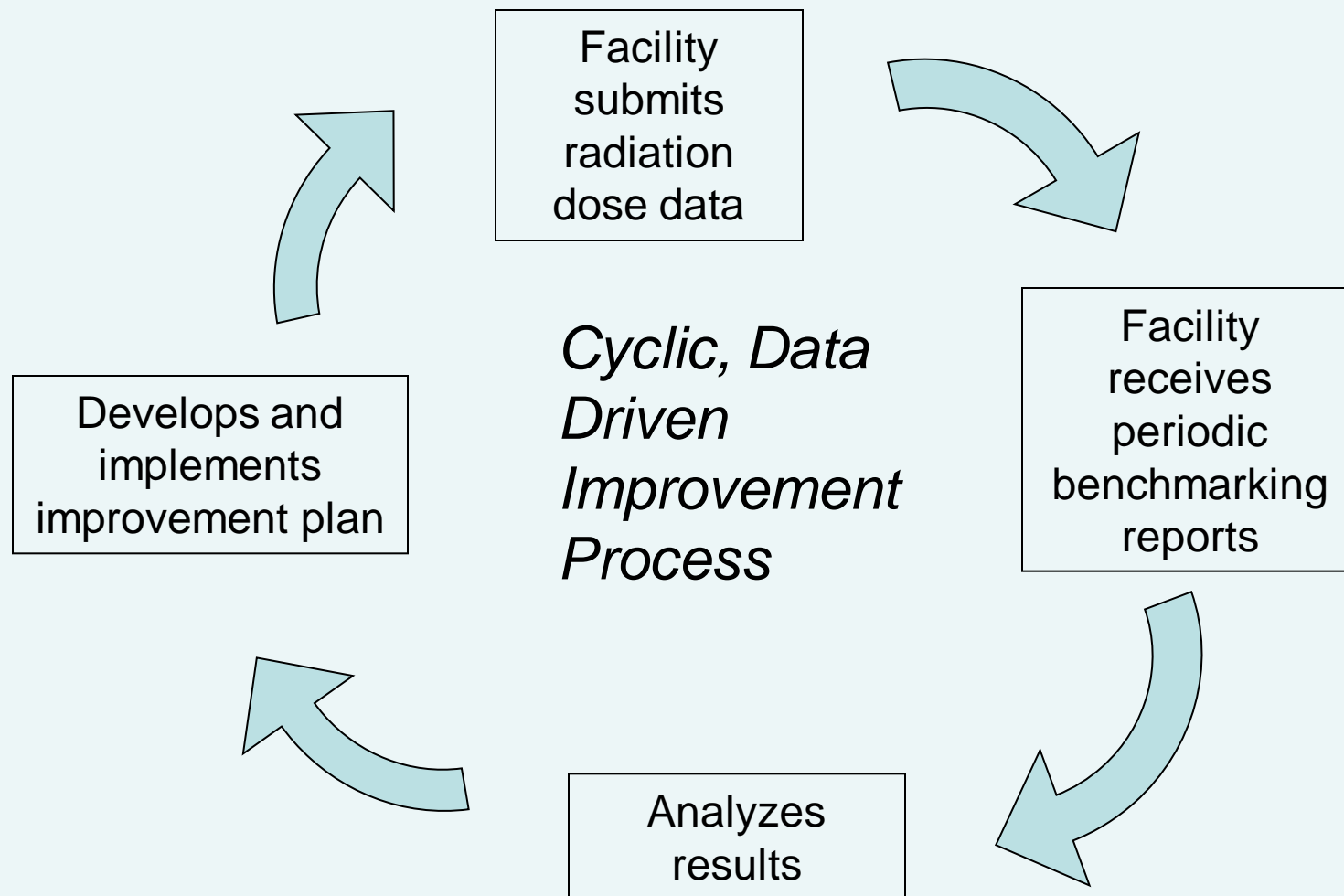
Local Facility

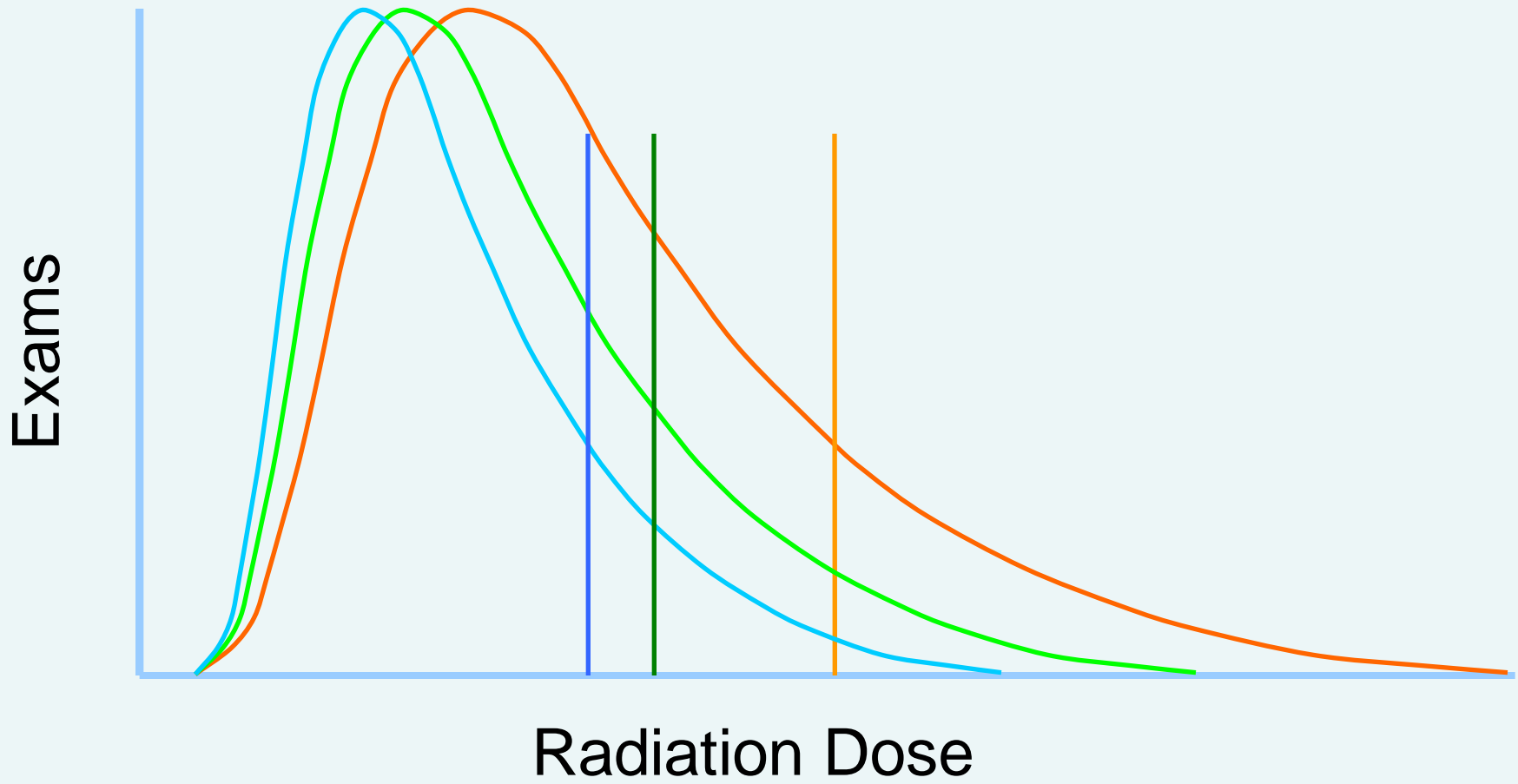


Central Facility



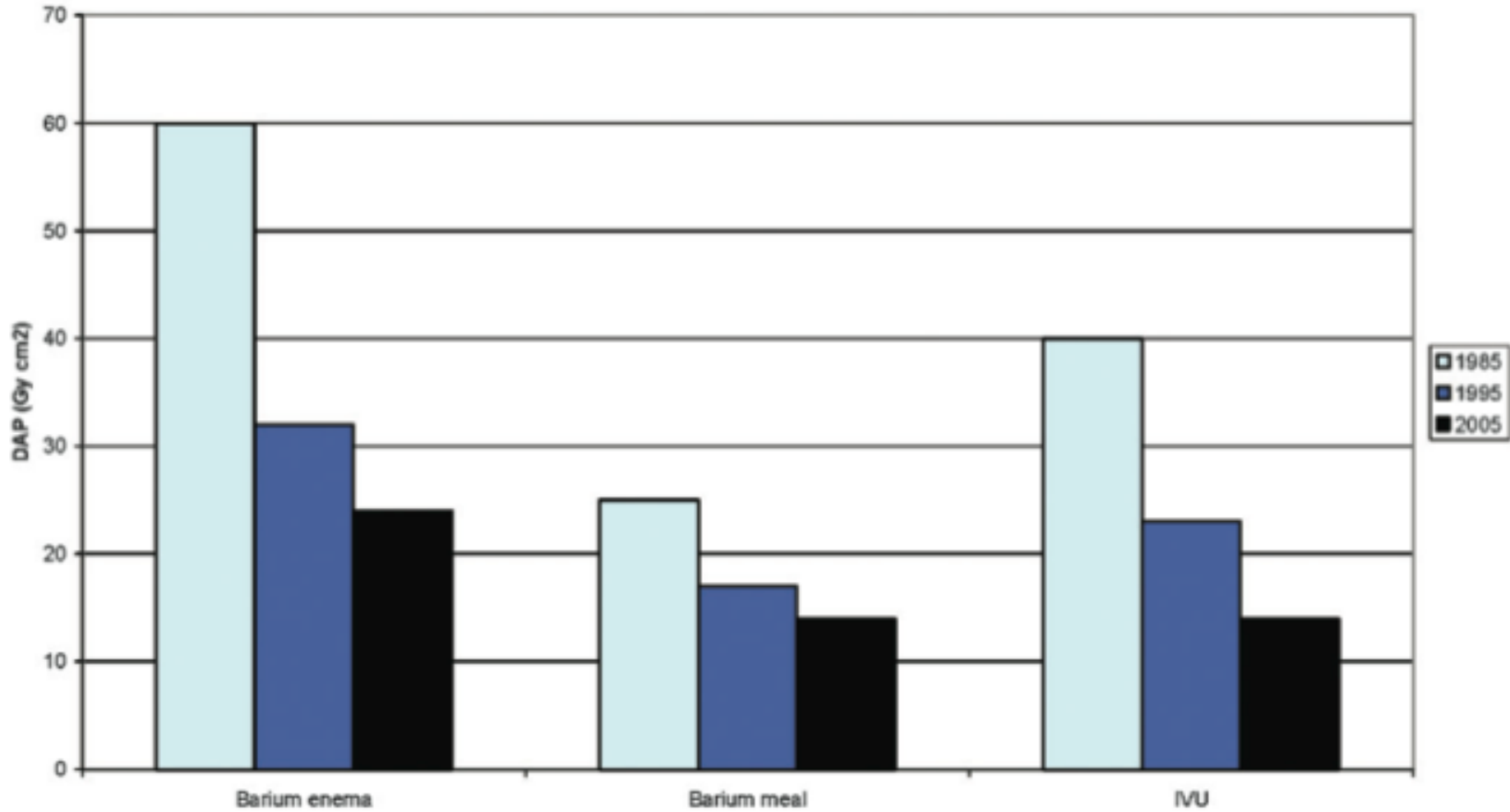
Local data/Comparison to DRL





# DRLs Work!

- UK: Recalculated every 5 years based on the results of national surveys
- 2000 DRLs
  - 20% lower than 1995 DRLs
  - $\approx$  half of mid-1980's DRLs
- Use of DRLs is *mandatory* in the EU
  - EU Council Directive 97/43/Euratom



**Figure 4.** Third quartiles for dose–area product (DAP) per examination. IVU, intravenous urography.



# Federal Guidance Report 14

- Recommendations for Agency actions:
  - For each type of examination, Federal facilities and agencies should promote the development of national reference levels for use as quality assurance and quality improvement tools.



