

The IAC Standards and Guidelines for Dental CT Accreditation

Table of Contents

All entries in Table of Contents are linked to the corresponding sections.

Introduction	
Part A: Organization	4
Section 1A: Personnel and Supervision STANDARD – Dental or Medical Director(s) STANDARD – Dental or Medical Staff STANDARD – Technical Staff STANDARD – Medical Physicist or Qualified Expert STANDARD – Support Services	
Section 2A: Facility	10
Section 3A: Examination Reports and Records	11
Section 3A: Examination Reports and Records Guidelines	
Section 4A: Dental Practice Safety	
Section 4A: Dental Practice Safety Guidelines	
Section 5A: Administrative STANDARD – Patient Confidentiality STANDARD – Patient or Other Customer Complaints STANDARD – Primary Source Verification STANDARD – Indications STANDARD – Ordering Process and Scheduling	
Section 6A: Multiple Sites (Fixed and/or Mobile)	17
Section 6A: Multiple Sites (Fixed and/or Mobile) Guidelines	
Part B: Instrumentation and Procedures	18
Section 1B: Instrumentation and Equipment	

Introduction

The IAC Standards and Guidelines for Dental CT Accreditation list the requirements and recommendations for the dental practice and/or dental specialty practice performing diagnostic and/or treatment planning maxillofacial computed tomography (CT) examinations using a cone beam CT system. For any practice using a conventional CT system, accreditation may be obtained through the non-dental IAC CT program at intersocietal.org/programs/ct-dental-ct/standards.

These accreditation Standards and Guidelines are the minimum standards for accreditation of dental CT practices. Standards are the minimum requirements to which an accredited practice is held accountable. Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable.

Facilities are encouraged to <u>contact the IAC</u> for guidance related to utilization of new technology not currently addressed in the IAC Standards.

Standards are printed in regular typeface in outline form. Guidelines are printed in italic typeface in narrative form.

These Standards became effective on September 1, 2015, with minor revisions published on September 12, 2018. Facilities applying for accreditation must comply with this version of the Standards.

In addition to all standards listed below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Dental or Medical Director(s)

- 1.1A The Dental or Medical Director must be a dentist or specialty dentist, board certified (or board eligible within two years of completion of training) in a dental specialty recognized by the American Dental Association (ADA) or the Royal College of Dentists of Canada; or a physician, certified by the American Board of Medical Specialties (ABMS), American Osteopathic Association, Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec in a relevant specialty. The Dental or Medical Director must have a license in good standing from the state or province in which the practice is located.
 - 1.1.1A <u>Dental or Medical Director Required Training and Experience:</u>

The Dental or Medical Director must meet at least one of the following criteria:

1.1.1.1A Formal Training

 Completion of residency in a dental specialty that included advanced radiology /imaging training as part of the curriculum approved by the ADA Commission on Dental Accreditation (CODA) or the Commission on Dental Accreditation of Canada (CDAC), with a letter of verification from the program director of the educational institution.

OR

 Board certified by an ADA recognized dental specialty certifying board that includes advanced radiology/imaging training and is recognized by CODA or CDAC.

OR

iii. Board certified (or board eligible within two years of completion of training) in a medical specialty recognized by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec and completion of a minimum of a four-month formal training program in CT with radiation safety training as part of the curriculum and/or at least one year (full-time equivalent) of CT experience with independent interpretation of at least 150 maxillofacial CT studies.

OR

1.1.1.2A Informal Training

i. Documented interpretation of at least 150 mentored* maxillofacial CT examinations.

AND

ii. Attendance in at least 20 hours of CT training with a letter of verification from the program director of the educational institution. Such training should be certified for ADA Continuing Education Recognition Program (CERP), Academy of General Dentistry (AGD) Program Approval for Continuing Education (PACE) and/or Category I continuing education (CE) credit. The 20 hours of CT training must include at least three hours of relevant radiation safety instruction.

*The case load recommendation may include studies from established teaching files or electronic online CE courses that include a post test or course competency.

OR

1.1.1.3A Established Practice

i. A dentist, specialty dentist or physician who has been interpreting CT studies for at least three years.

AND

ii. Has acquired 50 hours ADA CERP, AGD PACE and/or Category I CE (at least 15 hours of the CE must be CT-related training and include at least three hours of relevant radiation safety.

AND

iii. Has interpreted a minimum of 150 documented maxillofacial CT examinations over the course of their career.

1.1.2A Dental or Medical Director Responsibilities:

- 1.1.2.1A The Dental or Medical Director is responsible for all clinical services provided and for the determination of the quality and appropriateness of care provided.
 - i. The Dental or Medical Director may supervise the entire operation of the dental practice or may delegate specific operations to associate Dental or Medical Director(s) or dental or medical staff.
 - ii. The Dental or Medical Director is responsible for assuring compliance of the Dental or medical staff and technical staff to the Standards outlined in this document and the supervision of their work.
 - iii. The Dental or Medical Director must be an active participant in the interpretation of CT examinations performed in the practice. If not generating final reports, the Dental or Medical Director must provide documentation of review and acceptance of reports, or amendment of findings as appropriate.

