DTSS Practice Inspections

The initial stage of a DTSS contract application is administered by a local HSE office. When the initial processing has been completed and the documentation returned by the applicant to the local HSE office, the Dental Inspectorate is requested to carry out quality and safety validation checks.

There are two parts to this Inspectorate process. These are:

(a) Self-certification by the Contract Applicant and the Practice Principal/ Owner.
(b) Practice inspection.

(a) Self-Certification

The Practice Principal/Owner and the Contract Applicant are asked to complete separate Questionnaires.

Practice Principal

The Practice Principal/Owner is asked to complete two documents:

a. Practice Compliance Questionnaire – this must state
    a. the make and model of autoclave(s) in use and
    b. state the name of the medical physicist and date when last quality assurance exercise on the radiographic equipment was undertaken.

b. Autoclave Compliance Test Sheet – Confirms that the autoclave(s) in use are annually validated by a "Competent Person". This **must be completed** by the person who will or has validated your autoclaves currently in use. (Please note that validation is not servicing). One sheet should be completed for each autoclave in use.

Contract Applicant

The Contract Applicant has to complete a questionnaire and also forward a copy of their up-to-date CPR certificate to the Regional Dental Inspector.

An inspection will not be scheduled until these documents are fully completed and returned to the Regional Dental Inspector. The Practice must be in compliance with the Codes of Practice of the Irish Dental Council.

(b) Practice Inspection

On receipt of the completed questionnaires, the Practice Principal/Owner will be contacted to arrange a mutually convenient time and date for the practice inspection. It is not obligatory that the prospective Contract Applicant is present on this date

The inspection has two parts, namely a review of documentation and a physical inspection.

On the date of the practice inspection, all documentation specific to the practice and listed below **must** be available for inspection:

1. **Decontamination Documentation**
    a. Commissioning or Annual Validation of all autoclave(s) by a Competent Person.
    b. Evidence of daily and weekly testing of the autoclave(s) in use.
    c. Evidence of operational readings of the autoclave in use (e.g. Print Outs).

2. **Proof of Clinical Waste Management (including dental amalgam)**

3. **Proof of installation and operation of amalgam separator(s).**

4. **Practice Safety Statement**

5. **Radiology**
    a. Evidence of EPA registration at practice address
    b. Evidence of 2 Yearly Quality Assurance Report undertaken by a Radiological Protection Adviser. (This QA Report will be checked to verify X- Ray equipment in use).

6. **Medical Emergency Management**

    a. In date evidence of life support training
    b. Availability of emergency drugs kit and oxygen cylinder

During the physical inspection, the Dental Inspectors will also review the following areas:

1. Surgery is visibly tidy, cleanable and supports good infection control practice according to Irish Dental Council and HIQA guidelines.
2. Dental instruments are processed according to Irish Dental Council guidelines.
3. Dental Unit Water Lines are properly managed according to Irish Dental Council guidelines.
4. Hand Hygiene practice is according to SARI/WHO guidelines.

This is not an exhaustive list. The Dental Inspector may note other issues that will need to be addressed.

Example: Contract Applicant Questionaire

Applicant Name	
Practice Address	
Contact Number (s)	
Email	
Dental Council Number	
Expiry Date of CPR certificate	
Other DTSS contract numbers currently or previously held by you	
Are you currently employed in a salaried position with the HSE?	

Please indicate any period of dental practice outside of the Republic of Ireland

Country of Registration	Registration Number	Date of First Registration	Were any sanctions issued to you by the dental authorities in that country?

