



American National Standard/  
American Dental Association  
**Standard No. 1110-1**

# Dentistry — Validation Dataset Guidance for Image Analysis Systems Using Artificial Intelligence, Part 1: Image Annotation and Data Collection

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**Standards Consensus Body 12—AI and Knowledge Management**

**ADA** American  
Dental  
Association®



## **AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 1110-1 FOR DENTISTRY - VALIDATION DATASET GUIDANCE FOR IMAGE ANALYSIS SYSTEMS USING ARTIFICIAL INTELLIGENCE, PART 1: IMAGE ANNOTATION AND DATA COLLECTION**

The American Dental Association is an ANSI-Accredited Standards Developing Organization (since March 2000). The ADA's Standards Program is comprised of twelve standards Consensus Bodies, each with their own focused scope of work and representation from appropriate interests in the United States in the standardization of products and technologies within its scope. Consensus Bodies review and approve proposed standards and technical reports developed by its affiliated Working Groups.

Standards approved as ADA Standards by an ADA Consensus Body are eligible to be forwarded to the American National Standards Institute (ANSI) for approval as an American National Standard (thus creating an ANSI/ADA Standard). The American National Standards Institute granted approval of ADA Standard No. 1110-1 as an American National Standard on January 27, 2025.

The scope of ADA Consensus Body 12 on AI and Knowledge Management is:

*Development of standards deliverables for nomenclature and requirements for quality, integrity, aggregation, organization and analysis of patient-centric information, knowledge representation and artificial intelligence for dentistry.*

ADA Consensus Body 12 has representation from appropriate interests in the United States in the standardization of products and technologies within its scope.

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This is the first edition of ANSI/ADA Standard No. 1110-1.

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ANALYSIS SYSTEMS USING ARTIFICIAL INTELLIGENCE, PART 1: IMAGE  
ANNOTATION AND DATA COLLECTION**

**Foreword**

(This Foreword does not form a part of ADA Standard No. 1110-1 for Dentistry - Validation Dataset Guidance for Image Analysis Systems Using Artificial Intelligence, Part 1: Image Annotation and Data Collection).

A task group of ADA Working Group 12.7 on Artificial and Augmented Intelligence in Dentistry, chaired by Kimberly Harding, prepared ANSI/ADA Standard No. 1110-1 at the request of Robert Faiella, chair, Working Group 12.7 and Gary Guest, chair, ADA Consensus Body 12 on AI and Knowledge Management.

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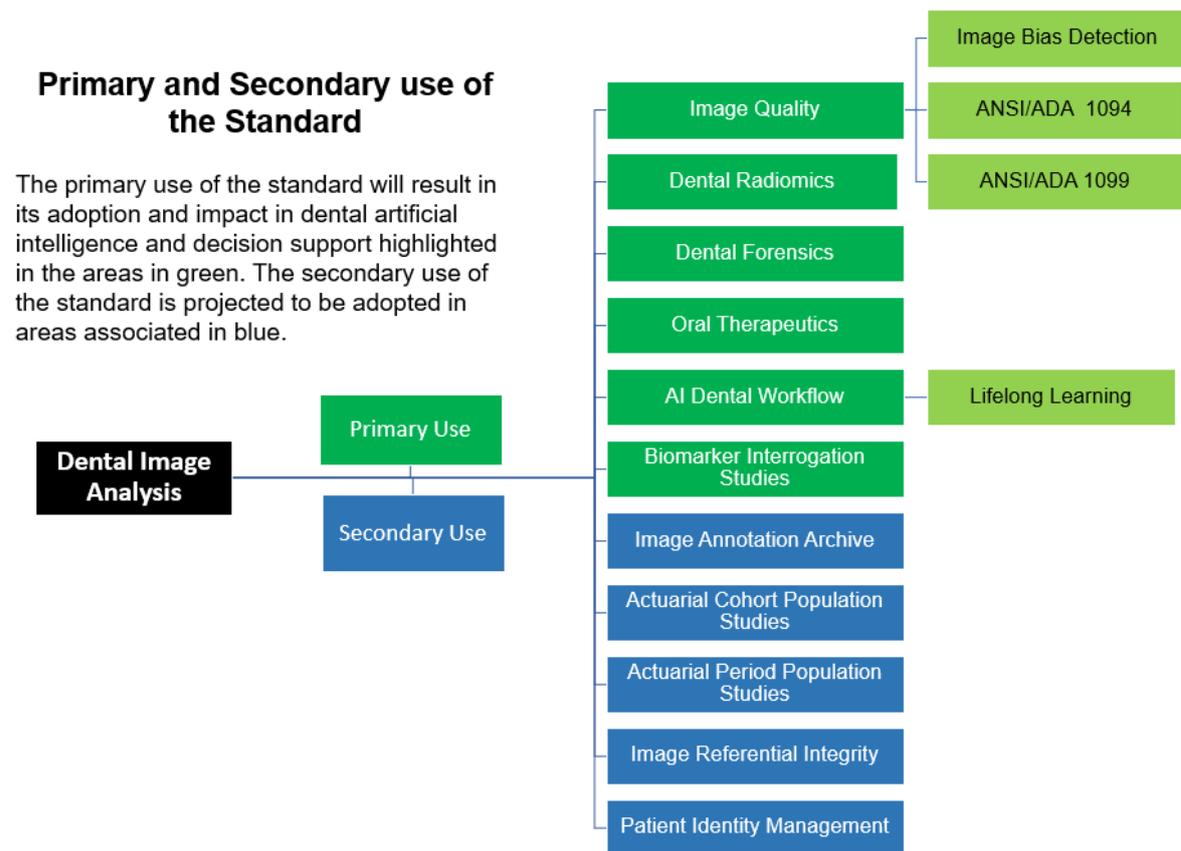
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## Introduction

The purpose of this standard is to provide dental image annotation and data collection standard criteria on 2D radiographs, for the purposes of image classification and recognition for use in clinical decision support. As a result, Artificial Intelligence (AI) can become a great utility within oral health care settings through these standardized image annotation practices. This standard includes AI image analysis associated with machine learning and deep learning efforts for diagnosis, treatment, administrative, research and development efforts.

## Use of AI in Dentistry for Clinical Decision Support

### The Value of Standard: AI Image Annotation & Data Collection



## Ethics of AI in Imaging

We are adapting excerpts of the “Ethics of Artificial Intelligence in Radiology: Summary of the Joint European and North American Multi-society Statement” [This is a condensed summary of an international multi-society statement on ethics of artificial intelligence in radiology produced

by the ACR, European Society of Radiology, RSNA, Society for Imaging Informatics in Medicine, European Society of Medical Imaging Informatics, Canadian Association of Radiologists, and American Association of Physicists in Medicine.] , as an ethical and normative reference for this standard, to be included in dental-based AI governance practices. The adapted excerpts below for dentistry, described how their principles for applying best practices to protect patients against the misuse of AI, and raise awareness to all key stakeholders (i.e. suppliers, producers, auditors, analysts, distributors, and consumers) of the technology of its value to patient care.

### **Key Ethical Issues as Radiology Incorporates Artificial Intelligence Products into Clinical Practice**

- Patient and provider risks associated with AI implementation must be assessed; this includes who is accountable in case of a sentinel event or wrong diagnosis.
- Determine which education and skills are needed to safely apply to your patients.
- Ensure that testing data accurately reflects the targeted clinical cohort.
- Establish processes to monitor the impact (outcomes, privacy, and unintended discrimination) of AI on your patients and dental care providers (automation bias).
- Monitor AI-driven autonomous and intelligent tools to verify they are working as expected in clinical care.
- Establish guardrails to determine when, and when not, to implement autonomous or intelligent mechanical agents.

### **Operations**

When an AI model is implemented, those responsible for any part of its life cycle should be able to answer these and other similar questions about the ethics of algorithms:

- Is the AI model transparent or an Interpretive AI model? Are you able to explain the compliant and non-compliant outcomes of the AI model “how it makes decisions” or at least reliably predict the results of our AI analysis in known data sets?
- How do you protect against malicious attacks on AI tools and data?
- How do you create sustainable version control for AI data, algorithms, models, and vended products?
- How will you minimize the risk of patient harm from malicious attacks and privacy breaches?
- How will you evaluate trained models before clinical application, for clinical effectiveness, ethical behavior, and security?
- How will you monitor AI models in clinical workflow to ensure they perform as predicted and that performance does not degrade over time?

### **Cybersecurity and Privacy for Patient Image Data**

This includes pre-conditions to data collection, image acquisition, images in transit and images at rest, to image acquisition and secondary storage systems.

- Ensure compliance to HIPAA-HITRUST
- Enable anonymization of patient information and de-identification from images under informed consent when sharing images

- Develop and maintain protocols to protect against malicious duplication of images (i.e., deep fakes and counterfeit copies)

### **Use of AI in Practice**

As radiology incorporates autonomous and intelligent AI products into widespread, demanding clinical practice, those responsible should be able to answer these and other similar questions about the ethics of this new practice paradigm:

- What are the patient and provider risks associated with this AI implementation, and what level of human oversight is necessary to mitigate these risks?
- What education and skills are needed to decide whether to apply AI to your patients and to use it safely and effectively when appropriate?
- How do you ensure that testing data accurately reflects the targeted clinical cohort?
- What processes should you implement to monitor the impact (outcomes, privacy, and unintended discrimination) of AI on our patients and providers (automation bias)?
- How do you continuously and actively monitor AI-driven autonomous and intelligent tools to verify they are working as expected in clinical care?
- What guardrails should you use to determine when, and more importantly when not, to implement autonomous or intelligent mechanical agents?

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## 1 Scope

This dental artificial intelligence standard identifies the required image data content and annotations for 2D radiographic image data analysis, to support AI-based decision support used for clinical and non-clinical research and development, patient care and administrative efforts.

This standard does not prescribe or endorse any specific AI implementation methodology or implementation guide for adoption.

NOTE: This is an initial definition of image annotation which will evolve as the science of AI matures across the domain of oral health.