1.1.3A Continuing Education (CE) Requirements for Reaccreditation:

- 1.1.3.1A The Dental or Medical Director must document at least 15 hours of ADA CERP, AGD PACE and/or Category I CE in dental/maxillofacial CT that have been acquired within the past three years.
- 1.1.3.2A A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
- 1.1.3.3A Yearly accumulated CE must be kept on file and available to the IAC CT, when requested.

Comment: If the Dental or Medical Director has completed training or certification, as specified under 1.1.1.1A in the past three years, the CE requirement will be considered fulfilled.

STANDARD – Dental or Medical Staff

1.2A The dental or medical staff must be a dentist or specialty dentist, board certified (or board eligible within two years of completion of training) in a dental specialty recognized by the American Dental Association (ADA) or by the Royal College of Dentists of Canada; or a physician certified in a relevant specialty recognized by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec. The dental or medical staff must have a license in good standing from the state or province in which the practice is located.

1.2.1A Dental or Medical Staff Required Training and Experience:

The dental or medical staff must meet at least one of the following criteria:

1.2.1.1A Formal Training

i. Completion of a residency in a dental specialty that included advanced radiology/imaging training and radiation safety as part of the curriculum approved by ADA Commission on Dental Accreditation (CODA) or Commission on Dental Accreditation of Canada (CDAC) with a letter of verification from the program director of the educational institution.

OR

 Board certified by an ADA-recognized dental specialty certifying board that includes advanced radiology/imaging training and radiation safety and is recognized by CODA or CDAC.

OR

iii. Board certified (or board eligible within two years of completion of training) in a medical specialty recognized by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec and completion of a minimum of a four-month formal training program in CT with radiation safety training as part of the curriculum and/or at least one year (full-time equivalent) of CT experience with independent interpretation of at least 150 maxillofacial CT studies.

OR

1.2.1.2A Informal Training

 Documented interpretation of at least 150 mentored* maxillofacial CT examinations.

AND

ii. Attendance in at least 20 hours of CT training with a letter of verification from the program director of the educational institution. Such training should be certified for ADA CERP, AGD PACE and/or Category I CE. The 20 hours of CT training must include at least three hours of relevant radiation safety instruction.

^{*}The case load recommendation may include studies from established teaching files or electronic online CE courses that include a post test or course competency.

1.2.1.3A Established Practice

 A dentist, specialty dentist or physician who has been interpreting CT studies for at least three years.

AND

ii. Has acquired 50 hours ADA CERP, AGD PACE, and/or Category I CE (at least 15 hours of the CE must be CT-related and include at least three hours of relevant radiation safety instruction.

AND

iii. Has interpreted a minimum of 150 documented maxillofacial CT examinations over the course of their career.

1.2.2A <u>Dental or Medical Staff Responsibilities</u>:

1.2.2.1A The dental or medical staff interprets diagnostic and/or treatment planning CT examinations in compliance with the requirements established by the Dental or Medical Director.

1.2.3A Continuing Education (CE) Requirements for Reaccreditation:

- 1.2.3.1A The dental or medical staff must document at least 15 hours of ADA CERP, AGD PACE and/or Category I CE in maxillofacial CT that have been acquired within the past three years.
- 1.2.3.2A A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
- 1.2.3.3A Yearly accumulated CE must be kept on file and available to the IAC CT, when requested.

Comment: If the dental or medical staff member has completed training or certification, as specified under 1.2.1.1A in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Technical Staff

- 1.3A The technical staff must meet the specific state or province requirements where the practice is located to perform dental radiographic procedures, have appropriate training and technical certification as noted below and documented experience in the use of a cone beam CT scanner for the performance of dental / maxillofacial CT imaging.
 - 1.3.1A <u>Technical Staff Required Training and Experience</u>:

Technical staff must meet at least one of the following criteria:

1.3.1.1A A dentist or specialty dentist, board certified (or board eligible within two years of completion of training) in a dental specialty recognized by the American Dental Association (ADA) or by the Royal College of Dentists of Canada; or a licensed physician certified by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec in a relevant specialty as well as a license in good standing from the state or province in which the practice is located.

OR

1.3.1.2A A dental assistant or dental hygienist state license or state certification, or authorization by the state radiation control/protection department, and in compliance with the state dental board regulations.