I agree to undertake the following:	**Yes**	**No**
I am familiar and compliant with Irish Dental Council Guidelines, Regulations and Codes of Practice		
I agree to inform patients of their entitlements under the DTSS		
I agree to comply with HSE protocols for identification and prioritisation of high risk patients		
I agree to comply with HSE Standard Operating Procedures		
I agree to keep appropriate records with updated medical history and consent		
I agree to provide appropriate documentation on request by the HSE and to reply promptly to correspondence from the HSE		
I understand that the panel number to be issued to me is specific to the location as specified in my contract and must not be used to treat patients at another location.		
I understand that I hold full responsibility for all claims made under this panel number.		
I understand that I must provide 3 months' notice (in writing) on exiting DTSS		
I am aware of my obligations as a mandated person under the Children First Act 2015.		
I am aware of my obligations and am compliant with GDPR (May 2018)		

Applicant's Signature_____ Date_____

Example: Practice Compliance Questionnaire

(*To be completed by the Practice Principal or Owner*)

Please indicate your compliance with the following by circling the appropriate answer:

Infection Prevention Control **Irish Dental Council Code of Practice Relating to Infection Control in Dentistry 2015** *http://dentalcouncil.ie/g_crossinfection.php*		
I am in compliance with the current Irish Dental Council Code of Practice relating to Infection Control in Dentistry(April 2015)	**Yes**	**No**
Code of Practice Section 2 – ***Standard Precautions***		
I and all staff members are observing hand hygiene procedures	**Yes**	**No**
Staff are provided with, and use, Personal Protective Equipment i.e. uniform, gloves, mask , eye protection	**Yes**	**No**
Contaminated areas are disinfected between patients and impervious barriers are in use	**Yes**	**No**
A protocol is in place to deal with needlestick injury	**Yes**	**No**
I have processes in place to reduce biofilm and improve water quality in the dental unit(s)	**Yes**	**No**
Code of Practice Section 3 – ***Decontamination of dental instruments***		
I use an ultrasonic bath or washer disinfector for cleaning instruments	**Yes**	**No**
I use an autoclave that complies with Irish Dental Council Code of Practice for the sterilization of all dental instruments including dental handpieces	**Yes**	**No**
State the make and model of the Autoclave(se: ***Make:_____*** ***Model:_____*** ***Year of Installation:_____***		
I confirm that this has been subject to a formal commissioning process and is routinely serviced	**Yes**	**No**
I confirm that annual validation of ultrasonic bath(s) and autoclave(s) is carried out by a Competent Person (as per Irish Dental Council Code of Practice relating to Infection Control in Dentistry(April 2015) section 3.2.4.2 and 3.2.6)	**Yes**	**No**
Operational readings from autoclave(s) (records of autoclave cycles) are checked and passed before any instruments are released for use	**Yes**	**No**
I confirm that I will provide documentation on the day of the inspection to demonstrate regular performance monitoring by periodic tests (e.g. weekly vacuum test, daily Helix test)	**Yes**	**No**
Staff are trained in decontamination processes specific to dental practice and comply with the site specific practice Infection Control Policy.	**Yes**	**No**

Healthcare Waste Management (Waste Management Acts 1996-2012)		
I have a contract/ agreement in place to ensure correct disposal of ***clinical waste*** ***sharps*** ***dental amalgam*** ***x ray developer solutions and /or other chemicals where appropriate***	**Yes**	**No**
An amalgam separator is installed and I am in compliance with EU Mercury Regulations (SI 2011/126, SI 2017/852 and SI 2018/533)	**Yes**	**No**
Health and Safety		
I am aware of my responsibilities to comply with the Safety Health and Welfare At Work Act 2005 and subsequent regulations and legislation	**Yes**	**No**
I have an up-to-date Practice Safety Statement	**Yes**	**No**
I have taken all reasonable measures to guard against the outbreak of fire on this premises, and to ensure as far as is reasonably practicable the safety of persons on the premises in the event of an outbreak of fire **(Fire Services Act 1981*)***	**Yes**	**No**
I have a medical emergency protocol including having an appropriate emergency drugs kit, oxygen cylinder and mask	**Yes**	**No**
I, and members of my staff, have been trained in cardiopulmonary resuscitation technique (CPR) and have been updated appropriately	**Yes**	**No**
Radiation Safety Legislation		
I and members of staff, involved in taking radiographs, have been trained and certified in radiation safety and have been updated appropriately.	**Yes**	**No**
This practice location has a certificate of registration with the EPA	**Yes**	**No**
Date of most recent Quality Assurance:_____ ***Name of RPA:_____***		

