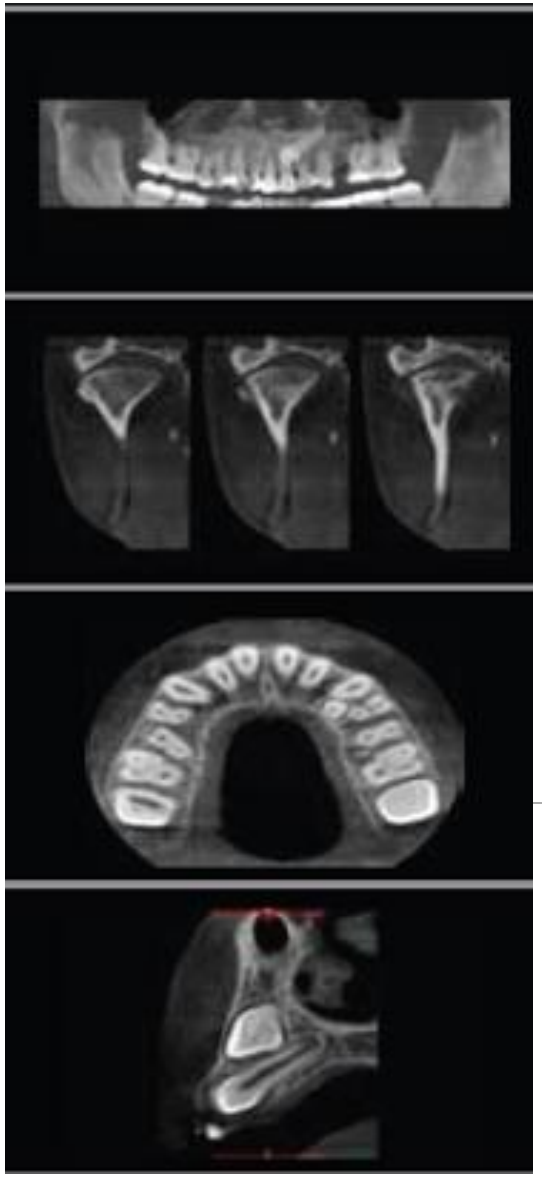


Dental Cone Beam CT Regulatory and Accreditation

ROBERT PIZZUTIELLO, FACR, FAAPM, FACMP
PRES., INSTRUMENT FO

Outline

Regulatory perspective

IAC – history and QC expectations, CBCT

Dental Cone-beam Computed Tomography

Medical X-ray In

Radiography

Computed Tom

Dental Cone-b
Tomography

Information for Industry

Dental CBCT systems are medical devices that are also radiation-emitting electronic products. The FDA regulates manufacturers of dental CBCT devices through the Electronic Product Radiation Control (EPRC) and medical device provisions of the Federal Food, Drug, and Cosmetic Act. Dental CBCT systems are classified under 21 CFR 892.1750.

For more information on bringing an X-ray imaging system to market and for post-market requirements see:

- Getting a Radiation Emitting Product to Market
- Device Advice: Complementary Regulatory Assistance
- Post-market Requirements (Devices)

FDA's webpages on Computed Tomography and Medical X-Rays provide mo
lists of industry resources relevant to dental CBCT systems.

t as of:

luct(s)
ıg Products

https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/dental-cone-beam-computed-tom

FDA – Information for Indutry

- Dental CBCT systems are medical devices that are also radiation-emitting electronic products.
- The FDA regulates manufacturers of dental CBCT devices through the Electronic Product Radiation Control (EPRC) and medical device provisions of the Federal Food, Drug, and Cosmetic Act.
- Dental CBCT systems are classified [as CT Scanners] under 21 CFR 892.1750.

https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/

CFR 1020.33

FDA regulates manufacturers

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER J--RADIOLOGICAL HEALTH

PART 1020 -- PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec. 1020.33 Computed tomography (CT) equipment.

(a) *Applicability.* (1) The provisions of this section, except for paragraphs (b), (c)(1), and (c)(2) are applicable as specified herein to CT x-ray systems manufactured or remanufactured on or after September 3, 1985.

