

Results: Survey for CBCT Regulations

Replies so far: 23

Countries: Czech Republic (CZ), Malta (MT), Denmark (DK), Norway (NO), Netherlands (NL), Belgium (BE), Latvia (LV), France (FR), Austria (AT), Hungary (HU), Spain (ES), Croatia (HR), Bulgaria (BG), Germany (DE), Slovenia (SI), Finland (FI), Cyprus (CY), Lithuania (LT), Italy (IT), Greece (GR), Poland (PL), United Kingdom (UK), Slovakia (SK)

Q1) Which authority (or authorities) is responsible for regulating CBCT radiography in your country?

CZ	Státní úřad pro jadernou bezpečnost - https://sujb.gov.cz ; and Ministry of Healthcare
MT	Radiation Protection Board
DK	National Institute of Radiation Protection - https://www.sst.dk/vidensbase/straalebeskyttelse
NO	The Norwegian Radiation and Nuclear Safety Authority (DSA)
NL	Authority for Nuclear Safety and Radiation Protection (ANVS)
BE	FEDERAL AGENCY NUCLEAR CONTROL FANC
LV	Ministry of Climate and Energy ; Environmental service; Radiation Safety centre
FR	Autorité de Sureté Nucleaire et de Radioprotection
AT	Federal Ministry Labour, Social Affairs, Health, Care and Consumer Protection; regional/district governments
HU	Hungarian Atomic Energy Authority / Országos Atomenergia Hivatal (OAH) – radiation protection licensing and inspection. National Public Health and Pharmaceutical Centre / Nemzeti Népegészségügyi és Gyógyszerészeti Központ (NNGYK) – medical radiation protection / patient dose guidance. Ministry responsible for health – health care and professional regulations.
ES	Spanish Nuclear Safety Council, Regional Ministry of health, AEMPS
HR	Ministry of the Interior
BG	Agency for Nuclear Regulation
DE	Federal Ministry for the Environment, Climate Action, Nature Conservation and Nuclear Safety
SI	Slovenian Radiation Protection Administration
FI	Säteilyturvakeskus (STUK), Radiation and Nuclear Safety Authority
CY	Ministry of Labour
LT	Radiation protection centre (State institution)
IT	Health Ministry drafts general principles; Regional Health Authorities (ASL/ULSS) for vigilance and installation authorizations

GR	(HELLENIC ATOMIC ENERGY COMMISSION) EEAE https://eeae.gr/
PL	In Poland, dental CBCT is regulated within the general legal framework governing the use of ionising radiation for medical exposure. The main authorities and institutions involved are: ● the Ministry of Health, which issues secondary legislation on medical exposure, radiation protection and quality assurance in medical radiology; ● the National Atomic Energy Agency (Państwowa Agencja Atomistyki – PAA), as the central authority for nuclear safety and radiological protection; ● the State Sanitary Inspection, in particular the Provincial State Sanitary Inspector (Państwowy Wojewódzki Inspektor Sanitarny – PWIS), which is the key authority responsible for authorisation and inspection of medical X-ray units and facilities; ● the National Centre for Radiological Protection in Health Care (Krajowe Centrum Ochrony Radiologicznej w Ochronie Zdrowia – KCOR), which supports implementation of radiation protection requirements, professional training and guidance. The main legal basis is the Atomic Law Act of 29 November 2000, together with implementing regulations of the Minister of Health concerning medical exposure and quality control of radiological equipment.
UK	GB-Wide Regulation - Health and Safety Executive (HSE) for IRR17
SK	Public Health Authority

Q 2) Which aspects of CBCT radiography are specifically regulated in your country? (Please select all that apply)

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Radiation protection and patient safety																							
Professional scope of practice (who may prescribe, perform and/or interpret)																							
Ownership of CBCT radiography equipment (who is allowed to own a unit)																							

Authorization/ licensing to install and operate equipment																								
Facility and infrastructure requirements (e.g., shielding, room approval)																								
Quality assurance and equipment control																								

Other comments:

Malta: All the Radiation Protection Board

Denmark: <https://www.sst.dk/vidensbase/straalebeskyttelse/lovgivning-tilsyn-og-doeognvagt/tilsyn-inden-for-straalebeskyttelse>
<https://stps.dk/sundhedsfaglig/tilsyn/tilsyn-med-behandlingssteder/tilsyn-med-tandomraadet>

Norway: Applicable to all: Regulations on Radiation Protection and Use of Radiation (Radiation Protection Regulations) and Guidance for the use of radiation within odontology. Guidance to Regulations for Radiation Protection and Use of radiation (Guidance No. 14).

The Netherlands: This requirement follows from the Dutch Basic Safety Standards Decree for Radiation Protection (Bbs), which is enforced by the Dutch Authority for Nuclear Safety and Radiation Protection (ANVS). Its practical implementation for dentists is set out in the KNMT Guideline on Radiology in Dental Practice.