Other Policies and Legislation		
I am in compliance with General Data Protection Regulations (May 2018)	**Yes**	**No**
I am aware of my responsibilities to comply with relevant Garda Vetting Legislation	**Yes**	**No**
I confirm that all labs used by this practice are registered with the Heath Products Regulatory Authority.	**Yes**	**No**
I am aware of my responsibilities in ensuring that patients are informed of their eligibility and entitlements to DTSS services	**Yes**	**No**

Practice Name	
Address	
Town	
County	
Eir Code	
Phone	
Email	
Practice Principal/Owner	

Practice Principal/ Owner's Signature:_____

Date:_____

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Example : Autoclave Compliance Test Sheet

to be completed by Competent Person (i.e. person qualified to validate the autoclave)

Dental Practice Address:

The autoclave in use complies with Irish Dental Council Code of Practice for the sterilization of all dental instruments including dental handpieces YES NO

State the make and model of the Autoclave:

Make:_____

Model_____

CE Number_____ ***Year of Installation*** _____

Data Logger or Printer attached Yes No

(if less than one year old please complete the commissioning section)

(if greater than one year old please complete the validation section)

Date of commissioning _____

Installation qualification: I confirm that the autoclave (s) has been supplied and installed in accordance with its specifications and that it is safe to operate.

Installation checks and tests completed are: (Please tick)

	Check or Test	Yes	No
A	Preliminary checks		
B	Electrical checks		
C	Functional checks		
D	Response to faults		

Operational qualification: I confirm that I have undertaken and provided documentary evidence that the autoclave(s) functions within predetermined limits when operated in accordance with the manufacturer's operating instructions/recommendations.

Tests completed include: (Please tick)

	Check or Test	Yes	No
A	Air leakage test		
B	Thermometric test		
C	Automatic Control Test and verification of Autoclave Instrument calibration		
D	Steam penetration test		
E	Helix Test that verifies that the sterilization plateau is no less than 3 minutes		
F	Load Dryness Test		

In accordance with IS EN 13060 the following **SCHEDULE OF TESTS** were undertaken: (Please tick)

	Test	Yes	No
1	Yearly Safety Checks		
2	Vacuum Leak Test		
3	Vacuum Leak Test (temperature and pressure sensors connected)		
4	Automatic Control Test		
5	Verification of Calibration of Sterilizer Instruments		
6	Thermometric Test for a small load		
7	Thermometric test for a full load		
8	Vacuum leak test (sensors removed)		
9	Bowie-Dick test for steam penetration		
10	Load Dryness Test		

	Yes	No
A V**alidation Report** has been issued (including a graph showing the full cycle and a zoom of the sterilisation plateau, all data for temperature and pressure recorded every second, and individual tests results logged and printed)		
A maintenance log book is kept on site and was reviewed by the undersigned		

I confirm that this autoclave(s) has been subject to a formal commissioning process (including Installation and Operational checks), that I am qualified to undertake these checks and a commissioning report has been provided.

I confirm that I have undertaken and provided documentary evidence that the autoclave(s) functions within predetermined limits when operated in accordance with the manufacturer's operating instructions/recommendations.

I confirm that the reference test instruments used have current INAB or UKAS calibration certificates.

I confirm that this autoclave(s) has been subject to a formal annual validation process (including Installation, Operational and Performance checks) and that I am qualified to undertake these checks. (A copy of Test Person Qualifications should be included in the validation report provided)

Due date of next annual validation: _____

Signed _____

Name_____

Job Title_____ ***Company:*** _____-_____

Preparing for a DTSS Dental Practice Inspection

A DTSS dental practice inspection will take approximately one hour. The following will be examined:

- **Decontamination (physical inspection)**

  - The surgery must support good infection control practice.