(2) The provisions of paragraphs (b), (c)(1), and (c)(2) are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSear

(d) **Quality assurance.** The manufacturer of any CT x-ray system shall provide the following with each system. All information required by this subsection shall be provided in a separate section of the user's instructional manual.

(1) **A phantom(s)** capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

(2) Instructions on the use of the phantom(s) including a schedule of testing appropriate for the system **variations for the indicated parameters**, and store as records, quality assurance data.

Effective Date: 01/20/2016
NYCRR 16. 59 - Use of CT Equipment
16.59 Use of Computed Tomography Equipment

(4) If the QC testing on the CT x-ray system identifies that a system operating para r has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients shall be limited to those exceptions permitted by establish structions of the licensed medical physicist or radiologist. Upon completion of corrective action, the QC testing shall be repeated to verify that the system is back

(5) Commencing one (1) year after the effective date of these forming CT scans on human beings shall ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the d d recorded. The dose delivered shall be recorded as Computed Tomography Dose Index volume ($CTDI_{vol}$), dose length product (DLP) eer reviewed scientific literature and acceptable to the Department. The dose received by a patient shall be recorded as organ dose c eer reviewed scientific literature and acceptable to the Department.

(6) The displayed dose shall be verified on an annual bas medical physicist to ensure that the equipment manufacturer's displayed dose is within 20% of the measured dose.

(7) Eighteen months after the effective date of these regulatio gnostic CT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the Depa their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the Departm tions new licensees or registrants will have 18 months to become accredited, but must demonstrate that they have initiated the accre of operations.

(8) Each registrant that performs CT scans on human beings shall est a procedure to ensure that:

(i) a request for a CT scan originates from a physician or other authoriz tioner familiar with the patient's clinical condition; and

(ii) the request includes sufficient information to demonstrate the medical on for the CT examination and allow for the proper performance and interpretation of the CT scan.

Dental CBCT exempt at this time

(7) "…shall be accredited by a nationally re
accreditation program that is acceptable
Department…"

CBCT Regulatory Attention is coming…

CRCPD H-44 Task Force on CBCT Charge:

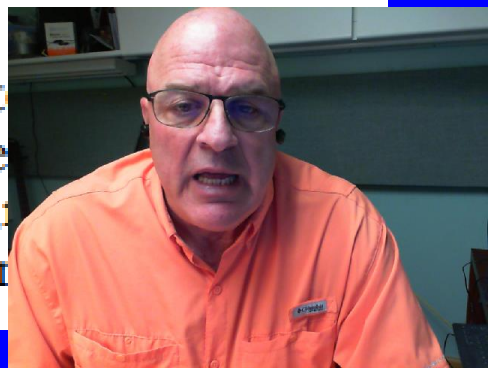
1. Develop and publish a "white paper" that would be helpful to radiation regulatory programs on diagnostic X-ray Cone Beam Computed Tomography (CBCT) used in dental and medical facilities, that describes the general principal of how the unit works, quality control tests and shielding requirements.

Survey of 50 state programs

- 24 states responded
- Survey Monkey
- NY, NJ, PA, CT, MA, etc.

- How does your state register CBCT units?
  - Eight states consider CBCT in the same category as conventional CT.
  - Seven states classify CBCT as standard radiographic machines. Four of these states classify CBCT according to machine use and register them as dental machines.
  - One state classifies machines as CBCT stationary, mobile, non-hospital, hospital, dental, medical, or veterinary.
  - One state registers CBCT as dental machines for strictly registration fee purposes.
  - Arkansas CBCT machines are regulated under the State Dental Board.

- Does your state currently have written guidance for CBCT?
  - Two participating states had written guidance.
  - Four states have begun the process of developing written guidance.
- Does your state require a physicist survey of CBCT units?
  - Ten states require a physicist survey.
    - Six states require acceptance testing.
    - Seven states require annual physics t
    - Two states require biennial physics te
  - One additional state requires a physicist su assemblies and at least biennially thereafte



BRP-XR-22

Cone Beam Computed Tomography Inspection

Facility **Registration**

Inspector **Date**

Unit Number | Tube Serial Number

Location/Room/Suite | Console Serial Number

Control Manufacturer | Manufacture Date

Control Model | Installation Date

Facility Type | Warning Label on Control Y N | Images per Month

Certified Y N | Physics Evaluation Y N | Physics Date

Operator Protection Y N | Beam Size Sat Y N

Modalities Available CBCT Pan Ceph Intra Occlusial

CBCT Mode SSD (cm) SDD (cm) SID (cm)