## 2 Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ANSI/ADA Standard No. 33, *Vocabulary Used in Dental Standards Development*

ANSI/ADA Standard No. 1094, *Quality Assurance for Digital Intra-oral Radiographic Systems*

ANSI/ADA Standard No. 1099, *Dentistry – Quality Assurance for Digital Panoramic and Cephalometric Radiographic Systems*

ISO/ANSI/ADA Standard No. 3950, *Designation system for teeth and areas of the oral cavity* (Available at ADAStore.org)

*ADA Code on Dental Procedures and Nomenclature (CDT)*

*ADA Systemized Nomenclature of Dentistry (SNODENT)*  
(Available at ADA.org)

*DICOM — Digital Imaging and Communications in Medicine*, NEMA Publication PS 3.1-PS 3.22  
(Available at <https://www.dicomstandard.org>)

*HL7® Consolidated Clinical Document Architecture (C-CDA)®*

*HL7® Version 2*

*HL7® FHIR®*  
(Available at <https://www.HL7.org>)

ISO 1942, *Dentistry — Vocabulary*

ISO/IEC TR 24368:2022, *Information technology — Artificial intelligence — Overview of ethical and societal concerns*

ISO/IEC 23894:2023, *Information technology — Artificial intelligence — Guidance on risk management*

ISO/IEC 5259-1:2024, *Artificial intelligence — Data quality for analytics and machine learning (ML)Part 1: Overview, terminology, and examples*

ISO/IEC 5259-3:2024, *Artificial intelligence — Data quality for analytics and machine learning (ML)Part 3: Data quality management requirements and guidelines*

ISO/IEC 5259-4:2024, *Artificial intelligence — Data quality for analytics and machine learning (ML)Part 4: Data quality process framework*

(Available at [ansi.org](https://ansi.org))

NIST AI 100-1, *Artificial Intelligence Risk Management Framework (AI RMF 1.0)*

(Available at <https://doi.org/10.6028/NIST.AI.100-1>)

*SNOMED Clinical Terminology (CT)*

(Available at [www.snomed.org/get-snomed](https://www.snomed.org/get-snomed))

### 3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ANSI/ADA Standard No. 33/ISO 1942 and the following apply.

#	Term	Definition	Source
<b>DICOM Terms</b>			
1	AI Hallucinations	<p>Hallucinations: AI hallucinations, also known as generative AI hallucinations, are when an artificial intelligence (AI) model produces inaccurate, misleading, or illogical information. These errors can occur in a variety of forms, such as when image recognition systems see objects that aren't there or language models generate nonsensical text.</p> <p>Insufficient data sets when training an AI model can increase the propensity of hallucination outcomes.</p>	<p>Published in final edited form as: J Am Coll Radiol. 2023 Sep; 20(9): 842–851.</p> <p>Published online 2023 Jul 27. doi: 10.1016/j.jacr.2023.06.025</p> <p>PMCID: PMC11192466</p> <p>NIHMSID: NIHMS1999605</p> <p>PMID: 37506964</p> <p>“Shortcuts” Causing Bias in Radiology Artificial Intelligence: Causes, Evaluation, and Mitigation</p>
2	Classic Image Storage SOP Class	An Image Storage SOP Class that is defined by an IOD that stores a single frame and defines the majority of the Attributes in the top-level Data Set.	Digital Imaging and Communications in Medicine (DICOM)

#	Term	Definition	Source
3	Combined Print Image	A pixel matrix created by superimposing an image and an overlay, the size of which is defined by the smallest rectangle enclosing the superimposed image and overlay.	Digital Imaging and Communications in Medicine (DICOM)
4	Dental Image and Data Repository	A data library or archive of dental images and structured and unstructured data sets. It may consist of one or more database management systems that collect, manage, and store patient-level data for treatment, healthcare operations, or research.	New term
5	Enhanced Image Storage SOP Class	An Image Storage SOP Class that is defined by an IOD that stores multiple frames and defines the majority of the Attributes in Functional Group Sequences.	Digital Imaging and Communications in Medicine (DICOM)
6	Legacy Converted Enhanced Image Storage SOP Class	A modality-specific Enhanced Image Storage SOP Class that is defined by an IOD that defines only generic Functional Group Sequences, which does not require information that is not present in Classic Image Storage SOP Class Instances and is intended for storage of converted Classic Image Storage SOP Class Instances when there is insufficient information to use a True Enhanced Image Storage SOP Class.	Digital Imaging and Communications in Medicine (DICOM)
7	Meta Service-Object Pair Class (Meta SOP Class)	A pre-defined set of SOP Classes that may be associated under a single SOP for the purpose of negotiating the use of the set with a single item.	Digital Imaging and Communications in Medicine (DICOM)
8	Non-Patient Object	A SOP Instance that adheres to a Composite Instance IOD Information Model specified in PS3.3, but does not have the Patient Information Entity as its root. Non-Patient Object SOP Instances may still contain patient-related identifiable information, e.g., Inventory SOP Instances	Digital Imaging and Communications in Medicine (DICOM)
9	Performed Procedure Step SOP Class	Any SOP Class that encodes the details about the performance of a procedure step.	Digital Imaging and Communications in Medicine (DICOM)
10	Performed Procedure Step SOP Instance	An instance of a Performed Procedure Step SOP Class. Note that all UPS instances are instances of the UPS Push SOP Class, which is capable of encoding details about the performance of a procedure step (in addition to details about the scheduled procedure step) and thus qualify as an instance of a Performed Procedure Step SOP Class.	Digital Imaging and Communications in Medicine (DICOM)

#	Term	Definition	Source
11	Preformatted Grayscale Image	An image where all annotation, graphics, and grayscale transformations (up to and including the VOI LUT) expected in the printed image have been burnt in or applied before being sent to the SCP. It is a displayable image where the polarity of the intended display is specified by Photometric Interpretation (0028,0004).	Digital Imaging and Communications in Medicine (DICOM)
12	Preformatted Color Image	An image where all annotation, graphics, and color transformations expected in the printed image have been burnt in or applied before being sent to the SCP.	Digital Imaging and Communications in Medicine (DICOM)
13	Real-World Activity	That which exists in the real world that pertains to specific area of information processing within the area of interest of the DICOM Standard. Such a Real-World Activity may be represented by one or more computer information metaphors called SOP Classes.	Digital Imaging and Communications in Medicine (DICOM)
14	Real-World Object	That which exists in the real world upon which operations may be performed that are within the area of interest of the DICOM Standard. Such a Real-World Object may be represented through a computer information metaphor called a SOP Instance.	Digital Imaging and Communications in Medicine (DICOM)
15	Related General SOP Class	A SOP Class that is related to another SOP Class as being more generalized in terms of behavior defined in the Standard, and that may be used to identically encode an instance with the same Attributes and values, other than the SOP Class UID. In particular, this may be the SOP Class from which a Specialized SOP Class (see PS3.2) is derived.	Digital Imaging and Communications in Medicine (DICOM)
16	Service Class User (SCU)	The role played by a DICOM Application Entity (DIMSE-Service-User) that invokes operations and performs notifications on a specific Association.	Digital Imaging and Communications in Medicine (DICOM)
17	Service Class Provider (SCP)	The role played by a DICOM Application Entity (DIMSE-Service-User) that performs operations and invokes notifications on a specific Association.	Digital Imaging and Communications in Medicine (DICOM)
18	Service Class	A collection of SOP Classes and/or Meta SOP Classes that are related in that they are described together to accomplish a single application.	Digital Imaging and Communications in Medicine (DICOM)
19	Service-Object Pair Instance (SOP Instance)	A concrete occurrence of an Information Object that is managed by a DICOM Application Entity and may be operated upon in a communication context defined by a specific set of DIMSE Services (on a network or interchange media). A SOP Instance is	Digital Imaging and Communications in Medicine (DICOM)

#	Term	Definition	Source
		persistent beyond the context of its communication.	
20	True Enhanced Image Storage SOP Class	A modality-specific Enhanced Image Storage SOP Class that is defined by an IOD that defines modality-specific Functional Group Sequences, Attributes and sets of values, and is intended for creation by acquisition devices.	Digital Imaging and Communications in Medicine (DICOM)
<b>Terms and Definitions: Patient Data Description</b>			
21	Address	The address of the patient.	ADA Dental Claim form Completion Instructions
22	City/ State/ Zip	The city, state, and zip code of the patient.	ADA Dental Claim form Completion Instructions
23	Date of Birth	The date of birth of the patient.	ADA Dental Claim form Completion Instructions
24	Gender (M/F/U)	The gender of the patient.	ADA Dental Claim form Completion Instructions
25	Name (Last, First, Middle, Initial, Suffix)	Name of the patient.	ADA Dental Claim form Completion Instructions
26	Patient ID (Assigned by Dentist)	The unique identifier assigned by the provider to the patient.	ADA Dental Claim form Completion Instructions
<b>Procedure Data Description</b>			
27	Area of oral cavity	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
28	Description	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
29	Secondary Diagnosis Code	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
30	Primary Diagnosis	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
31	Procedure Code	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
32	Procedure date	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
33	Tooth Number(s) or Letter(s)	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
34	Tooth Surface(s)	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions

<b>Terms and Definitions: Patient Data Description</b>			
<b>35</b>	Tooth System	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>Treatment Data Description</b>			
<b>36</b>	Auto Accident State	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>37</b>	Date of Accident	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>38</b>	Missing Teeth Information: Permanent: 1-32	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>39</b>	Missing Teeth Information: Primary: A-T	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>40</b>	Place of Treatment: Home	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>41</b>	Place of Treatment: Inpatient Hospital	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>42</b>	Place of Treatment: Nursing Facility	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>43</b>	Place of Treatment: Other (For all applicable places of treatment that the ADA references, please refer to <i>CMS Provider of Services File - Hospital &amp; Non-Hospital Facilities</i> .)	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>44</b>	Place of Treatment: Outpatient Hospital	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>45</b>	Place of Treatment: Provider's Office	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>46</b>	Place of Treatment: Skilled Nursing Facility	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>47</b>	Place of Treatment: Telehealth	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>48</b>	Replacement of Prosthesis (Y/N) if Y, Provide date of prior placement.	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>49</b>	Treatment of Orthodontics Indicator (Y/N) If Y, provide date appliance place and months of treatment remaining.	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>50</b>	Treatment resulting from auto accident	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>51</b>	Treatment resulting from occupational illness/injury	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions

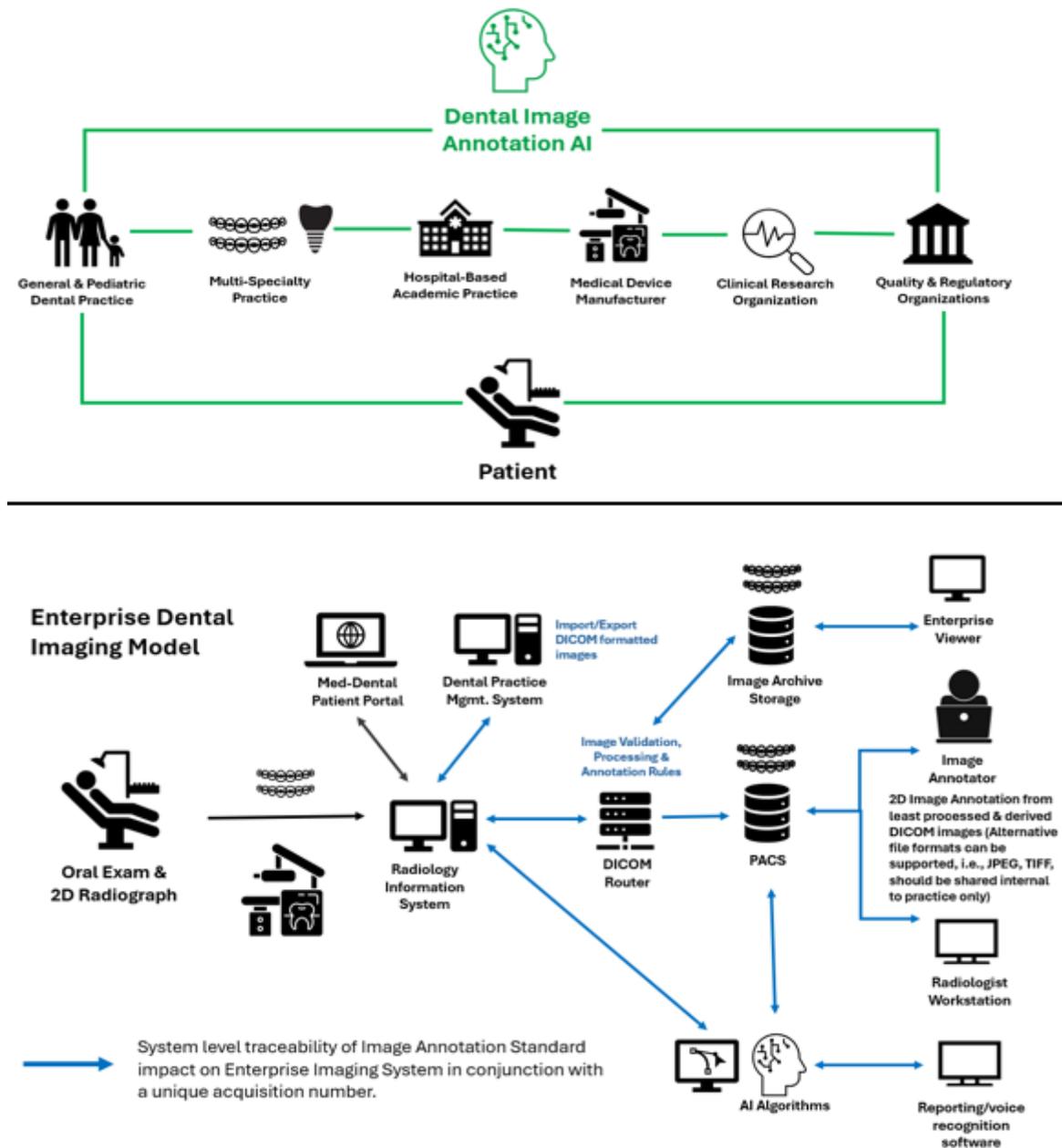
<b>Terms and Definitions: Patient Data Description</b>			
<b>52</b>	Treatment resulting from other accident	See Dental Claim Form Instructions	ADA Dental Claim form Completion Instructions
<b>Image Annotation &amp; Data Labeling Quality Assurance</b>			
<b>53</b>	Accuracy	The fraction of total samples accurately predicted to the sum of the whole samples.	Recall, Specificity, Precision, F1 Scores and Accuracy (numpyinja.com)
<b>54</b>	Deep Fake	<p>Deepfake AI is a type of artificial intelligence used to create convincing images, audio and video hoaxes. The term describes both the technology and the resulting bogus content, and is a portmanteau of deep learning and fake.</p> <p>Deepfakes often transform existing source content where one person is swapped for another. They also create entirely original content where someone is represented doing or saying something they didn't do or say.</p> <p>The greatest danger posed by deepfakes is their ability to spread false information that appears to come from trusted sources.</p>	<a href="https://www.techtarget.com/whatis/definition/deepfake">https://www.techtarget.com/whatis/definition/deepfake</a>
<b>55</b>	Deep Learning	Deep learning is a method in artificial intelligence (AI) that teaches computers to process data in a way that is inspired by the human brain. Deep learning models can recognize complex patterns in pictures, text, sounds, and other data to produce accurate insights and predictions.	<a href="https://aws.amazon.com/what-is/deep-learning/#:~:text=Deep%20learning%20is%20a%20method,produce%20accurate%20insights%20and%20predictions.">https://aws.amazon.com/what-is/deep-learning/#:~:text=Deep%20learning%20is%20a%20method,produce%20accurate%20insights%20and%20predictions.</a>
<b>56</b>	F1 Score	F1 score computes the average of precision and recall, where the relative contribution of both of these metrics are equal to F1 score. The best value of F1 score is 1 and the worst is 0. What does this mean? This means a perfect model will have a F1 score of 1 – all of the predictions were correct.	<a href="https://arize.com/blog-course/f1-score/#:~:text=F1%20score%20compute%20the%20average,of%20the%20predictions%20were%20correct.">https://arize.com/blog-course/f1-score/#:~:text=F1%20score%20compute%20the%20average,of%20the%20predictions%20were%20correct.</a>

<b>Terms and Definitions: Patient Data Description</b>			
<b>57</b>	Inter-Annotator Agreement (Human-based interaction)	Inter-annotator agreement (IAA) is the degree of consensus or similarity among the annotations made by different annotators on the same data. It is a measure of how well the annotators follow the same guidelines, criteria, and standards for labeling the data.	<a href="https://www.linkedin.com/advice/1/how-do-you-measure-improve-inter-annotator-agreement#:~:text=Inter%2Dannotator%20agreement%20(IAA),standards%20for%20labeling%20the%20data.">https://www.linkedin.com/advice/1/how-do-you-measure-improve-inter-annotator-agreement#:~:text=Inter%2Dannotator%20agreement%20(IAA),standards%20for%20labeling%20the%20data.</a>
<b>58</b>	Inter-Annotator Agreement Reliability	Inter-annotator reliability (IAR) is the extent to which the annotations made by different annotators are valid, accurate, and trustworthy. It is a measure of how well the annotators capture the true or intended meaning, value, or category of the data.	<a href="https://www.linkedin.com/advice/1/how-do-you-measure-improve-inter-annotator-agreement#:~:text=Inter%2Dannotator%20agreement%20(IAA),standards%20for%20labeling%20the%20data.">https://www.linkedin.com/advice/1/how-do-you-measure-improve-inter-annotator-agreement#:~:text=Inter%2Dannotator%20agreement%20(IAA),standards%20for%20labeling%20the%20data.</a>
<b>59</b>	IOU: Intersection over union	Intersection over Union (IoU), also known as the Jaccard index, is the ratio of the 'area of intersection' to the 'area of the union' between the predicted and ground truth bounding boxes. Thus, the IoU meaning consists of the quantitative measurement of how well a predicted bounding box aligns with the ground truth bounding box.	<a href="https://www.viso.ai/what-is-intersection-over-union-iou/">What is Intersection over Union (IoU)? - viso.ai</a>
<b>60</b>	Least Processed Image	The least processed radiographic image is one where all user-controlled image processing or filters are turned off or minimized as much as possible and then the radiograph is acquired.	ANSI/ADA Standards 1099 and 1094
<b>61</b>	Negative predictive value	In machine learning, the negative predictive value is defined as the proportion of predicted negatives which are real negatives. It reflects the probability that a predicted negative is a true negative.	<a href="https://link.springer.com/referenceworkentry/10.1007/978-1-4419-9863-7_234#:~:text=Definition,negative%20is%20a%20true%20negative.">https://link.springer.com/referenceworkentry/10.1007/978-1-4419-9863-7_234#:~:text=Definition,negative%20is%20a%20true%20negative.</a>
<b>62</b>	Precision or Positive Predictive Value	In Machine Learning, the positive predictive value is defined as the proportion of predicted positives which are actual positives. It reflects the	<a href="https://link.springer.com/referenceworkentry/10.1007/978-1-4419-9863-7_256#:~:text=Definition,positive%20is%20a%20true%20positive.">https://link.springer.com/referenceworkentry/10.1007/978-1-4419-9863-7_256#:~:text=Definition,positive%20is%20a%20true%20positive.</a>

<b>Terms and Definitions: Patient Data Description</b>			
		probability a predicted positive is a true positive.	
<b>63</b>	Projectional image	Conventional dental radiographs are acquired by the projection of an image onto the image receptor and a such there is a radial magnification of the imaged object on the image receptor as well as a penumbra however an image acquired by CBCT is absent of magnification which has been shown to have a 1:1 accurate depiction of the anatomy.	Peter Mah
<b>64</b>	Orthogonal image	An orthogonal image is one that is acquired from a image such as CBCT where there is no image magnification.	Peter Mah
<b>65</b>	Specificity or True Negative Rate	The true negative rate (also called specificity), which is the probability that an actual negative will test negative. It is calculated as $TN / (TN + FP)$ . (TN = True Negative, FP = False Positive)	<a href="https://www.split.io/glossary/false-positive-rate/#:~:text=The%20true%20negative%20rate%20(also,as%20TN%2FTN%2BFP.">https://www.split.io/glossary/false-positive-rate/#:~:text=The%20true%20negative%20rate%20(also,as%20TN%2FTN%2BFP.</a>
<b>66</b>	Training Data Sets	Training data is an extremely large dataset that is used to teach a machine learning model. Training data is used to teach prediction models that use machine learning algorithms how to extract features that are relevant to specific business goals. For supervised ML (machine learning) models, the training data is labeled. The data used to train unsupervised ML models is not labeled.	<a href="https://www.techopedia.com/definition/33181/training-data">https://www.techopedia.com/definition/33181/training-data</a>
<b>67</b>	Unbiased (Biased mitigation techniques)	Free from bias, especially free from all prejudice and favoritism: eminently fair, an unbiased opinion.	<a href="https://www.merriam-webster.com/dictionary/unbiased#:~:text=%3A%20free%20from%20bias,a%20population%20parameter%20being%20estimated">https://www.merriam-webster.com/dictionary/unbiased#:~:text=%3A%20free%20from%20bias,a%20population%20parameter%20being%20estimated</a>

## 4 Dental Image Annotation in the Digital Dental Model

This clause depicts diagrams (Figure 1) that illustrate the 2D AI image annotation standard in the dental image workflow within the analog/digital dental domain. This provides the context of how the standard will be implemented, using the normative references and semantics associated with 2D image acquisition and annotation for AI image analysis (see Annex A, which provides the IHE workflow for AI imaging).