Belgium: FANC for all the selected aspects

Latvia: 1.Licensing for clinics 2.Certificated staff for work with CPCT, 1/per 5 years 3.Health check up 1/ per 2 years for staff. 4.Radiation field safety measurements 1 time in 5 years 5.Mobile X-ray dosimeters on employee clothing monitoring every 6 mounth.

France: Set up of the CBCT radiography unit : The authority is the Autorite de Surete Nucleaire et de Radioprotection (Nuclear Security and Radioprotection Authority) Professional Education: mandatory courses every 10 years for all the practitioners to be able to prescribe and realize any kind of radiography + mandatory courses once in a professional life to prescribe and realise CBCT radiography Internal quality control every 3 months + Annual quality control by certified body + Five-year control of radiology installation in dental office by a certification body

Austria: Strahlenschutzgesetz 2020 Zahnärztegesetz Allgemeine Strahlenschutzverordnung 2020 Medizinische Strahlenschutzverordnung

Hungary: 21/2018. (VII. 9.) EMMI Decree on protection of persons exposed to ionizing radiation in health care; 2/2022. (IV. 29.) OAH Decree on radiation protection, licensing, reporting and inspection; 60/2003. (X. 20.) ESzCsM Decree on minimum professional conditions for health care services; professional dental radiology guidance.

Germany: Radiation protection and patient safety- Radiation Protection Act, Radiation Protection Regulations, Federal Ministry.

Professional scope of practice- Radiation Protection Act, Radiation Protection Regulations, Federal Ministry.

Authorization/licensing to install and operate equipment – Radiation Protection Act, Radiation Protection Regulations, Competent Authority of the federal states

Facility and infrastructure requirements – specific guidelines, Competent Authority of the Federal States

Quality assurance and equipment control – specific guidelines, Competent Authority of the Federal States

Slovenia: Ionising Radiation Protection and Nuclear Safety Act (ZVISJV-1) and implementing regulations

Finland: Radiation and Nuclear Safety Authority

Italy: D.Lgs. 101/2020 , adopting UE directive 2013/59/EURATOM, and D.Lgs 203/2022

Greece: A large number of application forms exist and mandatorily submitted to adeies@eeae.gr It is extremely difficult to attach all these requirements

Poland: Dental CBCT in Poland is not regulated by a separate CBCT-specific act, but by the broader framework applicable to medical exposure to ionising radiation, medical X-ray units, and radiological quality assurance. The key legal acts are: 1. Atomic Law Act of 29 November 2000 (Prawo atomowe), as amended – general framework for radiation protection, medical exposure, authorisation and supervision. 2. Regulation of the Minister of Health of 11 January 2023 on the safe use of ionising radiation for all types of medical exposure – regulates justification and optimisation of exposure, responsibilities of the referrer and practitioner, patient protection, local radiological procedures and training requirements. 3. Regulation

of the Minister of Health of 12 December 2022 on operational tests of radiological equipment and auxiliary devices – regulates acceptance and periodic testing / quality control of radiological equipment, including CBCT. 4. Regulation / national framework concerning standard radiological procedures in medical imaging, including dental radiology, applicable within the Polish medical exposure system. 5. Relevant provisions concerning sanitary authorisation and inspection of X-ray facilities exercised by the competent State Sanitary Inspection / PWIS.

The United Kingdom:

- Radiation protection and patient safety – HSE re IRR17
- Professional scope of practice (who may prescribe, perform and/or interpret) – General Dental Council
- Ownership of CBCT radiography equipment (who is allowed to own a unit) – HSE re IRR17
- Authorization/ licensing to install and operate equipment – HSE re IRR17
- Facility and infrastructure requirements (e.g., shielding, room approval) -HSE re IRR17
- Quality assurance and equipment control – HSE re IRR17 and IR(ME)R17 Inspectorate re IR(ME)R17

Slovakia:

- 1.Act No. 87/2018 Coll. on Radiation Protection Establishes the legal framework for protection against ionizing radiation. Implements Council Directive 2013/59/Euratom (Basic Safety Standards Directive). Covers: Justification of medical exposures. Optimization of radiation dose (ALARA principle). Responsibilities of healthcare providers and employers. Radiation protection of patients, workers, and the public. Licensing and registration of radiation sources. Quality assurance and quality control. Education and training of personnel. Implementing Decrees of the Ministry of Health of the Slovak Republic issued under Act No. 87/2018 Coll. These regulate, among other things: Operation of X-ray and CBCT equipment. Quality assurance and quality control programmes. Diagnostic Reference Levels (DRLs). Acceptance and constancy testing of radiological equipment. Requirements for radiation protection experts and medical physics support.
- 2.Act No. 576/2004 Coll. on Healthcare, Healthcare-Related Services and Amendments to Certain Acts Requires that every radiological examination, including CBCT, is clinically justified. Regulates patient information, informed consent where applicable, and medical record documentation.
- 3.Act No. 578/2004 Coll. on Healthcare Providers, Healthcare Professionals, Professional Organisations in Healthcare and Amendments to Certain Acts Regulates the licensing and operation of healthcare facilities. Establishes professional qualification requirements for healthcare personnel.