QA Phantom Y N | QC Testing Y N | (FOV values in cm squared, DAP in mGy x cm squared)

kVp Indicated | Indicated FOV | Measured FOV

mA | Time (s) | Indicated DAP | Measured DAP

Pulse Count | Dose Per Pulse

	kVp	Sec	Exposure mR	mR/sec	Tot Filt	HVL	Avg Exp Calc
1							Avg Exposure
2							Calculate Avg Exposure

Filtration Adeq Y N

Panoramic SSD (cm) SDD (cm) SID (cm)

kVp Indicated

mA | Time | Time Units | mAs

	kVp	Sec	Exposure mR	mR/sec	Tot Filt	HVL	Avg Exp Calc
1							Avg Exposure
2							Calculate Avg Exposure

Filtration Adeq Y N

Other SSD (cm) SDD (cm) SID (cm)

kVp Indicated

mA | Time | Time Units | mAs

	kVp	Sec	Exposure mR	mR/sec	Tot Filt	HVL	Avg Exp Calc
1							Avg Exposure
2							Calculate Avg Exposure

Filtration Adeq Y N

Scatter Protection Adequate Y N

Survey Equipment Used

Who is CDCPD?

CRCPD Publication: E-17-6

TECHNICAL WHITE PAPER:
CONE BEAM COMPUTED TOMOGRAPHY (CBCT)
FOR DENTAL APPLICATIONS
November 2017

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Mary Lally	Intersocietal Accreditation Commission
Bill DeForest, MS	American Association of Physicists in Medicine
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Jay Vaishnav	(Back-up)

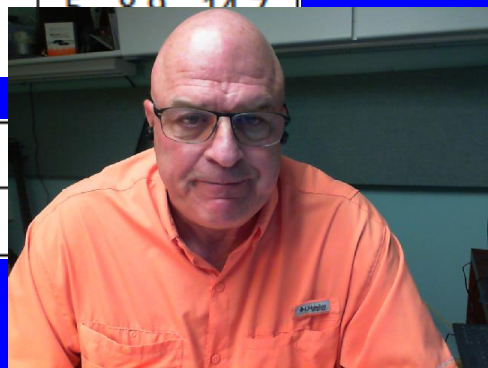
https://cdn.ymaws.com/www.crcpd.org/resource/collection/BF80D39C-1287-4A8F-8617-02537
6%20Technical%20White%20Paper%20-%20Cone%20Beam%20Compu.pdf

SUMMARY AND RECOMMENDATIONS

- The practice of conducting imaging demonstrations on employees during manufacturer training should be investigated during an inspection with violations issued where appropriate.
- CBCT examinations should use technique factor combinations that will provide acceptable images with the lowest possible doses. In addition, the smallest FOV should be used that would accomplish proper imaging of the area of interest.
- A QMP or a QE should provide shielding recommendations for new installations as well as machine replacement installations. Most states require some form of approval using guidance from *NCRP Report No. 177* (2017).
- A quality assurance program should be developed and followed. The program may be obtained through manufacturer guidelines or through one established by a QMP or a QE. Documentation of C required frequencies should be verified during record re
- Acceptance testing should be conducted by a QMP or a days of installation, replacement of a major component tube or detector), or software upgrade.

- A survey should be conducted by a QMP or a QE every two years for machines operating at less than 100 kV and 20 mA, and annually for machines operating at greater than 100 kV or 20 mA.
- Possession and use of a QC phantom and test protocols provided by the manufacturer should be verified.
- During inspections, checking the panoramic machines for CBCT capabilities is recommended. Some units require hardware upgrades to convert the machine to CBCT. Other units require only a software update. States may not be notified of the upgrades, making them unaware that the machines exist at a facility.
- The NCRP and the Task Force strongly discourage using CBCT units to take intraoral images (e.g., bitewing images). This practice results in higher patient exposures while providing lower spatial resolution.