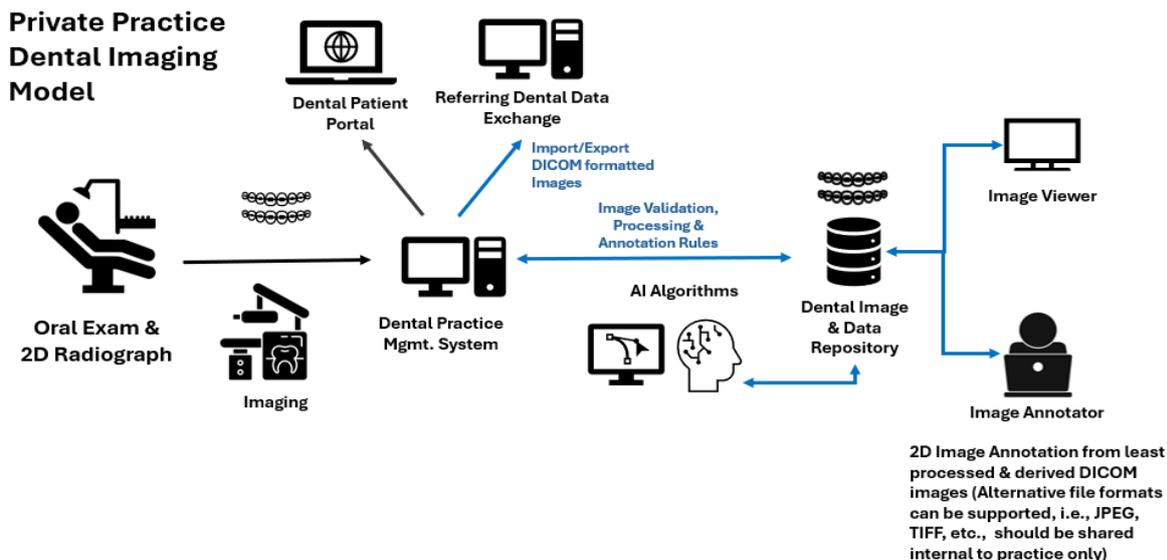


Figure 1.

Enterprise Dental Imaging Model [i.e. Large Hospital, Multi-Specialty Academic Facility] and Dental Private Practice Models with AI Integrated Systems, Supporting 2D Image Annotation Efforts Within an Oral Exam

### 5 Image Annotation Syntax and Semantic Methodology Recommendations for Dental Deep Learning systems (i.e., Lifelong learning Machines) Applying This Standard

This clause lists the required set of syntax, and semantic-based methodologies associated with 2D image annotation techniques used in dental imaging workflows that support the standard, to ensure consistent labeling of anatomical features of tooth number and surfaces (Figure 2). Given that radiographs are not free of visual defects during imaging acquisition or data exchange, it is a requirement of this standard to ensure that the terminology in Table 1 is adopted by the user as part of the lexicon of the standard for adherence.

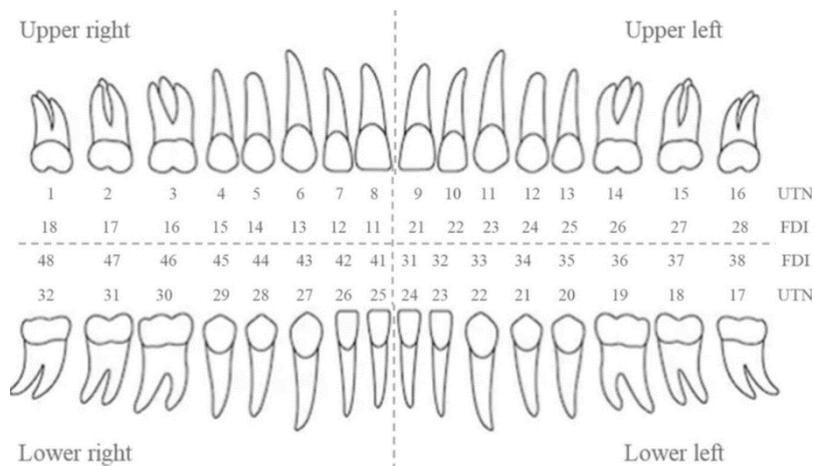


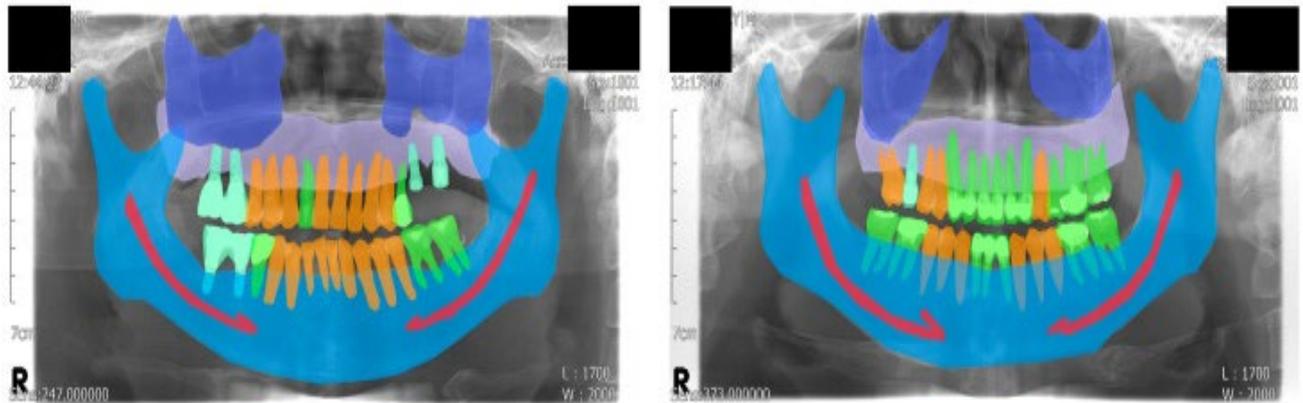
Figure 2. ISO 3950 System for Tooth Numbering

Source: Universal tooth numbering (UTN) system and Fédération Dentaire... | Download Scientific Diagram (researchgate.net))

**Table 1 – AI Dental Image Annotation Semantic and Syntax Models**

<b>AI Dental Image Annotation Semantic/Syntax</b>	<b>Origin of Term in Dentistry or AI Domain</b>	<b>How it is Used in 2D Dental Image Annotation</b>	<b>References</b>
Least Processed Image	New to standard	As stated in ANSI/ADA Standard 1094, the least processed image is produced when “User controlled image processing or filters are turned off or minimized as much as possible.” There is some image processing inherent in every manufacturer’s imaging product prior to the presentation image that is displayed in the imaging system.	New to standard
Image Optimization	Radiography system calibration	The process of image optimization is to ensure an accurate depiction of the anatomic features that are free of image artifact and that anatomic information is not removed that may be caused by image processing or the application of filters.	ANSI/ADA 1094, ANSI/ADA 1099
Data Presentation	Assistive AI Algorithms	AI analyses dental radiograph and highlights high-risk regions.	ANSI/ADA 1094, ANSI/ADA 1099
Clinical Decision Support	Assistive AI Algorithms	AI analyses dental radiograph and provides risk score that is interpreted by clinician.	ANSI/ADA 1094, ANSI/ADA 1099
Conditional Automation	Autonomous AI Algorithms	AI analyses dental radiograph and makes a recommendation for root canal, with a clinician always available as backup.	ISO/IEC 2382:2015
High Automation	Autonomous AI Algorithms	AI analyses dental radiograph and makes a recommendation for a root canal, without a clinician available as backup.	11065:1992, 04, ISO/IEC [ISO/IEC 2382-27:1994, ISO/IEC TS 30105-9:2023, 3.6, ISO/IEC/IEEE 24765:2017, 3.1357, ISO/IEC 2382:2015, 2123130, [ISO/IEC 2382-27:1994
Full Automation	Autonomous AI Algorithms	Same as level high automation but intended for use in all populations and systems. (User Interface Automation, Robotic Process	ISO/IEC TR 13066-2:2016, 2.40, ISO/TR 11065:1992, 04, ISO/IEC [ISO/IEC

AI Dental Image Annotation Semantic/Syntax	Origin of Term in Dentistry or AI Domain	How it is Used in 2D Dental Image Annotation	References
		Automation, Electronic Design Automation, office automation system).	2382-27:1994, ISO/IEC TS 30105-9:2023, 3.6, ISO/IEC/IEEE 24765:2017, 3.1357, ISO/IEC 2382:2015, 2123130, [ISO/IEC 2382-27:1994
Orthopantomography panoramic teeth radiograph dataset (OPG)	Radiology	An Orthopantomogram (OPG) or Dental Panoramic Radiograph is a panoramic scanning dental radiograph of the upper and lower jaw. It shows a two-dimensional view of both the jaws from ear to ear.	Source: Sensors   Free Full-Text   Deep Learning Models for Classification of Dental Diseases Using Orthopantomography X-ray OPG Images (mdpi.com)
Modified Palmer Notation (MPN)	Palmer Notation	Automatic Teeth Recognition for 2D Dental Panoramic Radiographic Images for Deep Learning AI systems using CNN-based architecture models. [source: <a href="https://link.springer.com/chapter/10.1007/978-981-33-4582-9_5">https://link.springer.com/chapter/10.1007/978-981-33-4582-9_5</a> ].	ISO 3950
Panoptic Segmentation (See Figure 3)	Panoptic Segmentation	Deep Learning-Based Segmentation of Various Structures Including Maxillary Sinus and Mandibular Canal using CNN-based architecture models. [source: Cha J-Y, Yoon H-I, Yeo I-S, Huh K-H, Han J-S. Panoptic Segmentation on Panoramic Radiographs: Deep Learning-Based Segmentation of Various Structures Including Maxillary Sinus and Mandibular Canal. <i>Journal of Clinical Medicine</i> . 2021; 10(12):2577. <a href="https://pubmed.ncbi.nlm.nih.gov/34208024/">https://pubmed.ncbi.nlm.nih.gov/34208024/</a>	Deep learning-based panoptic segmentation: Recent advances and perspectives - Chuang - 2023 - IET Image Processing - Wiley Online Library
Image Annotation Pedigree	New to standard	The consistent meta data that is physically and/or logically linked to an image, to ensure referential integrity (i.e., provenance) of the image and labeling to the source systems that initially acquired them and its reference to a unique patient. The criteria for meeting image annotation pedigree should meet the requirements outlined in sections 8, 9, 11 and 12 of this standard for DICOM conformant systems.	New to standard