Q3) Is prior authorization or licensing required to install and/or operate a CBCT radiography unit in your country? If yes, please specify the type of authorization and the issuing body.

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Yes																							
No																							

Other comments:

Malta: Radiation Protection Board

Denmark: Installation and operation of a CBCT radiography unit are subject to Danish radiation protection regulations. Depending on the specific application, registration, notification, or authorization is required. The competent authority is the Danish Health Authority (Sundhedsstyrelsen), which oversees radiation protection and the use of ionizing radiation sources.

Norway: CBCT can be used on patients. Operators need relevant and documented competence which is subject to approval by the DSA.

The Netherlands: LICENSING IS REQUIRED BY ANVS

Belgium: License to install a CBCT radiography: FANC License to operate a CBCT radiography: FANC

Latvia: Radiation Safety centre

France: To use a CBCT radiography unit, it is essential to obtain approval from the nuclear safety and radiation protection authority. Without this approval, it is not possible to bill patients or allow them to receive reimbursement from the French health insurance system.

Austria: District governments/commissioners

Hungary: Prior authorization/licensing is required to install and operate a CBCT/radiographic unit. The authorization is issued by the Hungarian Atomic Energy Authority / OAH

Spain: Director of Dental Radiodiagnosis installations

Bulgaria: Agency for Nuclear Regulation

Germany: Regional Dental Chambers, Competent Authority of the Federal States

Slovenia: Slovenian Radiation Protection Administration

Finland: Radiation and Nuclear Safety Authority

Cyprus: Authorized radiophysicist, under the ministry of labour

Lithuania: Radiation protection centre (State institution)

Italy: To install a CBCT dental studies must comply to different requirements: 1) structural 2) legal (mandatory inspection; data protection) 3) training (mandatory ECM for all interested members) Authorizations are provided by the NHS regional authority (ASL/ULSS)

Greece: Indicatively attached the following: Granting a notification number Proof of registration Authorisation

Poland: A dental CBCT unit cannot be installed and used without prior regulatory steps. In Poland, operation of a medical X-ray unit requires authorisation from the Provincial State Sanitary Inspector (PWIS). Before installation and use, the facility must also have appropriate radiation protection / room design documentation, including shielding assessment and approval where required. In addition, CBCT should be treated within the broader radiodiagnostic framework under the Atomic Law and medical exposure regulations, rather than within the narrow exemption applicable only to certain simple intraoral dental X-ray activities.

The United Kingdom: Health and Safety Executive, Certificate of Registration.

Slovakia: Pursuant to Act No. 87/2018, a Decision is issued regarding the Registration of an activity involving exposure to radiation through the use of dental X-ray equipment. Issued by Regional Public Health Authority

Q4) Which of the following are legally authorized to prescribe (order) a CBCT examination in your country? (Select all that apply)

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Dentists																							
Dental specialists																							
Other																							

Other comments:

Norway: Medical doctors. Chiropractors only for musculoskeletal problems.

Belgium: Doctor General Medicine or doctor medical specialist

Austria: oral surgeons

Hungary: physicians/specialists where clinically justified.

Germany: Dentist with specialist training in CBCT

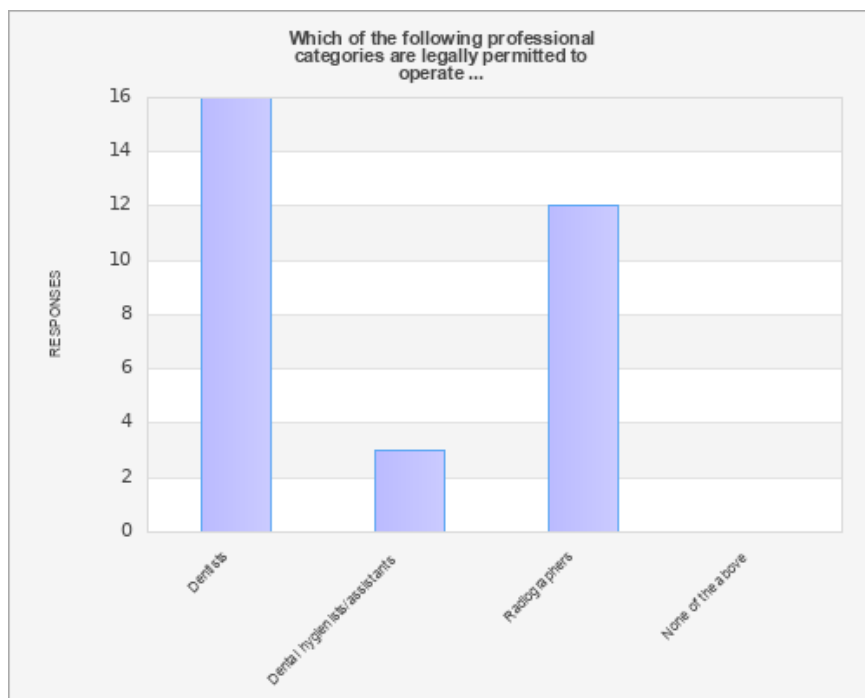
Poland: In Poland, CBCT referrals may be issued by dentists, including dental specialists, and medical doctors acting within the scope of their professional competence and responsibility for patient management. Polish legislation regulates medical exposure through the concepts of the referrer and the practitioner, rather than through a separate CBCT-specific referral act.