Manufacturer	Model	kVp Available	Available mA	X-Ray Exposure Time (s)	Scan Time (s)
3M	Iluma	120	1 - 3.8		7.8 for 190°, 20 to 40 for 360°
Biolase	DaVinci	90	10		10, 15, 20, 30
Carestream (Kodak)	CS 8100	60 - 90	2 - 15		7 - 15
Carestream (Kodak)	CS 9000	60 - 90	2 - 15		
Carestream (Kodak)	CS 9100	60 - 90	2 - 15		
Carestream (Kodak)	CS 9300	60 - 90	2 - 15		12 - 18
Imaging Sciences International	i-CAT Classic	120	3 - 7		20
Imaging Sciences International	i-CAT	120	3 – 7		20
Imaging Sciences International	i-CAT Precise	120	5		4.8, 8.9, 12.6, 23
Imaging Sciences International	i-CAT Next Generation	120	5		5, 8.9, 14.7
NewTom	5G	110	1 – 20	3.6 – 6.7	
NewTom	VGi Flx	110	1 – 20	3.6 – 6.7	



Compliance Guidance for

DENTAL CONE BEAM COMPUTED TOMOGRAPHY (CBCT) QUALITY ASSURANCE MANUAL

(1st Edition)

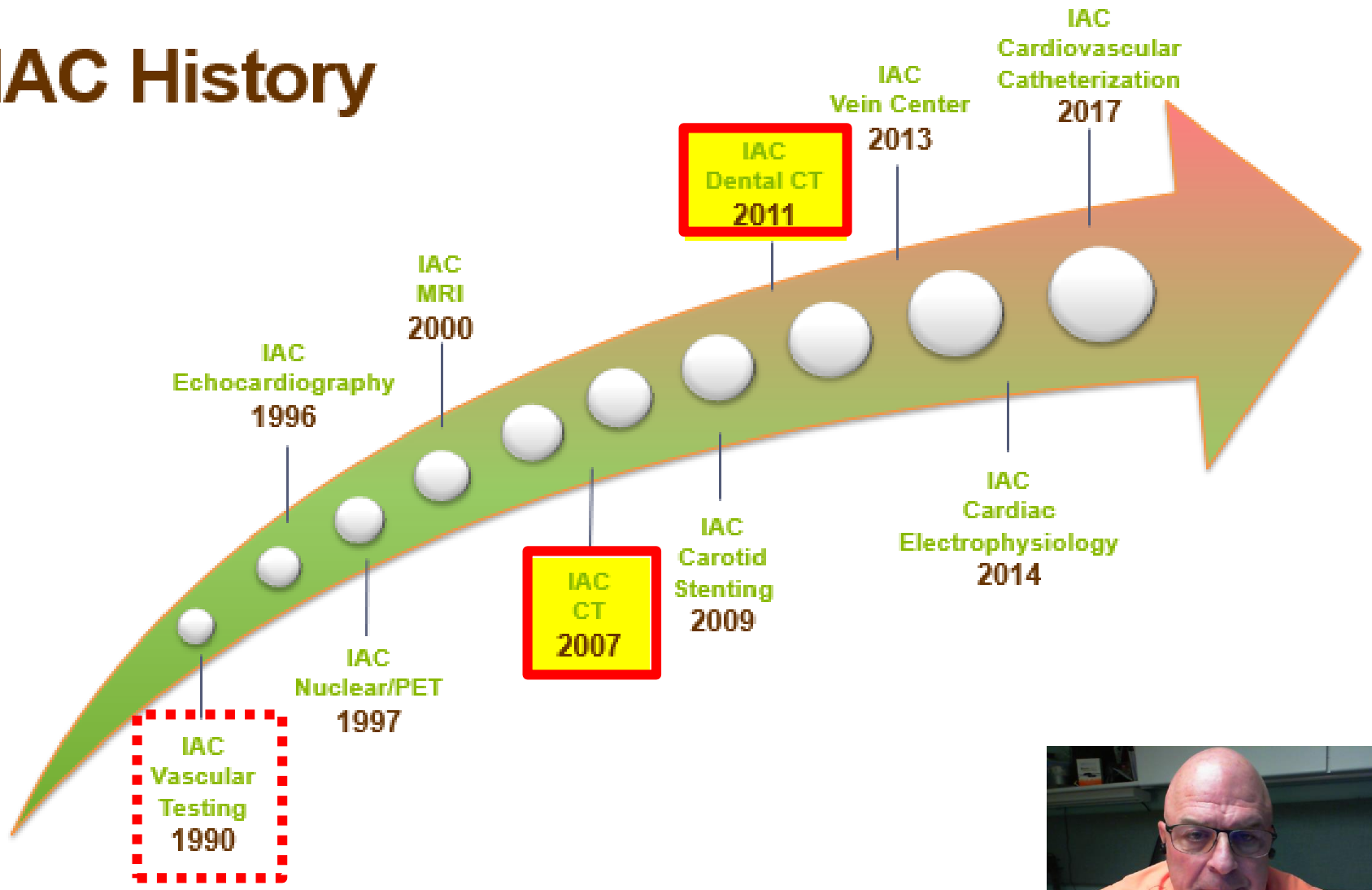
New Jersey Department of Environmental Protection
Bureau of X-ray Compliance
PO Box 420, MC 25-01
Trenton NJ 08625-0420
FAX: (609) 984-5811
Email: BXC@dep.nj.gov
Website: http://www.xray.nj.gov