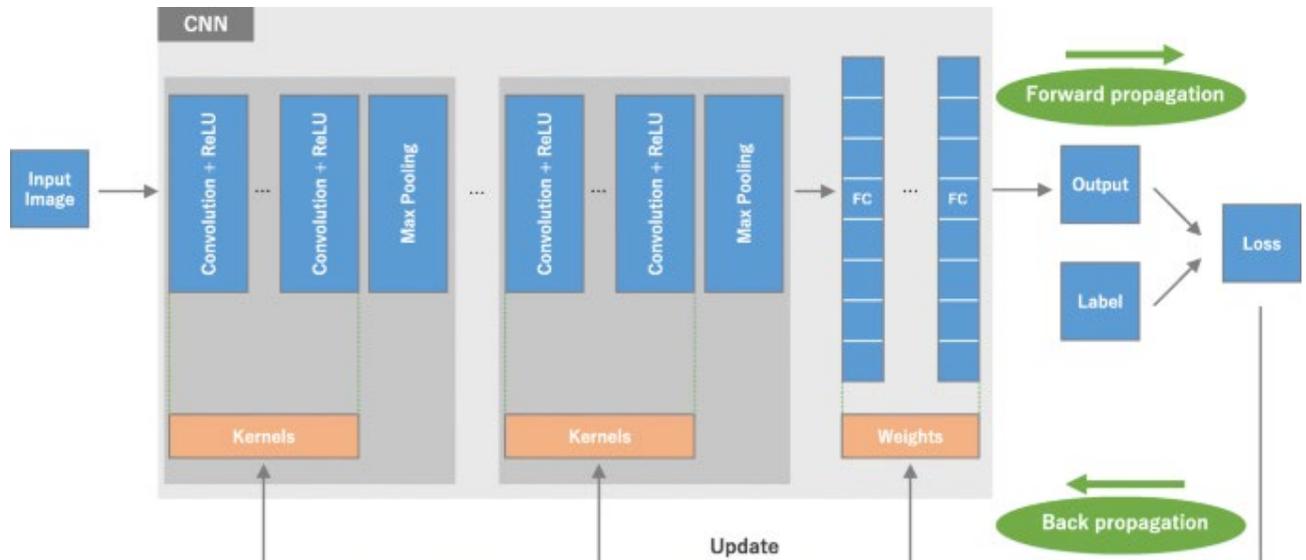


**Figure 3 – Example Panoptic Segmentation**

Visualized examples of the annotation results. A total of eight classes were used, including the background class. Four classes were assigned to semantic segmentation: maxillary sinus, maxilla, mandibular canal, and mandible. Three classes were assigned to instance segmentation: normal tooth, treated tooth, and dental implant.

[Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8230590/figure/jcm-10-02577-f001/>]

## 6 AI Reference Architecture Model Recommendation for Dental AI Image Annotation and Classification



**Figure 4 – Convolutional Neural Network Application in Radiology and the AI Data Training Process**

[Source: <https://insightsimaging.springeropen.com/articles/10.1007/s13244-018-0639-9>]

A convolutional neural network (CNN) (figure 4.) is composed of a stacking of several building blocks: convolution layers, pooling layers (e.g., max pooling), and fully connected (FC) layers. A model's performance under particular kernels and weights is calculated with a loss function through forward propagation on a training dataset, and learnable parameters, i.e., kernels and weights, are updated according to the loss value through backpropagation with gradient

descent optimization algorithm. ReLU, rectified linear unit [Source: <https://insightsimaging.springeropen.com/articles/10.1007/s13244-018-0639-9>]

## **6.1 Selection of AI Reference Architecture Model to Support Image Classification and Pattern Recognition for 2D Image Annotation and Labeling**

This subclause focuses on an AI reference architecture model that is required to support the DICOM Image Object Displays (IODs) for image annotation. There are several established and many emerging AI reference architecture models used within healthcare, the life sciences, and imaging specifically, that specialize in supporting 2D imaging annotation capabilities. The CNN reference architecture model is one of the AI architecture patterns that meets the criteria of conformance for the standard when used in conjunction with the specifications of this document.

### **6.1.1 CNN Reference Architecture Criteria for Required Use with the Standard**

CNN-based AI architecture models have been shown to support evidenced-based 2D image annotation and classification studies for deep learning architecture ecosystems in radiology for a variety of modalities, in both dental and medical disciplines. Some of the key attributes of CNN reference architectures are the following [Source: <https://www.nature.com/articles/s42256-022-00452-0>]:

- Transfer and adaptation
- Overcoming catastrophic forgetting
- Exploiting task similarity
- Task agnostic learning
- Noise tolerance
- Resource efficiency and sustainability

Therefore, given the dynamic nature and speed of AI innovation, we are highlighting the domain of CNN as an evidenced-based example for this standard. In terms of limitations related to CNN as a reference architecture, this standard cannot attest its efficacy for visible light images or 3D images.

## **6.2 Image Annotation, Data Collection, and Data Labeling Methods Requirements for Standard**

Table 2 is an approved listing of data labeling techniques that must be selected from for 2D image annotation in conjunction with the standard for compliance, including alternative formats, if necessary.

**Table 2 – Image Annotation and Data Collection Methods**

#	Method Name	DICOM Approach (Annotation, Data Collection, Labeling)	Image Annotation Standard Criteria	AI Architecture Model Use	Dental Normative Reference(s)	Alternative Formats to DICOM
1	Image Classification	Ideal image condition should be stored in its native image size or if it is stored with compression, it must be a Lossless Compression format (This is dependent upon the ability of the imaging system to recreate and store the radiograph in its native image size format if it the image is not compressed.).	The requestor has received the least or minimally processed image from the modality manufacturer attached with presentation states (pre-defined digitized views to enhance the image in an image viewer)	Agnostic	Visible Light is omitted. This only includes Gray Scale. ADA 1094, 1099, DICOM Standard (2023).	JPEG 2000, BMP, TIFF, PNG (Lossless compression formats)
2	HL7 FHIR (Fast Health Information Resource (Future) 4.x Image Study	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
3	Object Detection	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
4	Image Data Collections	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
5	Instance Segmentation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
6	2D Bounding Boxes	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
7	Semantic Segmentation (or picture segmentation)	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
8	Landmark & Key Annotation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1

#	Method Name	DICOM Approach (Annotation, Data Collection, Labeling)	Image Annotation Standard Criteria	AI Architecture Model Use	Dental Normative Reference(s)	Alternative Formats to DICOM
9	Polygon Annotation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
10	Line & Polyline Annotation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
11	Image Transcription	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
12	Text Annotation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1

## 7 Required AI Lifelong Learning Machines (LLL) Types Used in Conjunction with the Standard

Table 4 is an approved listing of training methodologies that must be selected from and be applied to LLL machines that rely upon 2D image annotation to execute its capabilities. Exclusions will apply to Visible Light only.

**Table 3 – AI LLL Machine Type Alignment to Standard**

#	LLL Training Methodology	DICOM Approach (Annotation, Data Collection, Labeling)	Image Annotation Standard Criteria	AI Architecture Model Use	Dental Normative Reference(s)	Exclusions
1	Developmental and Curriculum Learning	Ideal image condition should be stored in its native image size or if it is stored with compression, it must be a Lossless Compression format.	The requestor has received the least or minimally processed image from the modality manufacturer attached with presentation states (pre-defined digitized views to enhance the image in an image viewer)	Agnostic	ADA 1094, 1099, DICOM	Visible Light is omitted. This only includes Gray Scale.
2	Multi-Task Transfer Learning	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1

#	LLL Training Methodology	DICOM Approach (Annotation, Data Collection, Labeling)	Image Annotation Standard Criteria	AI Architecture Model Use	Dental Normative Reference(s)	Exclusions
3	Curiosity and Intrinsic Motivation	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
4	Crossmodal Learning	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
5	Deep Learning Survival Analysis	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1
6	YOLO (You Only Look Once) Real Time Object Detection	Same as row 1	Same as row 1	Same as row 1	Same as row 1	Same as row 1

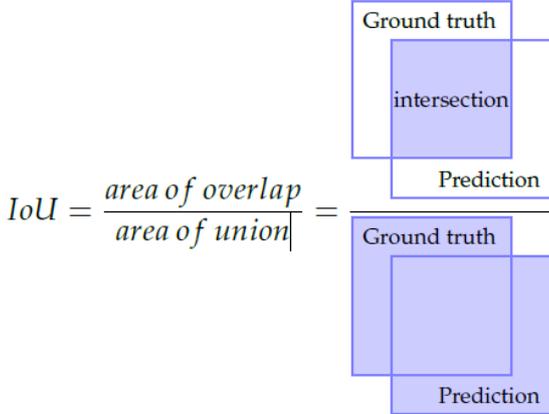
## 8 AI Image Annotation & Data Labeling Quality Assurance Requirements

Table 4 lists the required standard quality assurance criteria that shall be used for image annotation based on the detection of industry-identified quality error categories. This table can serve as an input for an Image Annotation Quality Assurance Plan and serve as an integral part of the quality control efforts when AI is being considered for image analysis of 2D dental images. All of the items in this list shall be examined from a quality control process to ensure consistent image annotation outcomes for input into the 2D image analysis development process is optimized.

**Table 4 – Image Annotation Standard Quality Assurance Criteria for Dental Imaging**

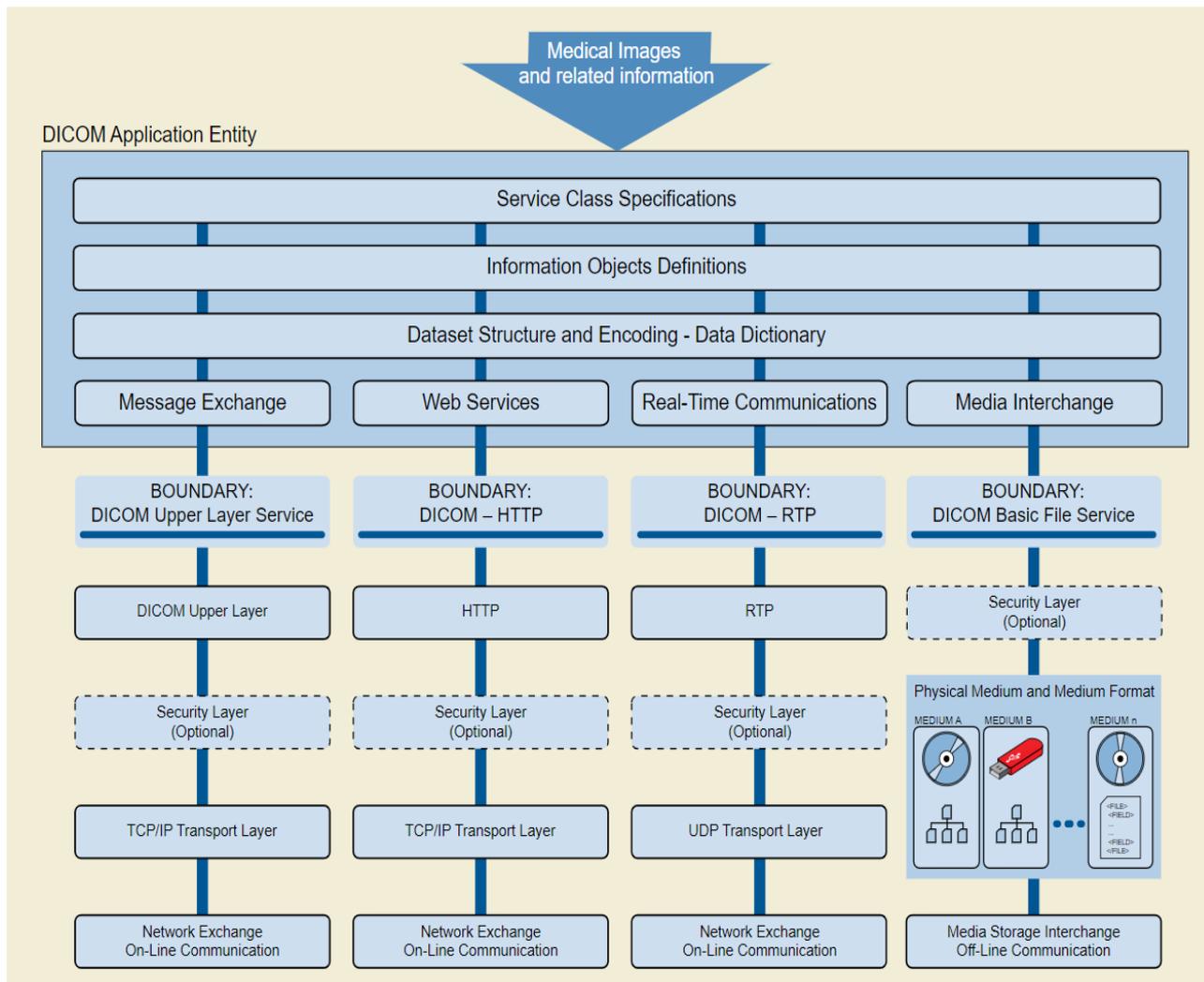
#	AI and Image Annotation QA Domain	AI Quality Assurance Normative References
0	<b>AI Governance</b>	<ul style="list-style-type: none"> <li>ISO/IEC TR 24368:2022 Information technology — Artificial intelligence — Overview of ethical and societal concerns</li> <li>ISO/IEC 23894:2023 Information technology — Artificial intelligence — Guidance on risk management</li> <li>ISO/IEC 5259-1:2024 Artificial intelligence — Data quality for analytics and machine learning (ML) Part 1: Overview, terminology, and examples</li> <li>ISO/IEC 5259-3:2024 Artificial intelligence — Data quality for analytics and machine learning (ML) Part 3: Data quality management requirements and guidelines</li> </ul>
0a	<b>AI Ethics</b>	
0b	<b>Risk Management</b>	
0c	<b>Business Continuity</b>	
0d	<b>Data Quality Process &amp; Regulatory Science</b>	