The United Kingdom: Dentists -with adequate/ recommended CBCT training

Slovakia: Maxilo-facial surgeons, Radiologists

Q5) Which of the following professional categories are legally permitted to operate CBCT radiography equipment in your country? (Select all that apply)

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Dentists																							
Radiographers																							
Dental hygienists/assistants																							
Other																							



Other comments:

Malta: qualified nurse with special training

Norway: Dentists only if relevant continuing education. Dentists can delegate to dental hygienists/assistants if No, but the task can be delegated if relevant continuing education and the task is supervised.

Austria: radiologists, oral surgeons

Spain: Dental hygienist/assistants always with a dentist

Germany: Dental assistants, Radiology assistants

Greece: Dentists holding MSc degree in dental/orofacial radiology

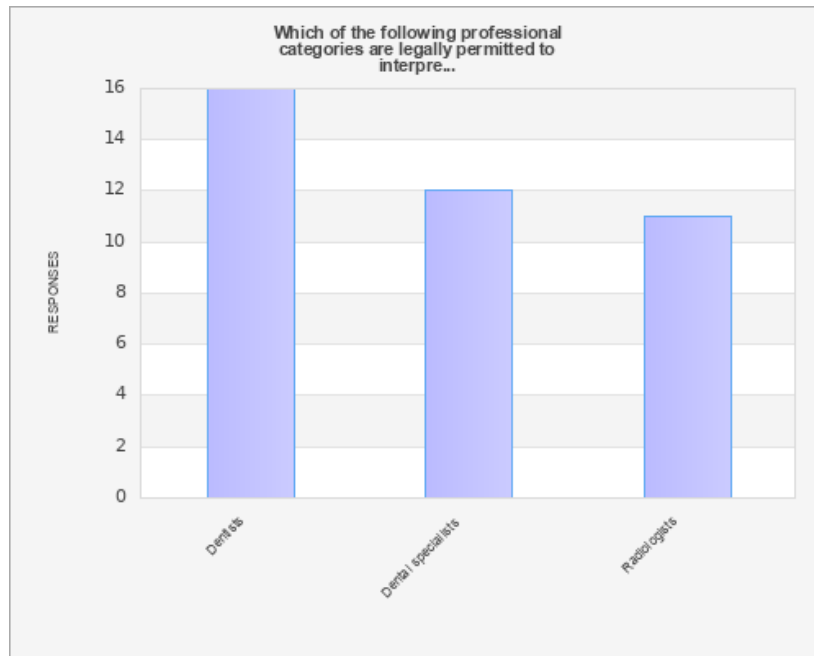
Poland: Medical radiologists; In Poland, operation of medical X-ray equipment is regulated through radiation protection law, required training / authorisation, and the internal procedures of the healthcare facility rather than through a detailed CBCT-specific list of professions. In dental practice, CBCT may be operated by dentists, medical radiologists. Radiographers are also legally qualified to operate radiological equipment.

The United Kingdom: Dentists and Dental hygienists/assistants - with adequate/ recommended CBCT training. Dental therapists and dental nurses (if trained and entitled)

Slovakia: Dental specialists

Q6) Which of the following professional categories are legally permitted to interpret/diagnose panoramic radiographs in your country?

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Dentists																							

[illegible]

Other comments:

Austria: oral surgeons

Poland: In Polish dental practice, dentists interpret dental radiographs, including panoramic radiographs, within the scope of dental diagnosis and treatment. Radiologists may also interpret such imaging studies. Polish law does not reserve interpretation of routine dental radiographs exclusively to radiologists.

The United Kingdom: Dentists- with adequate/recommended CBCT training

Slovakia: Maxilo Facial Surgeons

7) What are the minimum education and training requirements for dental professionals using CBCT radiography in your country?