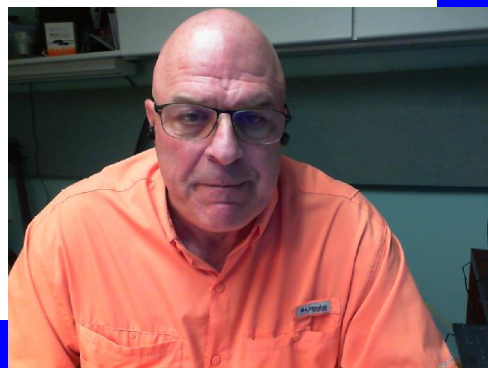
Outline

Regulatory perspective

IAC – history and QC expectations, CBCT

IAC History


IAC
Vascular
Testing
1990
IAC
Nuclear/PET
1997
IAC
Echocardiography
1996
IAC
MRI
2000
IAC
CT
2007
IAC
Carotid
Stenting
2009
IAC
Dental CT
2011
IAC
Vein Center
2013
IAC
Cardiac
Electrophysiology
2014
IAC
Cardiovascular
Catheterization
2017



IAC Sponsoring Organizations

Alliance of Cardiovascular Professionals

American Academy of Neurology (AAN)

AAOS American Academy of Orthopaedic Surgeons

American Academy of Otolaryngology-Head and Neck Surgery

AAOMS

AAPM

American College of Phlebology

American College of Surgeons (ACS)

ACNM

aium

ASDS American Society for Dermatologic Surgery

ASE American Society of Echocardiography

American Society of Neuroradiology

ASNR

ASNC

asrt American Society of Radiologic Technologists

Heart Rhythm Society

International Society for Musculoskeletal Imaging in Rheumatology (ISEMIR)

AANS CNS Cerebrovascular Section

Neurocritical Care Society

PACES

SCAI The Society for Cardiovascular Angiography and Interventions

SCMR

Society for Vascular Medicine

SVN Society of Vascular Nursing

SVS Society for Vascular Surgery

SVU

Society of Cardiovascular Anesthesiologists

Society of Cardiovascular Computed Tomography

SDMS

Society of Interventional Radiology

Society of Neurointerventional Surgery SNIS

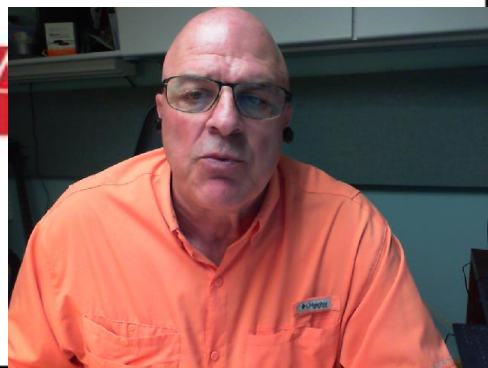
SNMMI

SNMMI Society of Nuclear Medicine and Molecular Imaging Technologist Section

Society of Pediatric Echocardiography

Society of Radiologists in Ultrasound (SRU)