#	AI and Image Annotation QA Domain	AI Quality Assurance Normative References
		<ul style="list-style-type: none"> <li>ISO/IEC 5259-4:2024 Artificial intelligence — Data quality for analytics and machine learning (ML) Part 4: Data quality process framework</li> </ul>
<b>1</b>	<b>Image Annotation Errors</b>	<p>All areas within the table are required within ANSI/ADA 1094, ANSI/ADA 1099 and NIST AI 100-1 Artificial Intelligence Risk Management Framework.</p> <p><b>Recommended</b> It is recommended that the user reference Table 1, AI Dental Image Annotation Semantic and Syntax Models, to verify what level of AI is being used within the organization; Table 2, what kinds of image annotation and data collection methods are being used; and Table 3, what lifelong learning machines are being used to drive the user's Image Annotation QA planning strategy.</p>
1a	Image Quality (ANSI/ADA 1099 and ANSI/ADA 1094)	
1b	Occluded/Partial Subjects (i.e., overlapping images that are not diagnostic)	
1c	Overlapping Annotations	
1d	Image Annotation Procedures (i.e., DICOM Annotation Method)	
1e	Medical Tagging, Transcribing or Processing (i.e., DICOM Tag Image Type)	
1f	Image Annotation Meta Data	
<b>2</b>	<b>Image Annotation Machine Translation</b>	
2a	Terminology	
2b	Detection of AI Hallucination Results	
<b>3</b>	<b>Image Annotation Training Phrases</b>	
3a	Duplicates	
<b>4</b>	<b>Image Annotation Data Collection Quality</b>	
4a	Uniformity	
4b	Consistency	
4c	Comprehensiveness	
4d	Relevancy	
4e	Unbiased (Biased mitigation techniques)	
4f	Deep Fakes and Counterfeits	
<b>5</b>	<b>Entity Annotation</b>	
5a	Context	
<b>6</b>	<b>Image Data Labeling Quality</b>	
6a	F1 Score of 0.7	

#	AI and Image Annotation QA Domain	AI Quality Assurance Normative References
6b	<p>IOU: (Intersection over union) IOU is used to assess the accuracy of object detectors on a given dataset. It computes the intersection of two bounding boxes' union. The actual and predicted bounding boxes</p> <div style="text-align: center;">  <math display="block">IoU = \frac{\text{area of overlap}}{\text{area of union}}</math> </div> <p>are:</p> <p>Source: tikz pgf - Drawing intersection over union in equation - TeX - LaTeX Stack Exchange</p>	
6c	Inter-Annotator Agreement (Human-based interaction)	
6d	Inter-Annotator Agreement Reliability	
6e	Sensitivity/Recall or True Positive Rate	
6f	Specificity or True Negative Rate	
6g	Precision or Positive Predictive Value	
6h	Negative predictive value	
6i	Accuracy	
<b>7</b>	<b>Video Annotation</b>	
7a	Inconsistency	
<b>8</b>	<b>Computer Vision</b>	
8a	Deep Learning	
8b	Training Data Sets	

### 9 Image Annotation Standard Acceptance Criteria of the DICOM General Communication Model and DICOM Standard

The DICOM General Communication Model is a required protocol for the implementation of the standard. Therefore, this clause, including Table 5, provides a crosswalk of the standard’s alignment to the DICOM General Communication Model (Figure 5) and the DICOM Standard with an applicable syntax, semantic and format criteria component added as needed. This will enable the reader to understand how the standard is to be used in conjunction with the implementation of DICOM in the radiology workflow regardless of the radiology modality chosen.



**Figure 5 – DICOM General Communication Model**

[Source: [https://dicom.nema.org/medical/dicom/current/output/html/figures/PS3.1\\_5-1.svg](https://dicom.nema.org/medical/dicom/current/output/html/figures/PS3.1_5-1.svg)]  
 (DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)

**Table 5 – Image Annotation Standard Mapping to DICOM Standard**

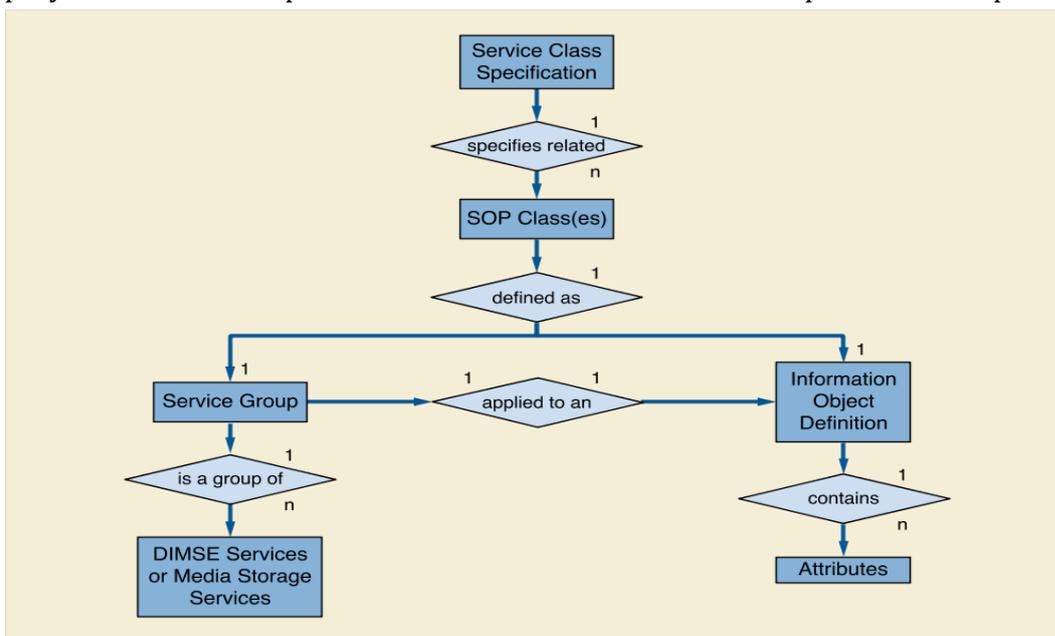
NOTE: This is a listing of the required technical capabilities of the DICOM standard that are necessary to implement as part of the adoption of the standard depending upon the modalities used.

#	DICOM Standard Section	Included in Standard (Y/N) (TBD by DICOM SMEs & WG)	Need to Apply Image Annotation Standard Syntax Criteria in Table 1. (Y/N, N/A)	Need to Apply Image Annotation Standard Semantics Criteria in Table 1. (Y/N, N/A)	Assumptions, Dependencies, Constraints, Exceptions
1	Conformance	Y	Y	Y	
2	Information Object Definitions (IOD)	Y	Y	Y	
3	Service Class Specifications	Y	Y	Y	
4	Data Structures and Encoding	Y	Y	Y	
5	Data Dictionary	Y	Y	Y	SNOMED/SNODENT, CDT
6	Message Exchange	Y	Y	Y	
7	Network Communication Support for Message Exchange	Y	Y	Y	
9	Media Storage Application Profiles	Y	Y	Y	
10	Media Formats and Physical Media for Media Interchange	Y	Y	Y	
12	Security and System Management Profiles	Y	Y	Y	
13	Content Mapping Resource	Y	Y	Y	
14	Explanatory Information	Y	Y	Y	
15	Web Services	Y (optional depending on solution architecture)	Y	Y	
16	Application Hosting	Y	Y	Y	
17	Imaging Reports using HL7 Clinical Document Architecture	Y (FHIR is also an option)	Y	Y	

#	DICOM Standard Section	Included in Standard (Y/N) (TBD by DICOM SMEs & WG)	Need to Apply Image Annotation Standard Syntax Criteria in Table 1. (Y/N, N/A)	Need to Apply Image Annotation Standard Semantics Criteria in Table 1. (Y/N, N/A)	Assumptions, Dependencies, Constraints, Exceptions
18	Transformations between DICOM and other Representations	Y	Y	Y	
19	Real-Time Communication	Y	Y	Y	

### 10 Minimum DICOM Data Set: Data Elements for Image Annotation Data Collection

This clause provides a listing of the minimum data set associated with the standard’s label (Figure 6). Each table consists of data descriptions that, jointly, enable the dental provider to conduct a CDT-level image verification inquiry and analysis. The process by which the image inquiry and validation is performed is determined between the requestor and responder.