CZ	medical school and regular re-training mostly theoretical
MT	CBCT course

DK	Licensed dentist + documented CBCT/radiation protection training (equipment operation, dose optimization, and image interpretation). No separate national CBCT certification is generally required, but competence must be documented and maintained.
NO	Operators of CBCT-machines: Dentist. Interpretation: Specialty in maxillofacial radiology.
NL	In the Netherlands, the KNMT Guideline on Radiology in Dental Practice refers to the European basic principles for the use of cone beam computed tomography (CBCT), as set out in European Radiation Protection No. 172: Cone Beam CT for Dental and Maxillofacial Radiology. Dentists who do not operate a CBCT unit themselves but refer patients for CBCT examinations are expected to have a basic understanding of its appropriate use. This includes, as a minimum: Indications for the use of CBCT in dentistry; The radiation dose associated with CBCT in relation to the diagnostic question; Basic knowledge of the interpretation of CBCT images. Dentists who operate a CBCT unit are required to complete additional training: TMS Dentistry – Cone Beam CT. This programme consists of a theoretical component, followed by device-specific practical training provided by the equipment manufacturer on the safe and appropriate use of the CBCT system.
BE	Initial qualification for regular radiography + for CBCT 30 hours of which 18 hours specific clinical exercises
LV	Medical education, Radiation safety certificate
FR	Dentist diploma + Professional Education: mandatory courses every 10 years for all the practitioners to be able to prescribe and realize any kind of radiography + mandatory courses once in a professional life to prescribe and realise CBCT radiography
AT	Completion of a university degree in dentistry, refresher training/continuing education for radiation safety officers
HU	Dental degree or relevant health-care qualification, plus appropriate training in dental radiology and radiation protection
ES	Dentist + director of dental radiodiagnosis installations
HR	Certification from competent institute for ionizing radiation
DE	A 16-hour course including the analysis of 25 images and exam.
SI	Basic education # Training in Protection Against Ionizing Radiation# and refresher additional educations
FI	A licensed dental degree (DDS/Licentiate in Dentistry) grants basic authorization to use CBCT equipment. However, to meet radiation legislation and STUK requirements, dentists must complete additional training and demonstrate competence: at least 20 hours of radiation protection training every five years, device-specific training before using new or updated equipment, and clinical skills including justification, optimization, and especially accurate interpretation of imaging data. If imaging is performed by other staff (such as a dental hygienist or radiographer), they must complete separate CBCT training provided by Metropolia or a similar university of applied sciences, including a written exam and a practical skills assessment.
CY	There are no specific requirements.
LT	Special courses for dentists and other eligible medicine specialists (36 h.). Also, before independently operating dental CBCT equipment, personnel must: complete an approved radiation protection training programme; receive CBCT-specific operational training (usually provided by the equipment manufacturer or supplier during installation); be formally authorised by the healthcare institution to perform the procedure; work within the scope of their professional competence and applicable radiation protection legislation.
IT	continuing education (mandatory every 3 years) on radiological protection

GR	10 semesters Bachelor degree in Dentistry (300 ECTS) and six semesters (180 ECTS) MSc degree in Orofacial radiology or (recently) SIX months Certified CPD programmes in Academic institutions .
PL	A dental professional using CBCT in Poland should have: 1. A primary professional qualification as a dentist (or another authorised healthcare professional, depending on role), and 2. Training in radiation protection of the patient / medical exposure, appropriate to the scope of duties, in accordance with the Atomic Law framework and implementing regulations, and 3. Practical training in the use of the specific imaging equipment and local radiological procedures required by the employer / facility. In practical terms, a dentist involved in CBCT should be trained in: ● radiation protection principles in medical exposure, ● justification and optimisation, ● patient safety, ● operation of the specific imaging system, ● quality assurance procedures and documentation applicable in the facility. Polish law does not provide one single separate national CBCT-only certificate for dentists; the system is based on professional qualification + radiation protection training + facility-based authorisation and local procedures.
UK	Initial qualification and Certificate in Dental Radiography where appropriate and then: Level 1 (Core) training in dental CBCT; Level 2 (Further) training for operators performing dental CBCT imaging; Level 2 (Further) training in dental CBCT justification and image interpretation. What are the minimum education and training requirements for dental professionals using CBCT radiography in your country? (Initial qualification + any certification requirements)
SK	complete medical/dental university education + Course on the Use of Sources of Ionising Radiation

8) Are dental professionals required to undergo continuing education or re-certification in radiation protection in your country? If yes, please specify the frequency and specific requirements.

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Yes																							
No																							

Other comments:

Malta: Course must be repeated every five years

Denmark: Dental professionals using CBCT must have radiation protection training and maintain competence through continuing education. There is generally no fixed national re-certification period, but employers must ensure ongoing training, documentation of competence, and updates when new technologies or procedures are introduced.

Norway: Yearly.

The Netherlands: General radiology: 4 hours of continuing education every 5 years. CBCT: 8 hours of continuing education every 5 years.

Belgium: 3 hours during 5 years.

Latvia: Once every 5 years for medical person.

France: Practitioners must complete 2 TRAINING COURSES: - Radiation protection training for patient safety; mandatory training that must be renewed every 10 years. This training is essential to be able to order and perform medical imaging procedures. - Training in the interpretation and ordering of CBCT scans: This training is completed only once and is mandatory for the reimbursement of imaging costs under the French healthcare system.