# U.S. Approaches to DRLs

# NEXT

- Nationwide Evaluation of X-Ray Trends
- Since 1973; FDA/CRCPCD collaboration
- National surveys of representative samples of U.S. clinical facilities
- Comprehensive data on radiation exposure, image quality and QA practices for selected imaging examinations
- Increasingly infrequent

# NEXT Data in Action

- CRCPD patient exposure and dose guide (2003)
- NCRP Report No. 160 on U.S. population exposure (2009)
- NCRP Report No. 172 on reference levels (2012)
- Possible initial DRLs for interventional cardiology (2012)

NCRP REPORT No. 172

**REFERENCE LEVELS  
AND ACHIEVABLE  
DOSES IN MEDICAL  
AND DENTAL IMAGING:  
RECOMMENDATIONS  
FOR THE UNITED STATES**



- Published 2012
- Much of the data from NEXT surveys
- All NEXT data are pre-2005



## Patient radiation doses in interventional cardiology in the U.S.: Advisory data sets and possible initial values for U.S. reference levels

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(Received 18 July 2012; revised 30 August 2012; accepted for publication 4 September 2012; published 27 September 2012)

**Purpose:** To determine patient radiation doses from interventional cardiology procedures in the U.S and to suggest possible initial values for U.S. benchmarks for patient radiation dose from selected interventional cardiology procedures [fluoroscopically guided diagnostic cardiac catheterization and percutaneous coronary intervention (PCI)].

- Published 2012
- Data from 2008-2009 NEXT survey



Where are we going to get  
new data?



# Radiation Dose Registries



# What is a Dose Registry?

- Information system
  - Collect and compare patient radiation dose data across facilities
- Standard methods of data collection
  - DICOM RDSR, IHE REM profile
- May or may not collect protected health information (PHI)

# Imaging Modalities

- CT
- Nuclear medicine
- Fluoroscopy
- Radiography

# Uses

- **Justification**
  - Has the proposed study already been done?
- **Optimization of protection**
  - Establishment of diagnostic reference levels
- **Individual risk assessment**
  - Communication of an estimate of stochastic risk for an individual patient
- **Research**
  - Utilization, collective population dose, epidemiologic studies, etc.



Purpose	PHI?	Facility data?	Dose data?
Justification	Yes	Yes	No
Optimization	No	Yes	Yes
Risk Assessment	Yes	No	Yes
Research	Ideally	Ideally	Yes

# Recording Patient Radiation Dose

- National Quality Forum Measure #0510—  
Exposure Time Reporting for Procedures Using  
Fluoroscopy (AMA Physician Consortium for  
Performance Improvement)
- National Quality Forum Measure #0739—  
Radiation Dose of Computed Tomography (CT)  
(UCSF)
- CMS Physician Quality Reporting System  
#145—Exposure Time Reporting for Procedures  
Using Fluoroscopy

# Radiation Dose Registry

- National Quality Forum Measure #0470—  
Participation in a systematic national dose index registry (American College of Radiology)
- CMS Physician Quality Reporting System (for 2014)—  
Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry (for CT)

# Federal Guidance Report 14

- Summary and recommendations for facility action:
  - Facilities should use reference levels as a quality improvement tool by collecting and assessing radiation dose data. Each facility should also submit its radiation dose data to a national registry, if and when such a registry is available

# Why a National Dose Registry?

- Accurate and objective data on patient radiation dose on a national basis
- Determine and disseminate national benchmarks (DRLs) for patient radiation dose
- Help individual facilities:
  - Compare to similar facilities across the U.S.
  - Target specific areas for improvement





# **A national patient radiation dose registry**

is an *infrastructure prerequisite* for

# **National diagnostic reference levels**



# Federal Guidance Report 14

## Reference Level Recommendation 2:

- National reference levels that are specific for the U.S. population should continue to be developed.