SVIN



IAC CT Sponsoring Organizations

AAPM

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

AMERICAN ACADEMY ORAL & MAXILLOFACIAL RADIOLOGY

SOCIETY OF CARDIOVASCULAR COMPUTED TOMOGRAPHY
The Professional Society Devoted Exclusively to Cardiovascular CT

ASA OMS

American Academy of Neurology (AAN)

SVS | Society for Vascular Surgery

SCAI

asrt
American Society of Radiologic

ASE
American Society of Echocardiography

ASNC

SNMMI SOCIETY OF NUCLEAR AND

IAC

- IAC Vascular Testing (ICAVL) | 1990
- IAC Echocardiography (ICAEL) | 1996
- IAC Nuclear/PET (ICANL) | 1997
- IAC MRI (ICAMRL) | 2000
- IAC CT (ICACTL) | 2007
- IAC Dental CT (ICACTL) | 2011
- IAC Carotid Stenting (ICACSF) | 2009
- IAC Vein Center
- IAC Cardiac Electrophys
- IAC Cardiovascular Cathe

CT and Dental CT Application Statistics

Currently Accredited CT Facilities and Dental CT Practices:

(December 2019)

This section contains statistics of all currently accredited CT facilities and Dental CT practices.

Note: Granted facilities and practices are accredited for three years after their date of decision.

Application Statistics – Cumulative Totals	CT	Dental CT
Total number of currently accredited facilities and practices:	699	20
Total number of currently accredited sites:	964	22

Accreditation Details – Testing Areas Currently Granted Accreditation	
Coronary Calcium Scoring	66
Coronary CTA	59
Neurological CT	119
Maxillofacial CT	
Body CT	
Vascular CTA	
Dental CT	

Accreditation Fees

(Effective 1/15/18)

$3,100 first CT

Multiple Site Fee Structure

- **$1,325** … per site for sites 2-3
- **$1,085** … per site for sites 4-10 (20% discount)
- **$875** … per site for each site over 10

IAC
INTERSOCIETAL
ACCREDITATION
COMMISSION
CT

The IAC Standards and Guidelines for CT Accreditation

IAC Standards and Guidelines for CT Accreditation ***(Published 8/15/2017, Revised 9/12/2018)***

https://www.intersocietal.org/ct/standards/IACCTStandards2018.pdf

Previous Physicist Guidance Document

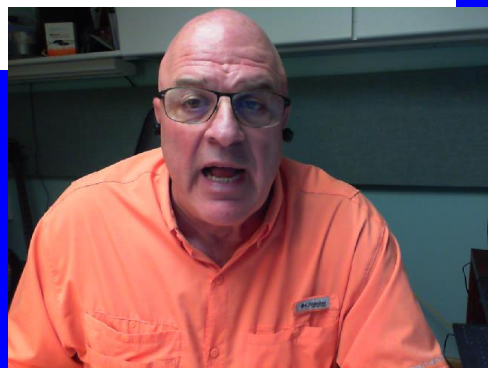
2. CT Dosimetry Reports for all scanners, including volume CT (VCT) or cone-beam CT (CBCT) scanners, must include:

   a. Measurements of exposure, and calculations of dose or dose index (or other appropriate dosimetry metric) which include comparison with some applicable reference standard, using the same units as the reference standard. The report must be clear about whether the results are acceptable, and identify corrective actions if the results are not acceptable.

   b. Dosimetry should be in units of pitch-corrected CTDI, point dose at the central ray, or MSAD for typical clinical protocols. The clinical protocol factors must be listed.

   c. Although CTDI is not rigorously defined for VCT or CBCT scanners, CTDI is also not rigorously defined for multislice CT scanner with beam thickness more than 1.0 cm. While imperfect, CTDI is the only metric for which reference standards currently exist. If possible, VCT or CBCT systems should be configured to use a z-axis collimation that is less than the length of the pencil chamber (if such a chamber is used). For example, temporal bone imaging protocols found on ENT scanners often meet this criterion. As new techniques for CT dosimetry are published, more rigorous methods should be used.

   d. The report must identify the phantom and radiation detection system used.