Austria: Every 5 years, lasting at least 4 hours

Hungary: Continuing radiation-protection education/re-certification is required according to the OAH radiation-protection training system. The exact level depends on the role; dental radiology workplaces usually require a radiation protection officer with valid extended-level radiation protection certification.

Croatia: every 5 years

Germany: A 8-hour course including exam every five

Slovenia: every 5 years

Finland: at least 20 hours of radiation protection training every five years

LT: Duration of initial training: Typically ranges from 14 to 60 academic hours. For example, personnel working with dental X-ray equipment are usually offered a 14–20 academic hour training programme. Duration of refresher (recertification) training: Refresher courses, which must be completed periodically (typically every 2–5 years), generally last 8–20 academic hours.

Italy: Mandatory continuing education is defined within D.Lgs. 101/2020. ECM dedicated courses should not subceed 15% of total credits.

Poland: Dental professionals involved in medical radiological procedures are required to maintain and periodically update their competence in radiation protection of the patient. For dentists performing dental radiological procedures, this obligation is generally fulfilled within a 5-year cycle under the Polish framework for radiation protection in medical exposure, through accredited education / training and the required educational credits in radiation protection.

The United Kingdom: Within a five-year period or sooner as/if appropriate. Under IRR17 and IR(ME)R17.

Slovakia: every 5 years

**9) Which of the following regulatory prerequisites must a dental practice meet before installing a CBCT radiography unit in your country?
(Select all that apply)**

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	DE	SI	CY	LT		GR	PL	UK	SK
Facility approval																					
Radiation shielding																					
Safety officer designation																					
Prior inspection																					
Other																					

Other comments:

The Netherlands: through the licence application to the ANVS, the following items: environmental analysis / site boundary dose assessment; diploma(s) of the supervising radiation protection officer(s); agreement with the clinical physicist; sample safety instructions / work procedures; sample protocol.

Latvia: Initial licence from Radiation Safety center

Hungary: workplace radiation protection rules, radiation protection documentation, equipment authorization/licensing.

Germany: Inspection in accordance with the relevant guidelines and standards

Slovenia: Facility approval at the beginning and annual review (inspection)

Finland: Premises where radiation sources are used have to be planned and implemented in such a way that the occupational exposure and public exposure is as low as possible when reasonable actions are implemented. Radiation shielding is implemented by using a material in the shielding that reduces the radiation dose rate. In the medical use of radiation, a medical physicist can act as a Medical Physics Expert or a Radiation Safety Expert. In dental X-ray practice, the medical physicist can, if necessary, provide advice on matters related to the radiation protection of patients, workers and the general public as well as on the design of the place of use

Cyprus: Annual check by radiophysicist.

LT: Facility approval, Radiation shielding, Safety officer designation, Comprehensive dental practice licensing process, including the evaluation of materials, healthcare professionals, and medical equipment.

PL: authorisation from the Provincial State Sanitary Inspector (PWIS); radiation protection documentation / room design approval; compliance with medical exposure and quality assurance requirements. Before installation and operation of a CBCT unit, the practice must have appropriate room design / radiation protection documentation, shielding assessment, and the necessary sanitary authorisation for the X-ray facility and equipment. In the Polish system, the closest equivalent of a “safety officer” is the Radiation Protection Officer (Inspektor Ochrony Radiologicznej, IOR) or another legally compliant radiation protection supervision arrangement required under the Atomic Law and implementing regulations

The United Kingdom:

- Notify the HSE of work with ionising radiation under IRR17 (unless an exemption applies).
- Risk assessment under IRR17.
- Local rules for radiation protection.
- Employer's procedures under IR(ME)R 2017.
- Entitlement and training of referrers, practitioners, and operators.
- Acceptance testing and commissioning of the CBCT equipment by a medical physics expert/service engineer.
- Quality assurance (QA) programme, including routine equipment testing.
- Appointment of a Medical Physics Expert (MPE) under IR(ME)R for CBCT services.
- Controlled area designation, where required.

10) What quality assurance measures are mandated for CBCT radiography equipment in your country? (Select all that apply)

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	BG	DE	SI	FI	CY	LT	IT	GR	PL	UK	SK
Acceptance testing																							
Periodic checks																							
Maintenance requirements																							
Reporting obligations																							

11) How does the inspecting authority monitor and enforce compliance in dental radiography practices?