**Figure 6 - DICOM Information Model**  
 (DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)  
 [Source: <https://dicom.nema.org/medical/dicom>]

### 10.1 DICOM Image Metadata included in Image Annotation Standard for Image Data Referential Integrity

This clause, including Table 6 and Figure 7, provides a listing and an example of the DICOM-based Image Annotation metadata that are required for this standard when performing 2D

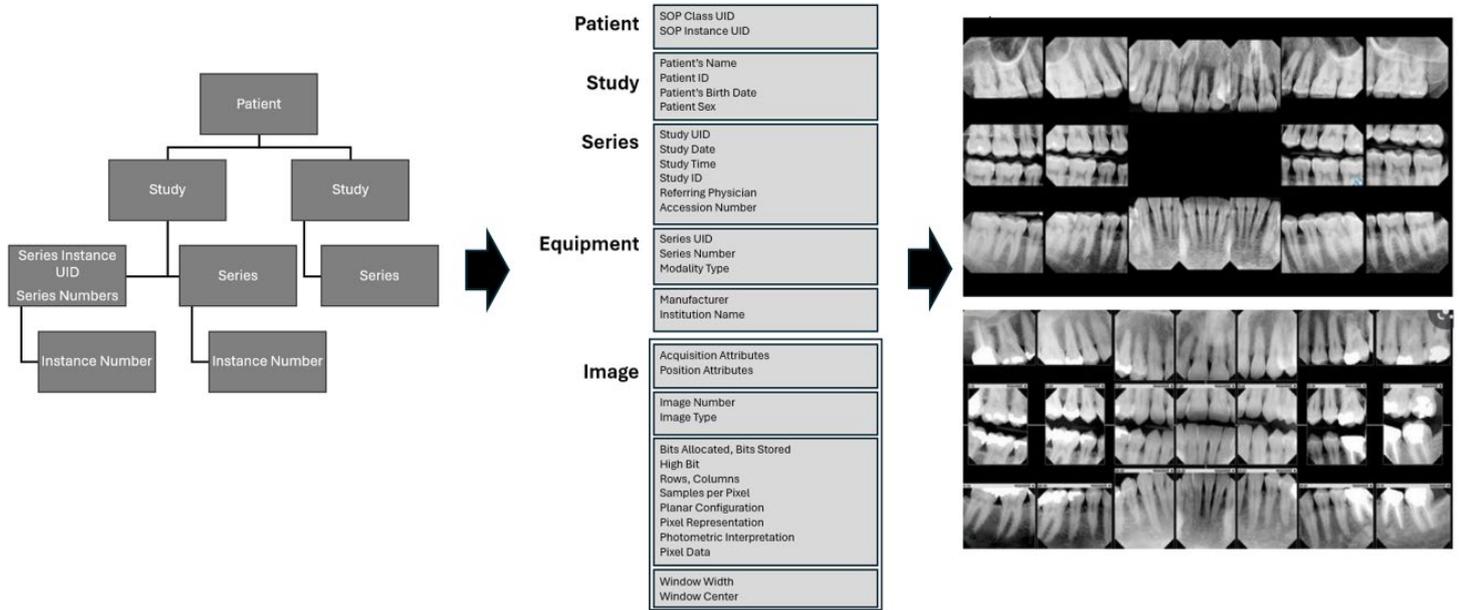


image annotation.

**Figure 7 – Image Object Display Diagram**  
(DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)

**Table 6 – DICOM Image Metadata Categories and Terms**

NOTE: This is a listing of the required data elements that must be captured and stored within a DICOM image for 2D image annotation. as defined by this standard. (DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)

#	DICOM Image Metadata Category	DICOM Image Metadata Term	Metadata for Image Annotation Criteria Required/Optional
1	Patient	SOP Class UID	All Required (except Intraoral sensor)
		SOP Instance UID	Required
2	Study	Study UID	Required
		Date of Study	Required
		Description	Required
		Refer Physician	Required
		Accession	Required
3	Series	Series UID	Required
		Modality	Required
		Description	Required

#	DICOM Image Metadata Category	DICOM Image Metadata Term	Metadata for Image Annotation Criteria Required/Optional
		Series Number	Required
		Body Part	Required
4	Equipment	Series UID	Required
		Series Number	Required
		Modality Type	Required
		Manufacturer	Required
		Institution Name	Required
5	Instance	Instance UID	Required
		Height (Rows)	Required
		Width (Columns)	Required
		Position	Required
		SOP Class UID	Required

## 11 Patient-Level Dental AI Image Annotation Provenance Data Dictionary

This clause, including Tables 7, 8, and 9, are the required data elements to complete a patient-level Image Annotation Dental Provenance Data Dictionary. The objective is to uniquely identify the clinical and administrative provenance of the image and its association with the patient, provider, and, if necessary, the payer organization for image referential integrity. This shall be included with the DICOM-level image annotation metadata in Table 6 on the image, as a means of traceability of the image to a unique patient and image source system(s). There are additional data elements that are optional and recommended, but not required, based on the needs of an organization for additional rigor for dental image referential integrity.

**Table 7 – Patient Data Description**

#	Patient Data Description	Metadata for Image Annotation Criteria Required, Optional	Patient-Level Referential Integrity Source System for Image Annotation	Normative Reference
1	Name (Last, First, Middle, Initial, Suffix)	Required	Practice Management System, EHR, RIS, PACS	ADA Claim Form, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA, DICOM
2	Date of Birth	Required	Practice Management System, EHR, RIS	ADA Claim Form, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA
3	City/ State/ Zip	Optional	Practice Management System, EHR, RIS	ADA Claim Form, DICOM Standard, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA

#	Patient Data Description	Metadata for Image Annotation Criteria Required, Optional	Patient-Level Referential Integrity Source System for Image Annotation	Normative Reference
4	Gender (M/F/U)	Optional	Practice Management System, EHR, RIS	ADA Claim Form, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA
5	Address	Optional	Practice Management System, EHR, RIS	ADA Claim Form, DICOM Standard, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA
6	Patient ID (Assigned by Dentist)	Optional	Practice Management System, EHR, RIS	ADA Claim Form, DICOM Standard, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA

**Table 8- Procedure Data Description**

#	Procedure Data Description (Applicable to CDT code set only)	Metadata for Image Annotation Criteria Required, Recommended, Optional	Patient-Level Referential Integrity Source System for Image Annotation	Normative Reference
3	Secondary Diagnosis Code	Recommended	Practice Management System, EHR, RIS	ADA Claim Form, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA, ICD-10, SNOMED, LOINC, ICD-10
4	Primary Diagnosis	Recommended	Practice Management System, EHR, RIS	ADA Claim Form, USCDI versions 3-5, HL7 FHIR 4.x, HL7 CDA, ICD-10

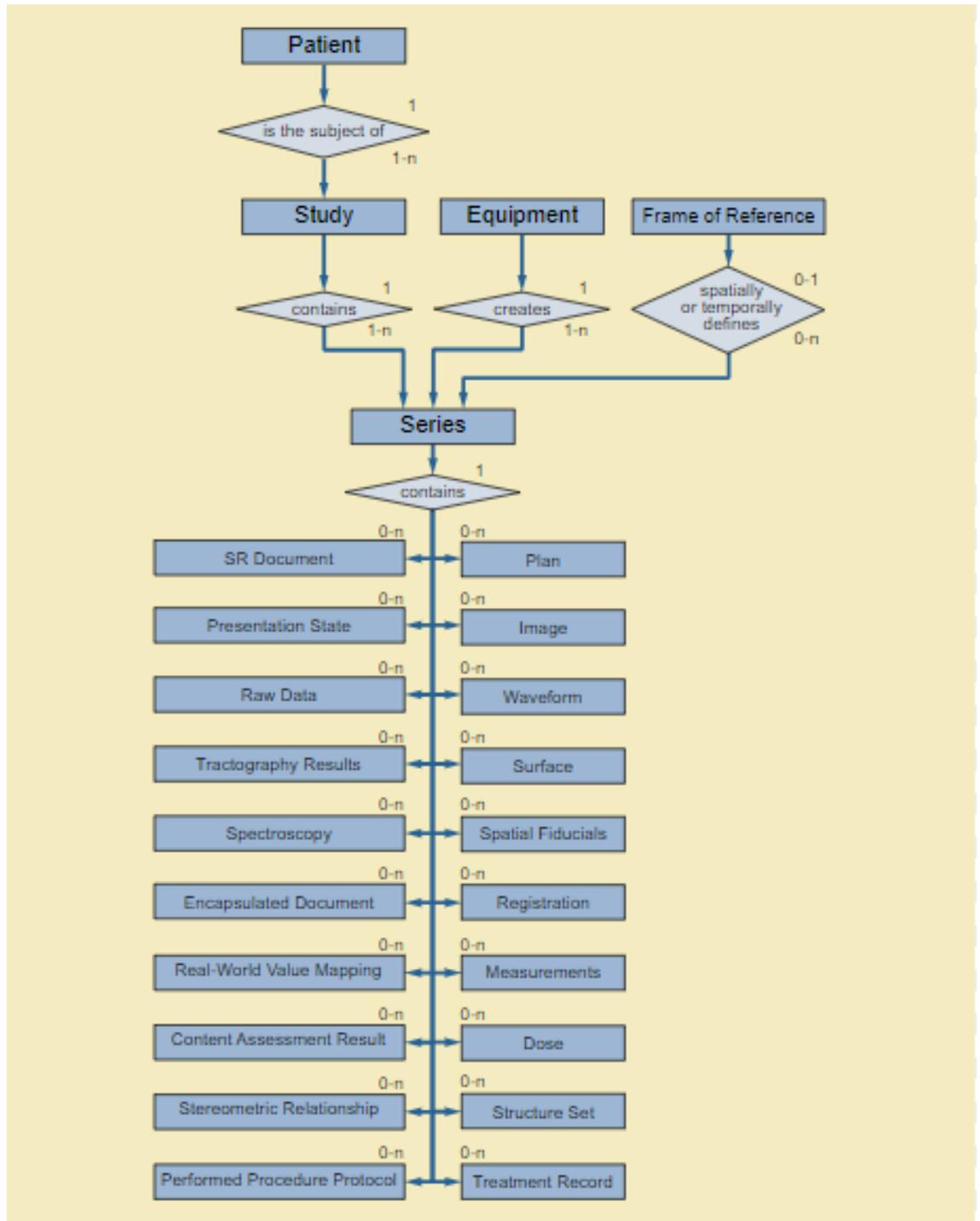
**Table 9- Treatment Data Description**

#	Treatment Data Description	Metadata for Image Annotation Criteria Required, Optional	Patient-Level Referential Integrity Source System for Image Annotation	Normative Reference
1	Auto Accident State	Optional	Practice Management System, EHR, RIS	ADA Claim Form
2	Date of Accident	Optional	Practice Management System, EHR, RIS	ADA Claim Form
4	Missing Teeth Information: Permanent: 1-32	Optional	Practice Management System, EHR, RIS	ADA Claim Form
5	Missing Teeth Information: Primary: A-T	Optional	Practice Management System, EHR, RIS	ADA Claim Form