OR

1.3.1.3A In states with no licensure for dental assistants or dental hygienists, a Dental Assistant National Board (DANB) certification, a Certified Dental Assistant (CDA) certification or Certified Orthodontic Assistant (COA) certification, with certification of training and education from an accredited educational program (e.g., CODA).

OR

1.3.1.4A A radiologic technologist with certification by the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) (i.e., RT).

AND for the pathways 1.3.1.1A, 1.3.1.2A and 1.3.1.3A:

1.3.1.5A At least three hours of documented, specific training in radiation safety relevant to CT testing.

AND for all pathways listed above (1.3.1.1A, 1.3.1.2A, 1.3.1.3A and 1.3.1.4A):

1.3.1.6A Received at least four hours of documented, equipment specific training in the operation of each CT scanning system employed. The training may be provided by the manufacturer or by a technical staff member with documentation of training provided by the manufacturer.

- 1.3.2A Technical Staff Responsibilities:
 - 1.3.2.1A The technical staff member(s) reports to the Dental or Medical Director.
 - 1.3.2.2A The technical staff member(s) assumes the responsibilities specified by the Dental or Medical Director and, in general, is responsible for the performance of clinical CT examinations and other tasks assigned.
- 1.3.3A Continuing Education (CE) Requirements for Reaccreditation:
 - 1.3.3.1A The technical staff member(s) must document at least 15 hours of ADA CERP, AGD PACE, Category 1 or Category A CE which must be relevant to dental/maxillofacial CT that have been acquired within the past three years.
 - 1.3.3.2A A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
 - 1.3.3.3A Yearly accumulated CE must be kept on file and available to the IAC CT, when requested.

Comment: If the technical staff member has completed training or certification, as specified under 1.3.1.1A in the past three years, the CE requirement will be considered fulfilled.

STANDARD - Medical Physicist or Qualified Expert

- 1.4A The medical physicist must be board certified by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Medical Physics (CCMP) in a discipline that includes diagnostic imaging. In states where medical physicists or qualified experts are licensed, registered or otherwise state-approved to measure dose and evaluate image quality at CT scanning facilities, these credentials are acceptable.
 - 1.4.1A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist or qualified expert in the collection of data.
 - 1.4.2A Continuing Education (CE) Requirements:
 - 1.4.2.1A The medical physicist must document at least 15 hours of Category I AMA,
 Commission on Accreditation of Medical Physicists Educational Programs
 (CAMPEP) or the American College of Radiology (ACR) Medical Education for Physicists (MEP) approved physics-related CE over a period of three years.
 - 1.4.2.2A A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
 - 1.4.2.3A Yearly accumulated continuing education must be kept on file and available to IAC CT, when requested.

STANDARD – Support Services

- 1.5A Ancillary personnel (i.e., clerical, clinical, etc.) necessary for safe and efficient patient care are provided.
 - 1.5.1A Supervision:
 - 1.5.1.1A The Dental or Medical Director must ensure that appropriate support services are provided in the best interest of patient care.
 - 1.5.2A <u>Support Services</u>:
 - 1.5.2.1A Clerical and administrative support must be sufficient to ensure efficient operation and record keeping.

Section 2A: Facility

STANDARD – Examination Areas

- 2.1A Diagnostic and/or treatment planning maxillofacial CT examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy.
 - 2.1.1A The performance of a diagnostic and/or treatment planning dental/maxillofacial CT examination requires adequate space.
 - 2.1.1.1A Patient privacy should be assured with the use of appropriate curtains or doors and must be in compliance with state regulations.
 - 2.1.1.2A A sink and antiseptic soap must be readily available and used for hand washing in accordance with the infection control policy of the dental practice.
 - 2.1.1.3A Direct visualization and audible monitoring of the patient must be available while protecting personnel from radiation exposure.
 - 2.1.1.4A The medical physicist or qualified expert must assess the shielding safety post installation and the facility is responsible for implementing the medical physicist or qualified expert's recommendations to keep exposures as low as reasonably achievable (ALARA).

Section 3A: Examination Reports and Records

STANDARD - Records

- 3.1A Provisions must exist for the generation and retention of examination data for all CT examinations performed.
 - 3.1.1A A system for recording and archiving CT data (images, measurements and final reports) obtained for diagnostic and/or treatment planning purposes must be in place.
 - 3.1.2A A permanent record of the images and interpretation must be made and retained in accordance with applicable state or federal guidelines for medical records.

(See Guidelines on Page 13 for further recommendations.)

3.1.3A Archiving media must include loss-less digital storage and a system for long-term, off-line digital storage.

STANDARD – Examination Interpretation and Reports

- 3.2A Provisions must exist for the timely reporting of examination data.
 - 3.2.1A All CT examinations must be reviewed promptly after the study is completed, as appropriate for the risk of clinically significant results at least within one working day. Results of examinations with critical findings must be communicated to the referring dentist or physician as quickly as clinically indicated. A record of the communication should be maintained.