CZ	/
MT	Inspections and reminders
DK	The inspecting authorities—specifically Sundhedsstyrelsen, Strålebeskyttelse (Danish Health Authority, Radiation Protection) and Styrelsen for Patientsikkerhed (Danish Patient Safety Authority)—monitor and enforce compliance in dental radiography through a combination of proactive licensing, rigorous documentation audits, mandatory third-party quality control, and direct physical inspections.
NO	Randomized and targeted supervision controls, information and discussion at national dental conferences and other dental meetings, advice on request, approval of CBCT clinics
NL	Digital inspections concerning the registration and licensing of X-ray equipment, as well as visits to practices, focused on ensuring possession of the correct registration or licence (authorization), compliance with competency requirements for working with radiation, full adherence to safety regulations relating to the X-ray equipment, and the quality of, among other things, administrative records.
BE	Inspection by licensed inspection and certification firm + visits by FANC
LV	Annual reporting
FR	Internal quality control every 3 months + Annual quality control by certified body + Five-year control of radiology installation in dental office by a certification body
AT	Regulatory inspections are carried out at the dental practice at regular intervals.
HU	The authority monitors compliance through licensing procedures, review of radiation-protection documentation, inspections, reporting obligations, and control of radiation protection and quality-assurance requirements.
ES	Compliance is monitored through physical prior and periodic inspections
HR	Testing CBCT radiography equipment

BG	Agency for Nuclear Regulation
DE	Competent Authority of the Federal States
SI	Slovenian Radiation Protection Administration, authorised radiation protection experts
FI	Radiation and Nuclear Safety Authority
CY	Ministry of Labour
LT	Radiation Protection Centre monitors compliance through: Risk-based inspections of dental practices using ionising radiation equipment (including intraoral X-ray, panoramic and CBCT units). Inspection frequency is determined by risk assessment rather than fixed statutory intervals. Review of documentation, including: licences or registrations for radiation practices; radiation protection programme; staff radiation protection training records; quality assurance and quality control documentation; maintenance and servicing records; patient exposure records where applicable. Verification of equipment compliance, including confirmation that: acceptance testing has been completed before clinical use; periodic quality assurance tests are performed by authorised specialists (for dental CBCT equipment, comprehensive quality assurance testing is generally required at least every two years); equipment is maintained according to manufacturer and regulatory requirements. Assessment of radiation protection measures, such as: justification and optimisation of exposures (ALARA principle); use of appropriate exposure protocols; patient and staff protection measures; local radiation safety procedures and responsibilities. Follow-up inspections when deficiencies have been identified or when complaints or incidents are reported.
IT	Each year, a qualified Radiation Protection Expert (Esperto di Radioprotezione – EDR) inspects the practice's radiographic equipment, assesses radiation exposure risks, and evaluates the organization and safety of the working environment. Following the inspection, the EDR records the findings in the Radiation Protection Register, which must be maintained by the dental practice and made available to the competent authorities upon request during inspections.
PL	Compliance is monitored primarily by the State Sanitary Inspection, especially the Provincial State Sanitary Inspector (PWIS). Monitoring and enforcement may include: ● review of authorisation / licensing documentation for the X-ray unit and facility; ● review of radiation protection documentation, shielding documentation and local procedures; ● verification of quality assurance records, operational test reports and maintenance documentation; ● on-site inspections of the facility and equipment; ● assessment of compliance with medical exposure and radiation protection requirements; ● orders to remedy deficiencies and other administrative measures in case of non-compliance.
UK	Compliance is monitored through inspections by the Care Quality Commission (CQC) and, for radiation protection under IRR17, the Health and Safety Executive (HSE). Inspectors review radiation risk assessments, local rules, staff training and entitlement, QA programmes, equipment testing and maintenance, clinical evaluation of radiographs, and incident records. Non-compliance may result in corrective action, Improvement or Prohibition Notices, prosecution (HSE), or regulatory enforcement by the CQC.
SK	Every provider of CBCT has to submit the protocol on the acceptance test of the X-ray device at the beginning and every year Test of stability of the X-ray device.

12) What is the required frequency of inspections for these dental radiography practices?

Reply	CZ	MT	DK	NO	NL	BE	LV	FR	AT	HU	ES	HR	DE	SI	CY	LT	IT	GR	PL	UK	SK
Only upon complaint or incident																					
Every 2 years																					
Every 3 to 5 years																					
Annually																					
Other																					

Other comments:

Norway: No fixed frequency. Inspections are performed as needed (upon complaint or incident) and otherwise as the DSA has capacity and considers there to be a need

Belgium: CBCT annually, regular radiography 3 years

The Netherlands: There is no fixed routine for inspections of practices; the most recent inspections took place in 2019 and 2022. Inspections may also be carried out in response to a complaint or an incident.

Latvia: Individual dosimeter supervising twice per year with dose cheking.

Bulgaria: 6 months, 3 years

Poland: Polish law does not appear to provide one single fixed CBCT-specific statutory interval for regulatory inspections of all dental radiography practices by the competent authority. Compliance is supervised by the sanitary authorities within the general radiation protection framework. However, CBCT equipment is subject to mandatory periodic operational testing at least once a year under the Polish regulations on operational tests of radiological equipment. Further clarification of practical requirements for dental CBCT is expected in connection with the planned update of the national standard radiological procedures in dental radiology.