#	Treatment Data Description	Metadata for Image Annotation Criteria Required, Optional	Patient-Level Referential Integrity Source System for Image Annotation	Normative Reference
6	Place of Treatment: Home	Optional	Practice Management System, EHR, RIS	ADA Claim Form
7	Place of Treatment: Inpatient Hospital	Optional	Practice Management System, EHR, RIS	ADA Claim Form
8	Place of Treatment: Nursing Facility	Optional	Practice Management System, EHR, RIS	ADA Claim Form
9	Place of Treatment: Other (For all applicable places of treatment that the ADA references, please refer to CMS Provider of Services File - Hospital & Non-Hospital Facilities.	Optional	Practice Management System, EHR, RIS	ADA Claim Form
10	Place of Treatment: Outpatient Hospital	Optional	Practice Management System, EHR, RIS	ADA Claim Form
11	Place of Treatment: Provider's Office	Optional	Practice Management System, EHR, RIS	ADA Claim Form
12	Place of Treatment: Skilled Nursing Facility	Optional	Practice Management System, EHR, RIS	ADA Claim Form
13	Place of Treatment: Telehealth	Optional	Practice Management System, EHR, RIS	ADA Claim Form
14	Replacement of Prosthesis	Optional	Practice Management System, EHR, RIS	ADA Claim Form
15	Treatment of Orthodontics	Optional	Practice Management System, EHR, RIS	ADA Claim Form
16	Treatment resulting from auto accident	Optional	Practice Management System, EHR, RIS	ADA Claim Form
17	Treatment resulting from occupational illness/injury	Optional	Practice Management System, EHR, RIS	ADA Claim Form
18	Treatment resulting from other accident	Optional	Practice Management System, EHR, RIS	ADA Claim Form

## 12 DICOM SOP Class Mapping to Image Annotation Standard

This section identifies the required list of specific SOP classes that can be chosen for the standard by specialty according to DICOM specifications.



**Figure 8 - Composite Instance Information Model**

(Source: [dicom.nema.org - /medical/dicom/Final/cp2135/](https://dicom.nema.org/medical/dicom/Final/cp2135/))

(DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)

Table 10 includes an approved listing of both DICOM Normalized SOP Classes [Normalized IOD (Information Object Definition)] and a set of DIMSE-N Services (DICOM Message Service Element – DIMSE) and Composite SOP Classes (Defined as the union of a Composite IOD and a set of DIMSE-C Services) within the Composite Instance Information Model (Figure 8.).

**Table 10 – Approved DICOM SOP Classes Mapped to Image Annotation Standard for Implementation**

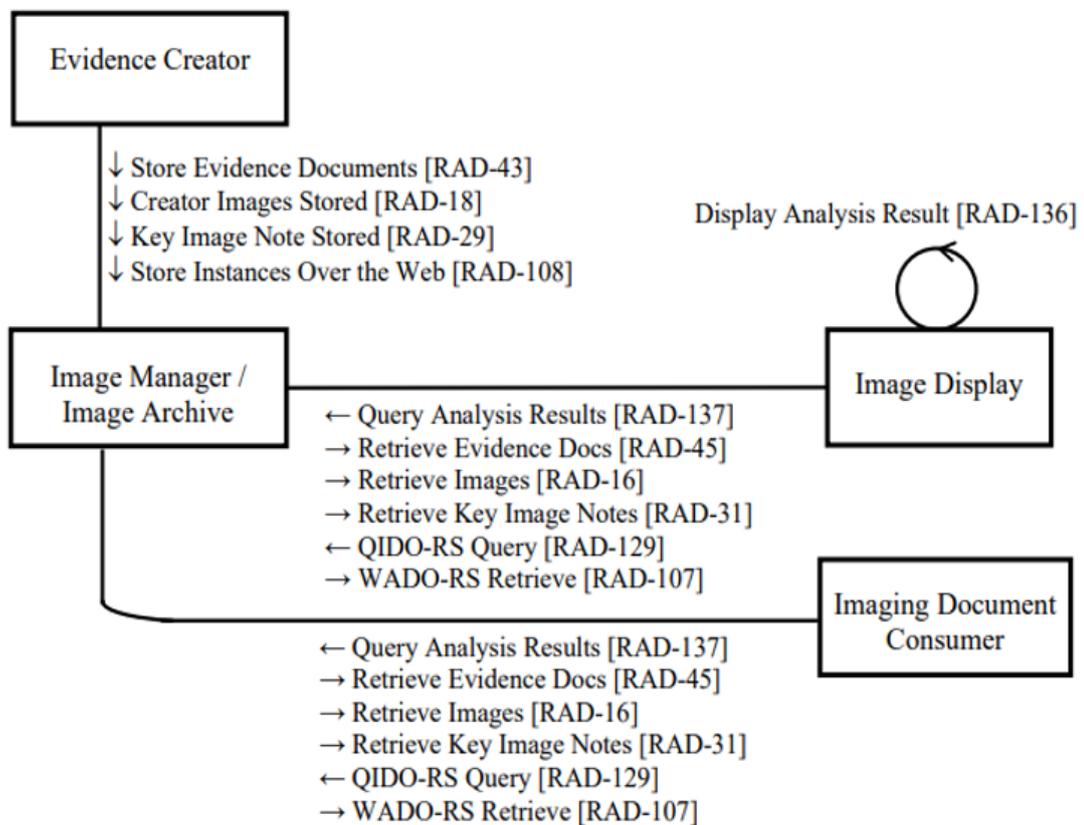
(DICOM — Digital Imaging and Communications in Medicine © 2024 NEMA)

#	SOP Class Name	SOP Class UID	IOD Specification (defined in <u>PS3.3</u> )	Specialization
1	Computed Radiography Image Storage [PSP plate in Dentistry]	1.2.840.10008.5.1.4.1.1.1	Computed Radiography Image IOD	
2	Digital X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.1	Digital X-Ray Image IOD	B.5.1.1
3	Digital X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.1.1	Digital X-Ray Image IOD	B.5.1.1
4	Digital Intra-Oral X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.3	Digital Intra-Oral X-Ray Image IOD	B.5.1.3
5	Digital Intra-Oral X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.3.1	Digital Intra-Oral X-Ray Image IOD	B.5.1.3
6	MR Spectroscopy Storage	1.2.840.10008.5.1.4.1.1.4.2	MR Spectroscopy IOD	
7	Enhanced MR Color Image Storage	1.2.840.10008.5.1.4.1.1.4.3	Enhanced MR Color Image IOD	B.5.1.8 B.5.1.23
8	Legacy Converted Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.4	Legacy Converted Enhanced MR Image IOD	B.5.1.6 B.5.1.23
9	Grayscale Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.1	Grayscale Softcopy Presentation State IOD	
10	Color Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.2	Color Softcopy Presentation State IOD	
11	Pseudo-Color Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.3	Pseudo-color Softcopy Presentation State IOD	

#	SOP Class Name	SOP Class UID	IOD Specification (defined in <u>PS3.3</u> )	Specialization
12	Blending Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.4	Blending Softcopy Presentation State IOD	
13	XA/XRF Grayscale Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.5	XA/XRF Grayscale Softcopy Presentation State IOD	
14	Advanced Blending Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.8	Advanced Blending Presentation State IOD	
15	Variable Modality LUT Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.12	Variable Modality LUT Softcopy Presentation State IOD	
16	Enhanced XA Image Storage	1.2.840.10008.5.1.4.1.1.12.1.1	Enhanced XA Image IOD	
17	Enhanced XRF Image Storage	1.2.840.10008.5.1.4.1.1.12.2.1	Enhanced XRF Image IOD	
18	Parametric Map Storage	1.2.840.10008.5.1.4.1.1.30	Parametric Map IOD	
19	Raw Data Storage	1.2.840.10008.5.1.4.1.1.66	Raw Data IOD	B.5.1.22
20	Spatial Registration Storage	1.2.840.10008.5.1.4.1.1.66.1	Spatial Registration IOD	
21	Spatial Fiducials Storage	1.2.840.10008.5.1.4.1.1.66.2	Spatial Fiducials IOD	
22	Deformable Spatial Registration Storage	1.2.840.10008.5.1.4.1.1.66.3	Deformable Spatial Registration IOD	
23	Segmentation Storage	1.2.840.10008.5.1.4.1.1.66.4	Segmentation IOD	
24	Surface Segmentation Storage	1.2.840.10008.5.1.4.1.1.66.5	Surface Segmentation IOD	
25	Tractography Results Storage	1.2.840.10008.5.1.4.1.1.66.6	Tractography Results IOD	
26	Real World Value Mapping Storage	1.2.840.10008.5.1.4.1.1.67	Real World Value Mapping IOD	
27	Surface Scan Mesh Storage	1.2.840.10008.5.1.4.1.1.68.1	Surface Scan Mesh IOD	
28	Surface Scan Point Cloud Storage	1.2.840.10008.5.1.4.1.1.68.2	Surface Scan Point Cloud IOD	

#	SOP Class Name	SOP Class UID	IOD Specification (defined in <u>PS3.3</u> )	Specialization
29	Procedure Log Storage	1.2.840.10008.5.1.4.1.1.88.40	Procedure Log IOD	B.5.1.5
30	Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Encapsulated PDF IOD	
31	Encapsulated CDA Storage	1.2.840.10008.5.1.4.1.1.104.2	Encapsulated CDA IOD	
32	Encapsulated STL Storage	1.2.840.10008.5.1.4.1.1.104.3	Encapsulated STL IOD	
33	Encapsulated OBJ Storage	1.2.840.10008.5.1.4.1.1.104.4	Encapsulated OBJ IOD	
34	Encapsulated MTL Storage	1.2.840.10008.5.1.4.1.1.104.5	Encapsulated MTL IOD	
35	Basic Structured Display Storage	1.2.840.10008.5.1.4.1.1.131	Basic Structured Display IOD	B.5.1.9

**Annex A**  
**(Informative)**  
**IHE (Integrated Health Enterprise) AI Workflow for Imaging (AIW-I)**



**Figure A.1 – IHE AIW workflow**

This IHE AIW-I profile (Figure A.1) standardizes storage and display of AI Results for image interpretation. It works in conjunction with the DICOM standard, and the standard has a quality control dependency upon it for systems that utilize the DICOM standard. It establishes baseline data handling and presentation capabilities for an image display product to be “AI-Ready” (AIR). Result generation products can leverage these data formats to be compatible with a variety of displays and site workflows. AIR defines:

- A set of result “primitives”
- Encoding requirements for each primitive (DICOM-based storage)
- Transactions for moving that content around
- Baseline display requirements for each primitive

(source: [https://wiki.ihe.net/index.php/AI\\_Results](https://wiki.ihe.net/index.php/AI_Results))

## **Bibliography**

*CMS Provider of Services File - Hospital & Non-Hospital Facilities*

(Available at <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities>)

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