(See Guidelines on Page 13 for further recommendations.)

3.2.2A A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs significantly from the preliminary report.

(See Guidelines on Page 13 for further recommendations.)

- 3.2.3A CT examinations must be interpreted and reported by the Dental or Medical Director or by a member of the dental or medical staff of the CT dental practice.
 - 3.2.3.1A Final dentist or physician interpretations of dental/maxillofacial CT examinations must be available within two working days. The final verified, signed report must be available in a timely fashion, generally within four working days.
- 3.3A CT examination reporting must be standardized in the dental practice. All dentists and physicians interpreting CT examinations in the dental practice must agree on a standardized report format for diagnostic and/or treatment planning CT examinations.
 - 3.3.1A The final report must accurately reflect the content and results of the study. The report must include, but may not be limited to the:
 - 3.3.1.1A patient name or ID;
 - 3.3.1.2A age or date of birth;
 - 3.3.1.3A date of the examination:
 - 3.3.1.4A clinical indications leading to the performance of the examination;

- 3.3.1.5A an adequate description of the test performed including the:
 - i. name of the examination;
 - ii. protocol used in the examination;
 - iii. quality of the study.
- 3.3.1.6A an overview of the pertinent results of the examination;
- 3.3.1.7A whether the scan was adequate for treatment planning (if applicable);
- 3.3.1.8A appropriate recommendation for follow up of incidental findings;
- 3.3.1.9A the reasons for limited examinations (if applicable);
- 3.3.1.10A a summary of the pertinent test findings or treatment plan parameters;
- 3.3.1.11A comparison with previous studies (if applicable and available);
- 3.3.1.12A reports must be typewritten;
- 3.3.1.13A dentist/physician signature line (the printed name of the interpreting dentist or physician) and is manually or electronically signed by the interpreting dentist or physician;
- 3.3.1.14A date of signature and/or verification.

(See Guidelines on Page 13 for further recommendations.)

Section 3A: Examination Reports and Records Guidelines

- 3.1.2A Critical reconstructed CT data should be readily retrievable for comparison with new examinations.
- 3.2.1A A record of the communication should be maintained.
- 3.2.2A If preliminary results are provided by an interpreting dentist or physician, the final report should be generated within two working days.
- 3.3.1A In addition to the requirements, it is recommend that the final report include:
 - documentation of dose reduction technique if used (e.g., low energy and/or dose modulation) is recommended in the report;
 - details of any non-standard patient preparation or treatment, if required, should be included in the final report;
 - appropriate recommendation for follow up of incidental findings;
 - the reasons for limited examinations (if performed);
 - comparison with previous studies (if available).

Section 4A: Dental Practice Safety

STANDARD – Dental Practice Safety

4.1A Patient and employee safety is ensured by written policies and procedures, approved by the Quality Improvement (OI) Committee or the Dental or Medical Director.

(See Guidelines on Page 15 for further recommendations.)

4.1.1A Patient Identification – For all clinical procedures there must be a process that assures accurate patient identification prior to initiating the procedure. It is preferable that this be done using at least two pieces of information that are provided by the patient and compared with existing documents.

(See Guidelines on Page 15 for further recommendations.)

- 4.1.2A Radiation dose for CT acquisition must be set at the lowest values that are consistent with satisfactory image quality for the study ordered.
- 4.1.3A There must be at least one BLS certified staff member on site for all CT exams.
- 4.1.4A The dental practice must have a written procedure in place for handling acute medical emergencies.
- 4.1.5A The dental practice must comply with the currently published ALARA recommendations for personnel and subscribe to dose optimization for patients. The use of higher than recommended radiation doses must be justified. For pediatric patients, protocols must be modified to reduce radiation exposure, where appropriate or possible.
- 4.1.6A A separate, radiation shielded control room or area must be used by staff during acquisitions. No staff should routinely enter the CT room or area when the x-ray tube is active.
- 4.1.7A Staff radiation exposure must be monitored per state requirements and reviewed by the QI Committee. The results must be communicated to the staff member.
- 4.1.8A There must be restriction of the public to radiation areas.
- 4.1.9A A policy for documentation of adverse events (i.e., falls, injuries, complaints) must be in place.
- 4.1.10A Patient Pregnancy Screening Policy For all clinical procedures, there must be a process that assures that patients who may be pregnant are identified. This must be documented and should contain the signature/initials of the patient and/or technical staff member verifying the information. This procedure must include explanation of the proper steps to be taken if a patient may be or is pregnant.
 - 4.1.10.1A If a diagnostic CT examination is needed for a patient who is pregnant, knowledgeable staff (e.g., Dental/Medical Director or other designee) must discuss the potential risk to the fetus and document the general content of the discussion.
 - 4.1.10.2A If determined that the study will not be performed, then the patient must receive options for alternative care.