  - Dental instruments must be properly processed for infection control purposes according to Irish Dental Council guidelines. For example:
    - Instruments should be cleaned in either a suitable ultrasonic bath using an enzymatic cleaner, or in a washer-disinfector.
    - Any instruments not for immediate use must be bagged prior to autoclaving.
    - The autoclave must be suitable for sterilising bagged and narrow hollow (lumened) instruments, such as dental handpieces. Type B autoclaves will meet these requirements. If an autoclave is not Type B, the dentist must consult the manufacturer's information manual to ensure compliance.
    - Dental handpieces must be cleaned and oiled according to manufacturer's instructions.
    - Please note that all new dental premises opened after 1st January 2016 (whether in new or pre-existing buildings) must have a separate decontamination room (LDU) and must at least be fitted out to provide for a washer-disinfector. In addition, a separate decontamination room (LDU) must be included in the plans for the extension of any existing dental premises into a larger area.

  - Dental Unit Water Lines must be cleaned and disinfected to reduce biofilm build-up. Advice should be sought from the dental unit manufacturer or supplier.

  - Hand Hygiene practice must be according to SARI/WHO guidelines, see https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhai/guidelines/File,15060,en.pdf

    The following is advised
    - Designated hand-washing sinks suitable for the purpose
    - The designated sinks should not be used to wash or rinse instruments
    - Palm operated soap dispenser
    - Palm operated alcohol gel dispenser
    - Wall mounted paper towel dispenser
    - Handwashing poster visible at the handwashing sink

- **Decontamination (documentation)**

The following documentation must be available on the day of the inspection

- Evidence of ***Commissioning*** or Annual ***Validation*** by a Competent Person.
    - ***Commissioning*** happens when an autoclave is first placed in a location. It is the process of obtaining and documenting evidence that the equipment has been **supplied** and **installed** in accordance with its specifications by the manufacturer, that it is safe to operate and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions. Note that it is not acceptable to simply buy an autoclave and use it without commissioning.
    - ***Validation*** is an annual process whereby the performance of the autoclave is tested by a Competent Person. It is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. Each annual validation involves a series of performance tests on the autoclave which are carried out by a Competent Person.
    - Where the autoclave is less than one year old the Dental Inspector will look for commissioning documents.
    - If the autoclave has been installed for more than one year, proof of annual validation documentation will be sought.
    - Before a practice inspection can be scheduled a Competent Person must complete an Autoclave Compliance Test Sheet for each autoclave in use. This confirms autoclave validation/commissioning in advance of the inspection. (An example of this Test Sheet is on Page 8 and 9)

- Evidence of **daily and weekly testing** of the autoclave in use.
    - **Daily** – the Helix or Bowie-Dick test
        - The Helix test is designed to test for steam penetration through a length of a narrow hollow lumen, such as is present in a dental handpiece. The Bowie-Dick test is designed to test for steam penetration through porous surfaces. As such, the Helix test may be considered more directly relevant to dental practice.
        - The test must be conducted in an empty chamber, or according to manufacturer's instructions.
        - The Helix test may be used for those autoclaves which specify a "Bowie-Dick" cycle unless specifically indicated otherwise on the manufacturer's manual.
    - **Weekly** – the vacuum test
        - This is designed to test that the vacuum is maintained (i.e. no air is leaking into the autoclave). If air pockets exist, sterilisation cannot be assured.
        - This must be carried out on a completely cold autoclave, thus it is recommended that this test is carried out on the first cycle of the week.

- A specific cycle is present on most machines for this purpose. If no such cycle is present, the manufacturer's instructions or the supplier should be consulted.

- Evidence of operational readings of the autoclave in use (for example print-outs).

- All practices must maintain a log book for each autoclave, recording daily and weekly tests and, preferably, the cycle number and date of sterilisation of each load.

- Ideally, each record of a sterilisation cycle should be checked and passed before instruments from that autoclave load are released for use. The correct temperature and time for the cycle (e.g. 134ºC for at least 3 minutes) should be verified.