CT Standards written by board members to apply to MDCT and CBCT Systems

Dental Standards added 2016

Physicist Guidance revised 2018

IAC
INTERSOCIETAL ACCREDITATION COMMISSION
CT

The IAC Standards and Guidelines for CT Accreditation

IAC
INTERSOCIETAL ACCREDITATION COMMISSION
DENTAL CT

The IAC Standards and Guidelines for Dental/Maxillofacial Computed Tomography (CT) Practice Accreditation Using Cone Beam Technology

https://www.intersocietal.org/ct/se
https://www.intersocietal.org/ct/standards/IA

Reports - Requirements

- Name, date, signature
- Data, phantoms/equipment used
- Calibrations not to exceed 24 months
- Pass/Fail evaluations, with reference limits
- Review of site QC (Daily)
- State Compliance
- Observations
- Recommendations

https://www.intersocietal.org/ct/standards/IACCTStandards2

Medical Physicist or Qualified Expert Guidance Document

IAC CT Standard Requirements for the MPor QE:

Per the *IAC Standards for CT Accreditation*, Section 1.5.1A:

The medical physicist must be board certified by the ABR, the ABMP, or the Canadian College of Medical Physics in a discipline that includes diagnostic imaging.

Comment: In states where medical physicists or qualified experts are licensed, registered or otherwise sta measure dose and evaluate image quality at CT facilities, these credentials are acceptable to be

Radiation Safety Training Session Provided by a Medical Physicist or Qualified Expert:

If a medical physicist or qualified expert provides radiation safety training for facility staff members:

Documentation must include a minimum of 3 hours continuing medical education (CME)/continuing education (CE) related to radiation safety, the course title, CAMPEP topic description or course topical outline should include radiation safety or radiation dose.

Any course specifically intended for medic physicists will typically be acceptable.

IAC CT Guidance for Surveys of Image Quality, Dose Assessments, Radiation Protection (i.e. Shielding Verification):

IMAGE QUALITY SURVEYS:

Image quality assessments must include the parameters specific to the CT scanner (conventional or cone beam.)

The report must contain the actual results of the assessments with comparisons of the results to the manufacturer specifications, and indicate "Pass" or "Fail" for each item.

Record in the report a description of the specific quality control (QC) phantom utilized.

Submit the phantom images performed with the the image quality results (facility does this).

RADIATION DOSE SURVEYS:

CT Dosimetry Reports for all scanners, including single slice CT, electron beam CT (EBCT), (MDCT) and cone-beam CT (CBCT) scanners must include:

The manufacturer, serial number and most recent calibration date of the dose measurement instrument used. Instruments should be calibrated at intervals not e
24 months.

Radiation measurements, (with the appropriate units of measure indicated), and calculations of dose, dose index ($CTDI_{vol}$), (DLP), (KAP)[1], the air kerma at the focus-to-detector distance $K_{a,i}$(FDD) [1] (or other appropriate dosimetry metric).

Analysis of dose (for representative clinical protocols) must include comparison with some applicable reference values or manufacturer's specification, using the same units as the reference standard or specification.

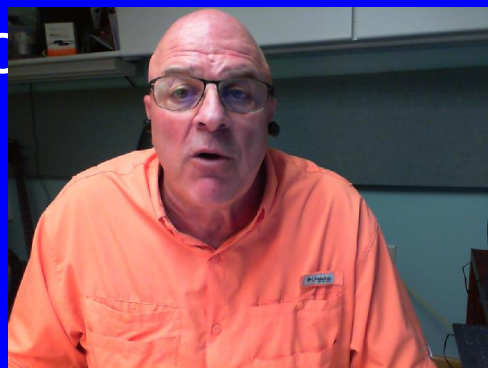
The report must be clear about whether the results are acceptable, and identify suggested corrective actions for improvement if the results are not acceptable.

The report must identify the phantom use

Dosimetry measurements and analysis should be performed for the most commonly used clinical protocols at the facility.

At a minimum these should include, if they are used at the facility, adult head, adult abdomen, pediatric head, pediatric abdomen and low-dose lung screening.

Dosimetry should be reported in units of CTDIvol, point dose at the central ray, or Dose Length Product (DLP) for typical clinical protocc



As new techniques for CT dosimetry are published, more rigorous methods should be used. If the full length of the pencil chamber is exposed, use 100 mm for N*T in the CTDI calculation.