Section 4A: Dental Practice Safety *Guidelines*

- 4.1A Imminent life threatening situations may override the patient preparation and identification at the discretion of the treating dentist.
- 4.1.1A Examples of patient specific identifiers include the patient's identification bracelet, hospital identification card, driver's license, or asking the patient to state his or her full name or birth date avoiding procedures in which the patient can answer "yes" or "no."

Section 5A: Administrative

STANDARD – Patient Confidentiality

5.1A All dental practice personnel must ascribe to professional principles of patient-dentist/physician confidentiality, as legally required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

5.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the practice and how the practice handles complaints/grievances.

STANDARD - Primary Source Verification

5.3A There must be a policy in place identifying how the practice verified the medical education, training, appropriate licenses and certifications of the Dental or Medical Director, all dental or medical staff members and all technical staff members and any other direct patient care providers.

STANDARD – Indications

- 5.4A CT testing is performed for appropriate indications.
 - 5.4.1A Verification of the Indication A process must be in place in the dental practice for obtaining and recording the indication. Before a CT study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.

STANDARD - Ordering Process and Scheduling

- 5.5A CT testing is appropriately ordered and scheduled.
 - 5.5.1A Ordering Process The CT order and requisition must clearly indicate the type of study to be performed, the reason(s) for the study and the treatment plan or clinical question(s) to be answered. The order/requisition must be present in the medical record of the patient.
 - 5.5.2A Sufficient time for patient assessment and testing must be allotted.

Section 5A: Administrative *Guidelines*

Sample documents are available for each of the required policies listed in Section 5A on the IAC Dental CT website at intersocietal.org/dental/main/sample_documents.htm.

Section 6A: Multiple Sites (Fixed and/or Mobile)

STANDARD – Multiple Sites

- 6.1A When testing is performed at more than one physical facility, the dental practice may be eligible to apply for a single accreditation as a multiple site dental practice if the following criteria are met:
 - 6.1.1A all facilities have the same Dental or Medical Director;
 - 6.1.2A all CT examinations are interpreted by dental or medical staff included in the application;
 - 6.1.3A all dental practices utilize the same medical physicist or qualified expert;
 - 6.1.4A all CT examinations are performed by technical staff included in the application;
 - 6.1.5A technical and interpretive quality assessment, as outlined in Section 2C: QI Measures must be evaluated for all CT testing sites.

Section 6A: Multiple Sites (Fixed and/or Mobile) Guidelines

Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at intersocietal.org/iac/legal/policies.htm.

Part B: Instrumentation and Procedures

Section 1B: Instrumentation and Equipment

STANDARD – Instrumentation

- 1.1B All cone beam CT imaging devices in use must be appropriate for the dental/maxillofacial region being imaged and must be FDA approved for the specific imaging task.
- 1.2B The cone beam CT equipment specifications and performance must meet all state, federal and local requirements, as well as the manufacturer's published performance specifications and current standards of medical and/or dental practice for maxillofacial examinations performed.
- 1.3B The cone beam CT systems utilized for dental/maxillofacial diagnostic and/or treatment planning studies must include, at a minimum, adequate hardware and software to perform and store all maxillofacial examinations.
- 1.4B The computer software and reconstruction systems used for cone beam CT maxillofacial examinations must be appropriate for the study performed and must be capable of image processing appropriate to the imaging task.
- 1.5B For all cone beam systems:
 - 1.5.1B all data are to be reviewed in a digital, on-screen medium.
 - 1.5.2B monitor specifications must be sufficient to prevent any loss of resolution of CT images and to display the thinnest reconstructed images available.
 - 1.5.3B must have capability to display data in standard contrast/scale settings.
 - 1.5.4B must have capability to adjust brightness and contrast settings manually.
 - 1.5.5B datasets used for archiving must be DICOM compatible.

(See Guidelines on Page 19 for further recommendations.)

Section 1B: Instrumentation and Equipment *Guidelines*

1.5B If images are transmitted to another location for interpretation, the original resolution should be maintained.

Should have the capability to optimize the field of view based on the anatomy of interest (if appropriate to the type of CT unit).

Section 2B: Equipment Quality Assurance

STANDARD – Quality Assurance (QA)

2.1B There must be a written comprehensive QA Program to provide a standard of measurement for cone beam CT system performance and the documentation of any variance thereof. A Quality Improvement (QI) Committee and/or the Dental or Medical Director must provide oversight to these procedures.

(See Guidelines on Page 22 for further recommendations.)