The United Kingdom: Annually- electrical and mechanical check, Every 3 to 5 years- quality assurance check

Slovakia: Annually at the CBCT, every 2 years at the Orthopantomograph/Intraoral x-ray

13) Which of the following sanctions can be imposed for non-compliance in dental radiography practices?

Reply	CZ	MT	DK	NO	NL	LV	FR	AT	HU	ES	HR	BG	DE	CY	LT		GR	PL	UK	SK
Fines/ Financial penalties																				
Suspension of the practice license																				
Revocation of the practice license																				
Formal warnings																				
Other																				

Other comments:

Norway: Suspension and revocation of the business' approval for the use of CBCT. Report to the police.

The Netherlands: If an inspector identifies a violation, the ANVS may apply one or more enforcement measures. These can range from a warning to administrative and/or criminal sanctions, including the suspension of activities involving the X-ray equipment. If a violation is found, the ANVS will always carry out a follow-up inspection.

Latvia: Dismantling the appliance's power cord

Austria: disciplinary consequences

Bulgaria: Yes, there are sanctions for non-compliance.

Germany: Yes, there are sanctions for non-compliance.

Cyprus: Closure until compliance.

Poland: administrative orders requiring corrective action; possible refusal, restriction or withdrawal of the authorisation to use the X-ray unit or conduct the regulated radiological activity. In the Polish legal framework, sanctions for non-compliance may include formal warnings, administrative orders requiring corrective action, financial penalties, and — in serious cases — refusal, suspension or withdrawal of the authorisation / consent to

operate the X-ray unit or radiological facility by the competent sanitary authority. In this context, “revocation of the practice licence” should be understood not as revocation of the dentist’s professional licence, but rather as withdrawal of the regulatory authorisation to conduct the radiological activity or operate the X-ray facility.

The United Kingdom:

- Improvement Notices (issued by the HSE).
- Prohibition Notices (HSE), preventing certain activities until risks are controlled.
- Conditions on CQC registration, restricting how services are delivered.
- Criminal prosecution for serious breaches of IRR17 or IR(ME)R (where applicable).

14) What are the main challenges or gaps in the current regulatory framework for CBCT radiography in your country?

CZ	It is not covered by health care plans
DK	1. Subjective "Justification" Guidelines, 2. Shortage of Medical Physics Experts (MFE) 3. Rapid Technological Growth vs. Slow Legislation 4. Liability for "Incidental Findings"
NO	The regulatory framework works well.
NL	None
BE	Very restricted reimbursement by social security
LV	Complicate bureaucratic obstacles
FR	no gaps individualised at this time
AT	Different interpretations of the regulations in different districts.
HU	The CBCT-specific dental regulatory framework is partly embedded in general radiation-protection and health-care regulations rather than one single CBCT-specific regulation. Main challenges include variable awareness of CBCT indication criteria, documentation of justification, differences in training and interpretation competence, and the need for consistent QA and dose-optimization practice across dental offices.
ES	None
HR	Overadministration
DE	There are no gaps in the current regulatory framework for CBCT.
CY	We are in discussion with the ministry of labour to change the check period from annual to 2 years period.
LT	As per now there are no real gaps or challengers
GR	Possession and operation of CBCT devices by non properly trained personnel .

PL	The main challenges are: 1. Lack of a fully CBCT-specific regulatory layer Dental CBCT is regulated mainly through the broader framework for medical exposure and dental radiology rather than through a separate, dedicated CBCT statute. 2. Limited clarity on professional roles in dental CBCT The legislation does not always provide sufficiently detailed CBCT-specific guidance on which categories of dental personnel may independently operate CBCT equipment, under what supervision model, and with what level of dedicated training. 3. Training requirements are broad rather than CBCT-specific Radiation protection training is mandatory, but there is no single clearly defined national CBCT-specific competency pathway for dentists. 4. Variation in practical implementation between facilities Because regulation relies largely on the general framework, local implementation may differ in relation to protocols, documentation, staff authorisation and quality assurance procedures. 5. Need for continued emphasis on justification and optimisation As CBCT is increasingly available in dental practice, the regulatory framework should continue to emphasise appropriate indications, field-of-view limitation and dose optimisation in accordance with radiation protection principles. 6. Need for clearer dental CBCT guidance in national radiological procedures Further clarification is expected following updates to the Polish national standard radiological procedures applicable to dental imaging.
UK	The UK regulatory framework for dental CBCT is comprehensive; however, challenges include variation in CBCT reporting practices and operator competency, inconsistent access to specialist radiology reporting, differences in implementation of quality assurance programmes, the complexity of complying with multiple regulatory requirements, and variable inspection frequency due to the risk-based regulatory approach. In addition, rapid technological developments may outpace updates to guidance and training standards.
SK	Dental CBCT is not reimbursed by health insurance company