# Existing Registries

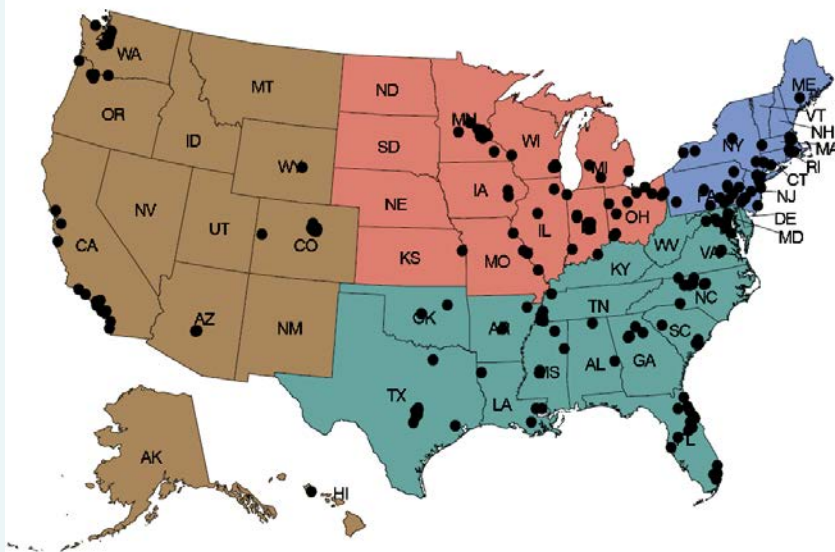
# Examples

- National Cardiovascular Data Registry (NCDR)  
IMPACT Registry
  - American College of Cardiology
  - Fluoroscopy time for certain cardiac interventional fluoroscopy procedures (other dose metrics and IF cardiology procedures to be added)
- Dose Index Registry (DIR)
  - American College of Radiology
  - Radiation dose data for CT (other imaging modalities to be added)

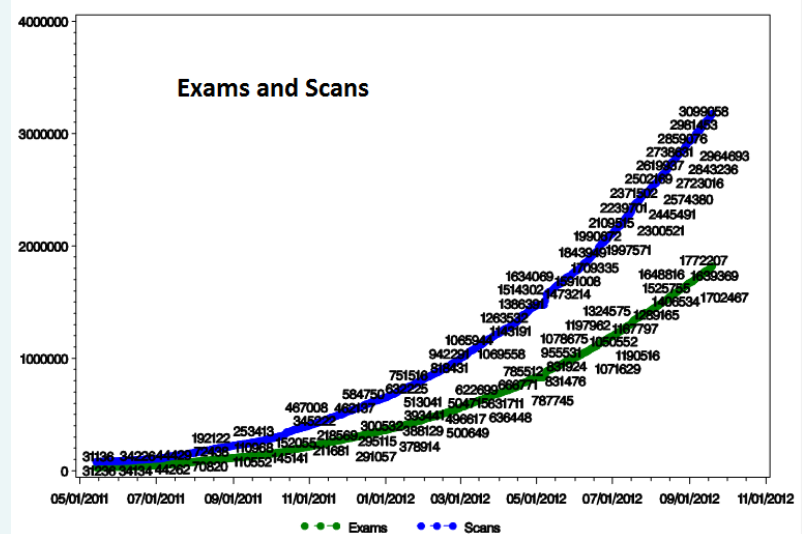
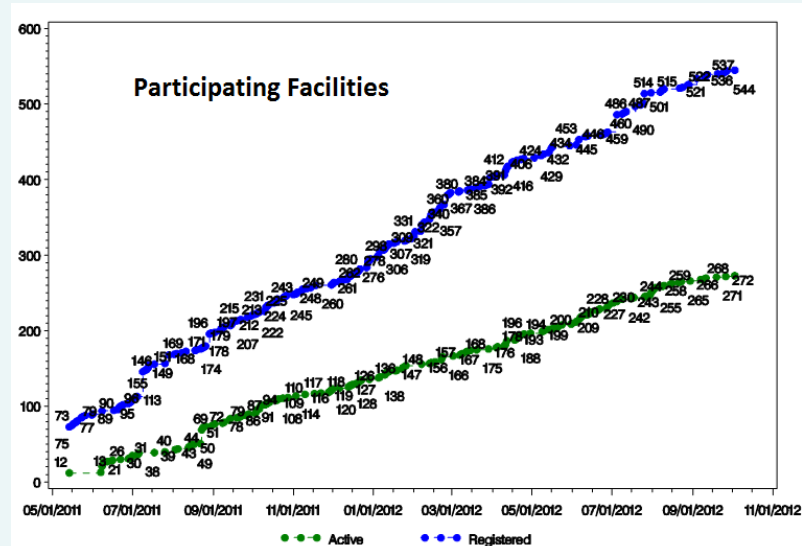
# DIR Status