- 2.2B The QA Program must consist of cone beam CT system installation acceptance testing and major upgrade acceptance testing.
 - 2.2.1B Acceptance testing must include a comprehensive evaluation of the system components, the Quality Control (QC) parameters included in Standards 2.3B and 2.4B, image performance and system performance as outlined in 21 CFR and applicable FDA guidance documents and performance of a radiation survey to verify the adequacy of installed lead shielding, if applicable.
 - 2.2.2B The system parameters must be compared to the manufacturer's system specifications and reviewed by the QI Committee and/or the Dental or Medical Director.
 - 2.2.3B A written report of the acceptance tests must be maintained at the CT dental practice. The report must be signed and dated by the person performing the tests.
 - 2.2.4B The medical physicist or qualified expert must perform the shielding design to ensure that occupational workers and members of the public are shielded according to NCRP Report 147, state regulation or other equivalent industry standards. This must be performed prior to installation of each new scanner.
 - 2.2.5B Patient dose measurements and image quality assessment of representative exams as compared to professional standards must be performed.
 - 2.2.6B A post-installation radiation shielding verification survey must be performed by the medical physicist or qualified expert that assesses the radiation exposure in the areas adjacent to the CT suite/shielded control area.

(See Guidelines on Page 22 for further recommendations.)

- 2.3B Routine (daily and/or periodic) QC tests are to be conducted according to performance measurements as outlined by the manufacturer. Federal standards require that CT manufacturers provide quality assurance testing instructions, recommended testing frequency, a quality control test phantom appropriate for the scanner and acceptable variations in parameter measurements.
 - 2.3.1B Daily quality control tests should include, at a minimum:
 - 2.3.1.1B mean CT number for water of representative components (as appropriate for the CT equipment);
 - 2.3.1.2B mean CT number of other reference material;
 - 2.3.1.3B image noise;
 - 2.3.1.4B artifact assessment;
 - 2.3.1.5B proper function of audible and visual patient safety equipment.

- 2.3.2B Periodic QC tests should include all from Standard 2.3.1B and:
 - 2.3.2.1B spatial resolution for high and low contrast objects;
 - 2.3.2.2B image uniformity;
 - 2.3.2.3B image display and storage devices;
 - 2.3.2.4B air calibration, if required.
- 2.4B Annual system performance measures must be evaluated using an appropriate phantom(s), determined by the medical physicist or qualified expert. The QC tests performed should include (as appropriate to the scanner) and will be required for any mid-cycle audits/site visits and at reaccreditation:
 - 2.4.1B contrast scale;
 - 2.4.2B mean CT number of water and reference materials;
 - 2.4.3B linearity;
 - 2.4.4B slice thickness;
 - 2.4.5B image quality (as noted in 2.3B);
 - 2.4.6B image display and storage devices;
 - 2.4.7B measurement and assessment of patient dose for representative examinations using CT dosimetry phantom(s) and instrumentation, in accordance with current professional standards and regulatory guidelines;
 - 2.4.8B safety analysis including an inspection of audible and visual equipment.
- 2.5B The QI Committee and/or the Dental or Medical Director must evaluate the medical physicist or qualified expert's recommendations and determine the QC tests to be performed on the CT scanner and ancillary equipment, the frequency of the testing and designate personnel to perform the test(s). Any corrective actions recommended by the medical physicist or qualified expert must be reviewed by the QI Committee and/or the Dental or Medical Director. If corrective actions are performed by the dental facility they must be reviewed and documented in the QI Committee minutes.
 - 2.5.1B Preventive maintenance (PM) service is required per the manufacturers' recommendations. If there are no manufacturer recommendations, PMs must be performed at least annually for each CT scanner at the dental practice.
 - 2.5.2B A complete log of PM, quality control tests and service records for all cone beam CT scanners and ancillary equipment must be maintained at the CT dental practice. The reports must be signed and dated by the person(s) performing the tests.

(See Guidelines on Page 22 for further recommendations.)

- 2.6B All QA results must be documented.
 - 2.6.1B QA documentation (policies, reports, records, etc.) must be maintained at the CT dental practice and made available to all personnel.

Section 2B: Equipment Quality Assurance *Guidelines*

- 2.1B QC tests, standards, thresholds, timelines and results should be reviewed and discussed on a quarterly basis by the QI Committee and/or the Dental or Medical Director.
- 2.2.1B The CT site-appointed medical physicist or qualified expert should perform the acceptance testing.
- 2.5B QC tests, standards, thresholds, timelines and results should be reviewed and discussed on a quarterly basis by the QI Committee and/or the Medical Director.
- 2.5.2B Scanner ancillary equipment inspection (e.g., monitoring equipment, processors, workstations, PACS, etc.) should also be included in the PM.