For CBCT scanners, dosimetry should include analysis of each clinical protocol commonly used at the facility.

At a minimum, adult and pediatric (as applicable) protocols should be evaluated, up to a maximum of 6 protocols. Additional dosimetry may b
performed, but is not required for accre

RADIATION PROTECTION SURVEYS (e.g radiation shielding verification surveys):

RPS must be performed after installation of new CT scanner or after major changes in CT scan room configuration, equipment location, or usage of areas adjacent to the CT scanner. Otherwise, the RPS is not required to be performed annually.

IAC CT requires that a post-installation RPS be submitted to demonstrate that the safety of the installation and the surrounding areas have been assessed. Therefore, it may be necessary to locate the original acceptance test report of the CT scanner to find the RPS.

For reaccreditation, the application proces
the applicant to indicate that no CT equipm
room configuration changes have been ma
resubmission of the RPS will not be neede

A complete RPS must include:

The manufacturer, serial number, and most recent calibration date of the survey instrument used. The survey instrument should be calibrated at intervals not to exceed 24 months;

A sketch (design) showing the layout of the equipment in the room, and identifying the surrounding areas (e.g., toilet, corridor, outside wall, exam room, office, etc.) and the [illegible] control area;

Measurements of radiation exposure (or exposure rate) obtained with an appropriately sensitive radiation measurement system;

Calculations to demonstrate compliance with weekly or annual exposure limits, which must include a determination of workload, identification of occupancy of each adjacent area, and identification of the applicable exposure limit (for controlled and non-controlled areas).

Note: Shielding designs are not required to b

Medical Physicist CT Survey Report

Facility Name:	[redacted]
Address 1:	
Address 2:	
City, State, Zip:	
Unit ID:	
Manufacturer:	Xoran
Model:	MiniCAT
Serial Number:	
Date of Manufacturer:	
Operator:	
Phantom s/n:	i-CAT and 4631058 Phantom
Dosimetry Equiment:	Kit #13 - AGDM, S/N 40-0200
CT Ion Chamber:	Radcal 10X6-3CT; s/n 05-0149

Survey Date:	10/15/2015
Report Date:	11/2/2015
Medical Physicist(s):	[redacted]
Signature(s):	[redacted]

Medical Physicist Test	Pass/Fail
Positioning accuracy	Pass
CT number accuracy	Pass
Slice thickness accuracy	Pass
Low contrast resolution	Pass
High contrast resolution	Pass
Image uniformity	Pass
Image noise	Pass
Radiation Beam Width	Pass
Radiation dosimetry	Pass
QC Program review	Pass

*This scanner is not FDA approved for low-contrast imaging. NYSDOH has provided a waiver for this test.

Technologist QC Evaluation	Pass/Fail
Artifact (Daily)	Pass
Image Noise (Daily)	Pass
Mean CT	
Calibrati	
Proper function of safety equipme	
Laser Alignment accuracy (	
Image Uniformity (	
CT Number of reference materials (	
Spatial Resolution (	
Hard Copy Device (laser printer -	
Dose Profile Width (Semi-	

Since publication of Guidance

IAC®
INTERSOCIETAL
ACCREDITATION
COMMISSION
CT

CT Medical Physicist or Qualified Expert Report
Guidance Document

Failures are less common,
but some problems persist

Common Weaknesses in Reports

- Physicist's signature
- Recommendations for improvement
- Pass/Fail reported
- Reported values not within specified limits, but "Pass"
- Specified limits
- Specified phantom
- Not enough protocols evaluated
- Specified measurement equipment/calibration date
- Protection Survey does not include any calculation of weekly dose in co
  non-contro

Dental: Common Reasons for "Delay"

Technical staff that do not have appropriate imaging and radiation safety training.

The CT scanner is not annually assessed by the medical physicist or qualified expert or an annual preventative maintenance performed by a service engineer, and the staff do not perform routine operator quality control phantom images. It cannot be confirmed that the scanner has good image quality and has acceptable radiation dose.

No radiation protection survey perfo

Review

Regulatory perspective

IAC – history and QC expectations, CBCT