- Launched in May 2011
- 544 facilities registered across the US; 272 contributing data
- Over 1.7 million exams
- Over 3 million scans

DIR Facilities  
January - June 2012



## June 2012





Scanner



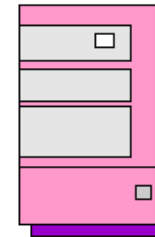
DICOM SR



TRIAD Site Server



Anonymized  
DICOM SR



DIR Database

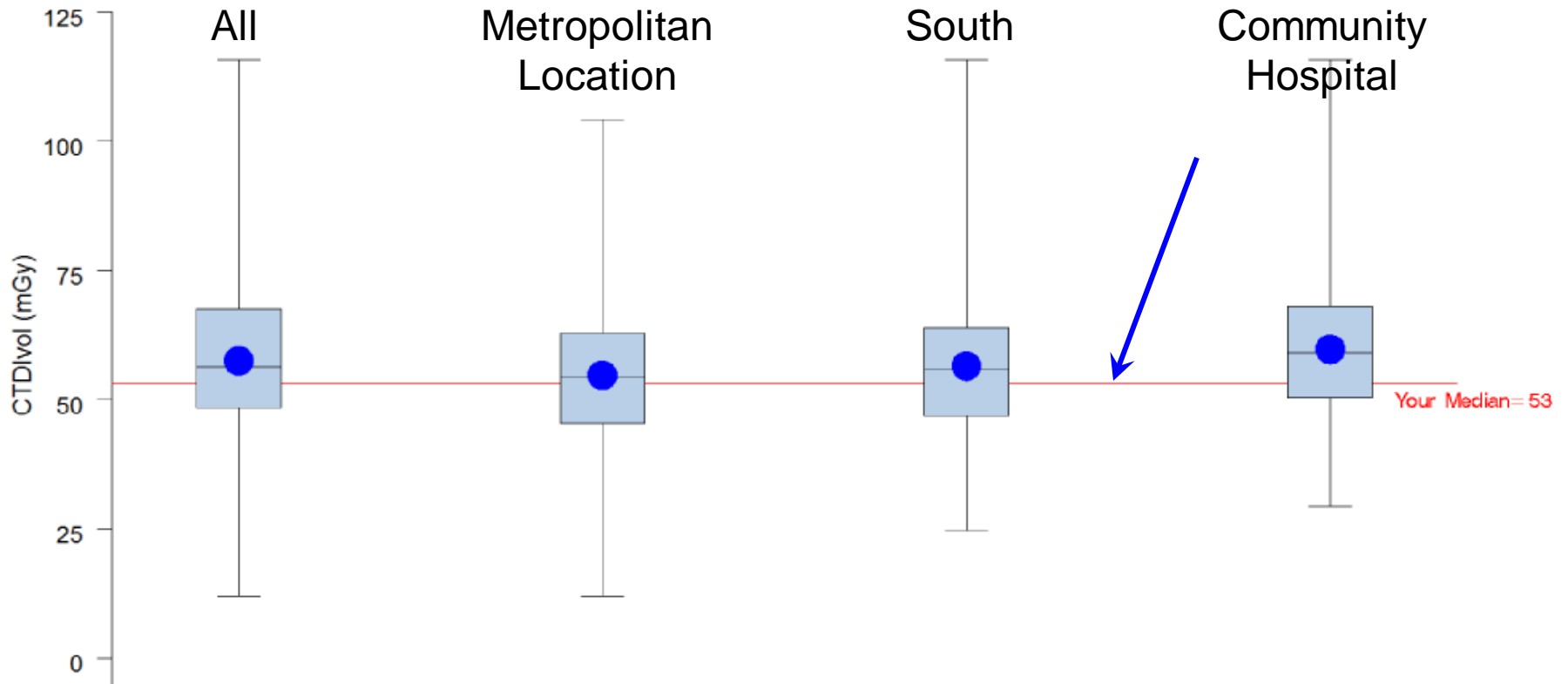


NRDR



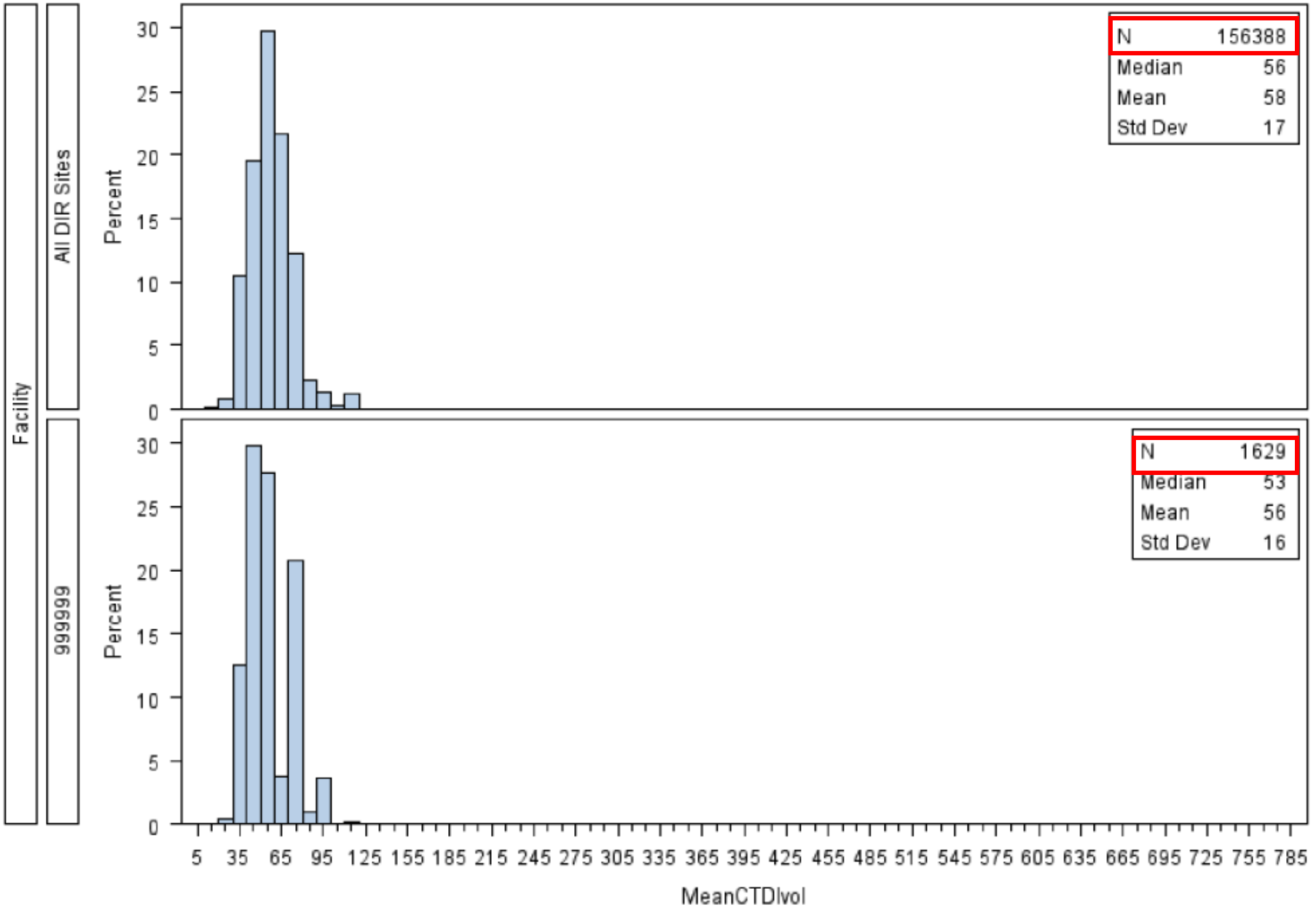
Feedback Reports

# Median CT HEAD BRN WO IVCON CTDIvol Per Scan



Summary Stats for Facility Median Value				
	DIR	Metropolitan Location	South Region	Community hospital
# of facilities	206	107	80	85
Median (mGy)	56	54	56	59
Mean (mGy)	58	55	57	60
Min (mGy)	12	12	25	29
Max (mGy)	116	104	116	116

# CT HEAD BRN WO IVCON CTDIvol Per Scan







# Mapping to RadLex Playbook

<b>RPID</b>	<b>Playbook Term</b>	<b>Scanner A and B</b>	<b>Scanner C</b>
RPID149051	CT ABD/PEL WO IVCON	CT ABD+PELVIS WO/CST	CT ABDOMEN & PELVIS WO IVC
RPID149050	CT ABD/PEL W IVCON	CT ABD + PELVIS W/CST	CT ABDOMEN & PELVIS W/IVC



# FDA's Role and Goals



## 21 USC 360ii

FDA has authority to:

Plan, conduct, coordinate, and support research, development, training and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation

# Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging



**Education and Communication**



**Appropriate Use**



**Facility Guidelines and Personnel Qualifications**



**Equipment Safety**



**Tracking Radiation Safety Metrics**



# **Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging**

February 2010

Center for Devices and Radiological Health

U.S. Food and Drug Administration



# Initiative Goal 2.1

- Goal: Requirements for CT and fluoroscopic device capability to record radiation dose information for use in patient medical records or a radiation dose registry.
- Radiation Dose Structured Report (RDSR)
  - Joint effort of industry, FDA, professional organizations
  - DICOM object that provides a format for automatic transmission of radiation-related data from the device
  - Implemented for CT, fluoroscopy, radiography

<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm>

# Initiative Goal 1.3

- Goal: The healthcare professional community, in collaboration with FDA, should continue efforts to develop DRLs for CT, fluoroscopy, and nuclear medicine procedures locally and also through a national radiation dose registry.
- National radiation dose registry
- National diagnostic reference levels

# Guiding Principles

- Registry participants should include all facilities where medical imaging using ionizing radiation is performed (e.g., medical offices, dental offices, chiropractors)
- Facilities should be able to participate at minimal or no cost



# Guiding Principles

- Aggregated data should be publicly and freely available
- Raw data should be accessible to researchers (with appropriate safeguards)



# Summary

# Summary

- A national radiation dose registry
  - Supports optimization of protection
  - Is a prerequisite for national DRLs
- Regulators, accreditation organizations and professional organizations cannot require either participation in dose registries or use of DRLs unless they exist
- Professional societies have demonstrated that dose registries are feasible

# Summary

- FGR 14 recommends use of national DRLs and submission of data to a national radiation dose registry
- Support for a national dose registry is consistent with the Federal public health mission
- Goals include universal participation and maximum possible dissemination of data
- Adequate image quality must be maintained



# Thank You!

Questions?

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