Section 3B: Elements and Components of CT Examination Performance

STANDARD – Elements of CT Examination Performance

- 3.1B Examination performance must include proper technique. All procedures must be explained to the patient and/or parents or guardian and informed consent obtained, if required.
 - 3.1.1B Elements of examination performance include as appropriate, but are not limited to:
 - 3.1.1.1B Proper patient positioning.
 - 3.1.1.2B Appropriate protocol selection based on:
 - i. clinical diagnosis;
 - ii. patient age;
 - iii. patient clinical presentation;
 - iv. contraindications.
 - 3.1.2B The dental practice must have a complete, written description of each protocol that is being utilized for each CT examination and the protocol(s) must include as appropriate:
 - 3.1.2.1B the indication for the study;
 - 3.1.2.2B anatomical region(s) to be imaged;
 - 3.1.2.3B utilization of the correct technique for the indication;
 - 3.1.2.4B clear criteria for deviating from protocols:
 - i. Modifications to the manufacturer's default protocols that increase patient dose above the site appointed physicist recommendation must be reviewed by a medical physicist prior to implementation of the proposed change(s) in order to assess impact on radiation dose and image quality.
 - ii. If the physicist deems that the proposed change(s) is appropriate, the dental practice must maintain documentation of the protocol change(s) that includes the rationale for the change, including the details of the change (exactly what changes were made to the technical parameters for the scans), and the physicist review of impact on dose and image quality.
 - 3.1.2.5B adherence to established practice guidelines. There may be allowance for exceptions if validated.
 - 3.1.2.6B all orientations/views that will be displayed;
 - 3.1.2.7B scanner settings to include (as appropriate):
 - i. field of view;
 - ii. resolution:
 - iii. time;
 - iv. KV;
 - v. mA/mAs.
 - 3.1.2.8B instruction on data archiving and transmission of images including what files are to be stored/transmitted.

Section 4B: Procedure Volumes

STANDARD - Procedure Volumes

4.1B The annual procedure volume must be sufficient to maintain proficiency in examination performance and interpretation. The annual procedure volume must be sufficient to maintain proficiency in examination performance and interpretation.

(See Guidelines below for further recommendations.)

Section 4B: Procedure Volumes Guidelines

4.1B A dental practice should perform a minimum of 300 CT examinations annually. The total volume of studies interpreted and performed by each staff member may be combined from sources other than the applicant dental practice. Lower volumes than those recommended here, however, should not dissuade a dental practice that is otherwise compliant with the IAC CT Standards from applying for accreditation

Part C: Quality Improvement

Please note: Standards that are highlighted within all of Part C: Quality Improvement will become effective on March 1, 2016. Facilities applying for IAC CT accreditation after March 1, 2016 will have to comply with the new QI requirements.

Section 1C: Quality Improvement (QI) Program

STANDARD - QI Program

- 1.1C The practice must have a written QI program for all imaging procedures. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:
 - 1.1.1C test appropriateness;
 - 1.1.2C technical quality and safety of the imaging;
 - 1.1.3C interpretive quality review;
 - 1.1.4C report completeness and timeliness; and
 - 1.1.5C radiation safety.

(See Guidelines below for further recommendations.)

1.2C The Dental or Medical Director, staff, and/or an appointed QI Committee must provide oversight to the QI program including but not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

(See Guidelines below for further recommendations.)

1.3C The use of a site appointed medical physicist or qualified expert is required for an annual survey to include: image quality evaluation, representative patient dose assessment and for oversight of the QI Program.

Section 1C: Quality Improvement Program Guidelines

- 1.1C The QI Committee should, at minimum, consist of the Technical Director, Dental or Medical Director, service engineer and/or site-appointed medical physicist.
 - The QI Program should also include a process for evaluating indicators such as backlog for scheduled examinations, late reporting, long patient waiting times and utilization review.
- 1.2C QI records should include, but not be limited to, image quality evaluation, dose assessment, peer review, correlation data and information gained from the areas outlined in Section 2C.

Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C	Practices are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C
	through 2.1.5C.

- 2.1.1C <u>Test Appropriateness</u>: The practice must evaluate the appropriateness of the test performed based on criteria published and/or endorsed by professional dental and/or medical organizations (if available) and categorize as:
 - 2.1.1.1C appropriate/usually appropriate;
 - 2.1.1.2C may be appropriate; or
 - 2.1.1.3C rarely appropriate/usually not appropriate.

(See Guidelines on Page 27 for further recommendations.)

- 2.1.2C <u>Technical Quality Review</u>: The practice must evaluate the technical quality of the images and the safety of the procedure. The review of the clinical image quality must include but is not limited to the evaluation of:
 - 2.1.2.1C review of the clinical images for clarity of the images and / or evaluation for suboptimal images or artifact;
 - 2.1.2.2C completeness of the study; and
 - 2.1.2.3C adherence to the facility imaging acquisition protocols.

(See Guidelines on Page 27 for further recommendations.)