- **Proof of proper Clinical Waste Management**

  - The practice must have a contract or a fixed arrangement in place with a licensed clinical waste disposal contractor for the safe disposal of clinical waste, including dental amalgam.

  - The waste disposal contractor must be licensed for this purpose

  - Information from the Health and Safety Authority may be viewed at https://www.hsa.ie/eng/your_industry/healthcare_sector/biological_agents_/healthcare_waste/

- **Proof of installation and operation of Amalgam Separator(s)**

  - It is a legal requirement to prevent the release of certain listed materials, including mercury, into the environment. The only technology available which can adequately achieve this in dental practice is the use of amalgam separators.

  - The output from all suction systems must pass through an amalgam separator.

  - The waste from the amalgam separator must be collected and disposed of by a licensed waste disposal contractor.

    The Irish Dental Council Code of Practice regarding Dental Amalgam (July 2018) can be viewed at www.dentalcouncil.ie/files/Code%20of%20Practice%20-%20Dental%20Amalgam%20(July%202018)%20-%2020180701.pdf

- **Practice Safety Statement**

  - *The purpose of a Safety Statement is to compel a business owner to identify the hazards present in a workplace and to put in place appropriate measures to*

eliminate or reduce these risks. It is a working document which must be reviewed and updated annually or when any new significant risk is identified. It must be read and signed by all staff members, and it must be readily accessible to all staff and employees at the premises. It must be compliant with Health and Safety Authority regulations.

- *The Dental Inspectorate recommends that the Safety Statement should have numbered pages and an index to allow important information to be accessed quickly in the event of an incident. On-site risk assessment and materials safety data sheets should be included.*

- Each dental practice is required under law to have a Safety Statement.

- Details can be obtained from the Health and Safety Authority at https://www.hsa.ie/eng/topics/managing_health_and_safety/safety_statement_and_risk_assessment/

- ***Evidence of compliance with Fire Safety Regulations***

  - *The* **Fire Services Act 1981**, *section 18 (2) states:*

    "It shall be the duty of every person having control over premises to which this section applies to take all reasonable measures to guard against the outbreak of fire on such premises, and to ensure as far as is reasonably practicable the safety of persons on the premises in the event of an outbreak of fire."

  - *Further details on the regulations may be obtained from this link to the Health and Safety Authority at* **https://www.hsa.ie/eng/topics/fire/**

- **Radiology**

  - Certificate of registration with the EPA will give details of the authorised person and location.
  - A Quality Assurance (QA) report for the X Ray equipment in use should be undertaken every 2 years by a Radiological Protection Advisor. The Inspector will check the name of the RPA and the date when this QA was undertaken. The QA Report must be available on the day of the inspection so that the Inspector can verify X- Ray equipment in use.
  - The Irish Dental Council code of practice may be viewed at http://www.dentalcouncil.ie/g_ionisingradiation.php

- Information from HIQA may be viewed here: https://www.hiqa.ie/areas-we-work/ionising-radiation

- **Medical Emergency Management**

  - Evidence of staff cardio-pulmonary resuscitation (i.e. basic life support) training.

  - Availability of emergency drugs kit
    - Drugs should be clearly labelled and the expiry date highlighted.
    - It is recommended that details should be attached to each drug container describing how the drug should be administered, by whom and in what circumstances.

  - Availability of oxygen cylinder and masks
  - The oxygen cylinder and masks must be readily accessible

FINAL NOTE:

The above is a guide to help a practitioner prepare for an inspection by the Dental Inspectorate. It is based on the experience of the inspection process to date. It is not an exhaustive list. The Dental Inspector may come across other issues that may need to be addressed.

Following the practice inspection, where the Inspector is satisfied that the premises meets the requirements, the Inspector will advise the HSE to process further the DTSS contract application for that practice location.

In the case where the premises has not passed the inspection, the Inspector will issue a feedback report outlining the necessary improvements required before the DTSS panel number can be processed.

When the inspection process has been completed, final processing of the contract application reverts to the local HSE.