2.1.3C <u>Interpretive Quality Review</u>: The practice must evaluate the quality and accuracy of the interpretation based on the acquired images.

(See Guidelines on Page 27 for further recommendations.)

- 2.1.4C <u>Final Report Completeness and Timeliness</u>: The practice must evaluate the final report for completeness and timeliness as required in the Standards.
- 2.1.5C Radiation Safety:
 - 2.1.5.1C The practice must evaluate patient radiation dose to include:
 - i. documentation of dosimetry data ranges (DLP; CTDIvol or dose as recorded on the system per sequence or cumulative per examination) for protocols used in the facility based on patient age and habitus;
 - ii. tracking of repeat CT examinations; and
 - iii. comparison of the patient radiation dose for each imaging protocol as determined by a medical physicist or qualified expert.
 - 2.1.5.2C The practice must document the available dose reduction techniques and clinical indications/contraindications for their use.
 - 2.1.5.3C The practice must review the results of staff occupational radiation exposure monitoring according to state regulations.

Section 2C: Quality Improvement Measures *Guidelines*

2.1.1C <u>Test Appropriateness:</u>

- A mechanism should be in place for education of referring dentists or physicians to improve the appropriateness of testing.
- A program for education and reporting should be developed and may include but is not limited to:
 - Patterns of adherence to Appropriate Use Criteria (AUC);
 - o Baseline rates of adherence;
 - o Goals of improvement of adherence to AUC;
 - o Measurement of improvement rate; and
 - Confidential comparison reports on patterns of adherence in aggregate by ordering dentist or physician, ordering practice and interpreting practice.

2.1.2C <u>Technical Quality Review</u>:

- Peer review may also be used to compare reproducibility.
- Dentists and physicians and technologists should be involved in the peer review process in order to achieve standardized protocols.
- Results of the peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve dentist, physician, technologist and patient confidentiality.
- Thresholds should be determined for each indicator (e.g., a threshold for the percentage of scans that should be free from motion artifact=90%).

2.1.3C Interpretive Quality Review:

- Peer review may be used to compare reproducibility of interpretation with previous interpretation, or with interpretation of the same study by other qualified dentists or interpreting physicians.
- Dentists and physicians should be involved in the peer review process in order to achieve standardized reporting.
- Results of peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve dentist, physician, technologist, and patient confidentiality.
- Clinical correlation and confirmation of results: For patient who have undergone CT examinations and surgical intervention or treatment, the results of the CT examination and other procedures may be compared. A process for reviewing variations between CT examination results and results of other procedures may be in place.

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

- 3.1C The practice must have a minimum of two QI meetings per year.
 - 3.1.1C The content of at least one meeting per year must include the reviews the results of the QI analyses.
 - 3.1.2C All staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation

- 4.1C QI Documentation and Record Retention
 - 4.1.1C The practice QI documentation must include, but not be limited to:
 - 4.1.1.1C the data for all of the QI measures above;
 - 4.1.1.2C a description of how the QI information is used to improve CT quality; and
 - 4.1.1.3C minutes from the QI meetings.
 - i. Participant list (may include remote participation and/or review of minutes).
 - 4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

Bibliography

- 1. American Association of Physicists in Medicine Report No. 3. Assessment of display for medical imaging systems. www.aapm.org/pubs/reports/OR_03.pdf
- 2. American Association of Physicists in Medicine Report No. 1. Phantoms for performance evaluation and quality assurance of CT scanners. www.aapm.org/pubs/reports/OR 03.pdf
- 3. Gray, J. E., Archer, B. R., Hobbs, B. B., Mettler, F. A., & et al. (2005). Reference values for diagnostic radiology: Application and impact. Radiology, 235, 354-358.
- 4. International Commission on Radiation Protection (ICRP) Publication 84. Pregnancy and Medical Radiation. www.icrp.org/docs/ICRP-84 Pregnancy s.pps
- 5. International Commission on Radiation Protection (ICRP) Report 87. CT Dose Management. www.icrp.org/docs/ICRP_87_CT_s.pps
- 6. National Council on Radiation Protection & Measurements (NCRP) (2004). Structural shielding design for medical x-ray imaging facilities report 147.
- 7. Prasad, K.N., Cole, W.C., & Haase, G.M. (February 2004). Radiation protection in humans: Extending the concept as low as reasonably achievable (ALARA) from dose to biological damage. British Journal of Radiology, 914, 97-9.
- 8. U.S. Food and Drug Administration Center for Devices and Radiological Health (CDRH) (2006). Performance standards for ionizing radiating products. Code of Federal Regulations: 21 CFR Sect. 1020.33. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1020.33
- 9. New Jersey Department of Environmental Protection. (2001). Compliance guidelines for computed tomography quality control. www.state.nj.us/dep/rpp/download/ctcgd.pdf