

## **DTSS Practice Inspections**

A number of Quality and Safety validation checks have been introduced as part of the approval process prior to awarding DTSS contracts.

The initial stage of a DTSS contract application is administered by a local HSE office. When the initial processing has been completed, the HSE office informs the Dental Inspectorate who then carry out the 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 owner / manager
- (b) Practice inspection

### **(a) Self-Declaration**

The Practice Principal and the Contract Applicant are asked to complete a separate Questionnaire. When these have been completed and returned to the Regional Dental Inspector, a mutually convenient time and date will be arranged for a Practice Inspection.

The Contract Applicant is also asked to forward a copy of their up-to-date CPR certificate with the completed Applicant Induction Questionnaire.

Please click on these links to view examples of the [contract applicant questionnaire](#) and the [practice questionnaire](#).

### **(b) Practice Inspection**

On receipt of the completed questionnaires, the Practice Owner / Principal / Manager 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. The practice **must** be in compliance with the Codes of Practice of the Dental Council.

On the date of the practice inspection, all documentation held by the practice on the following **must** be available for inspection:

- 1. Proof of Clinical Waste Management (including dental amalgam)**
- 2. Proof of installation and operation of amalgam separator(s).**
- 3. Safety Statement**

**4. Evidence of compliance with fire safety regulations**

**5. Up to date X Ray Licence including Schedule 2 and 3**

**6. Emergency Medical Care**

- a. Evidence of life support training
- b. Availability of emergency drugs kit and oxygen cylinder

**7. Decontamination Documentation**

- a. Commissioning or Annual Validation of autoclave by a competent person.
- b. Evidence of daily and weekly testing of the autoclave in use.
- c. Evidence of operational readings of the autoclave in use (e.g. Print Outs).

Further information on all of these requirements can be viewed by clicking [here](#).

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 Dental Council and HIQA guidelines on infection control.
2. Dental instruments and materials are properly treated for infection control purposes according to Dental Council guidelines.
3. Dental Unit Water Lines are properly managed according to Dental Council guidelines.
4. Hand Hygiene is properly managed according to SARI guidelines.

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

**Example: DTSS Contract Applicant Induction Sheet**

<b>Applicant Name</b>	
<b>Other Name</b>	<b>(if previously registered under any other name)</b>
<b>Contact Address (to complete if different from practice address)</b>	
<b>Contact Number (s)</b>	
<b>Email</b>	
<b>Dental Council Number</b>	

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

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

<b>Practice Address (for new contract)</b>	
<b>Other DTSS contract numbers currently or previously held</b>	

**I agree to undertake the following:**

	<b>Yes</b>	<b>No</b>
<b>To inform patients of their entitlements under the DTSS</b>		
<b>To comply with HSE protocols for the prioritisation of high risk patients</b>		
<b>To comply with HSE Standard Operating Procedures</b>		
<b>To keep appropriate records with updated medical history and consent</b>		
<b>To provide appropriate documentation on request by the HSE and to reply promptly to correspondence from the HSE</b>		
<b>To provide 3 months' notice (in writing) on exiting DTSS</b>		
<b>To understand my role and obligations as a mandated person under the Children First Act 2015</b>		

**Applicant's Signature** \_\_\_\_\_ **Date:** \_\_\_\_\_

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**Example: Practice Principal Quality & Safety Compliance Questionnaire**

*(To be completed by the practice principal or owner)*

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

(1) Infection Prevention Control		
Irish Dental Council Code of Practice Relating to Infection Control in Dentistry 2015		
<a href="http://dentalcouncil.ie/g_crossinfection.php">http://dentalcouncil.ie/g_crossinfection.php</a>		
<i>I am in compliance with the current Irish Dental Council Code of Practice relating to Infection Control in Dentistry(April 2015)</i>	Yes	No
<b>Code of Practice Section 2 – Standard Precautions</b>		
<i>I and all staff members are observing hand hygiene procedures</i>	Yes	No
<i>Staff are provided with, and use, Personal Protective Equipment i.e. uniform, gloves, mask , eye protection</i>	Yes	No
<i>Contaminated areas are disinfected between patients and impervious barriers are in use</i>	Yes	No
<i>A protocol is in place to deal with needle stick injury</i>	Yes	No
<i>I have processes in place to reduce biofilm and improve water quality in the dental unit(s)</i>	Yes	No
<b>Code of Practice Section 3 – Decontamination of dental instruments</b>		
<i>I use an ultrasonic bath or washer disinfector for cleaning instruments</i>	Yes	No
<i>I use an autoclave that complies with Irish Dental Council Code of Practice for the sterilization of all dental instruments including dental hand pieces</i>	Yes	No
<i>State the make and model of the Autoclave:</i>		
<i>Make:</i> _____		
<i>Model</i> _____		
<i>Year of Installation</i> _____		
<i>I confirm that this has been subject to a formal commissioning process and is routinely serviced</i>	Yes	No
<i>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 section 3.2.4.2 and 3.2.6)</i>	Yes	No
<i>Are operational readings from autoclave(s) (records of autoclave cycles) checked and passed before any instruments are released for use?</i>	Yes	No
<i>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)</i>	Yes	No

<i>Staff are trained in decontamination processes specific to dental practice and comply with the site specific practice Infection Control Policy.</i>	Yes	No
<b>(2) Healthcare Waste Management (Waste Management Acts 1996-2012)</b>		
<i>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</i>	Yes	No
<i>An amalgam separator is installed in compliance with SI 126 of 2011, EU Directive</i>	Yes	No
<b>(3) Health and Safety</b>		
<i>I am aware of my responsibilities to comply with the Safety Health and Welfare At Work Act 2005 and subsequent regulations and legislation</i>	Yes	No
<i>I have an up-to-date Safety Statement</i>	Yes	No
<i>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)</i>	Yes	No
<i>I have a medical emergency protocol including having an appropriate emergency drugs kit, oxygen cylinder and mask</i>	Yes	No
<i>I, and members of my staff, have been certified in cardiopulmonary resuscitation technique (CPR) and have been updated appropriately</i>	Yes	No
<b>(4) Radiation Safety Legislation</b>		
<i>I am aware of my responsibilities and compliance with SI 125 of 2000 and SI 478 of 2002</i>	Yes	No
<i>I, and members of staff, involved in taking radiographs, have been trained and certified in radiation safety and have been updated appropriately</i>	Yes	No
<b>(5) Other Policies and Legislation</b>		
<i>I am in compliance with Data Protection legislation (Data Protection Acts 1988 and 2003, and any subsequent regulations or legislation) and am registered with the Data Commissioner</i>	Yes	No
<i>I am aware of my responsibilities to comply with relevant Garda Vetting legislation and my obligations under the Children First Act 2015</i>	Yes	No
<i>I confirm that all labs used by this practice are registered with the Health Products Regulatory Authority.</i>	Yes	No

<i>I am aware of my responsibilities in ensuring that patients are informed of their eligibility and entitlements to DTSS services</i>	Yes	No
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<b>Practice Name</b>	
<b>Address</b>	
<b>Town</b>	
<b>County</b>	
<b>Phone</b>	
<b>Email</b>	
<b>Practice Owner</b>	

**Owner's or Manager's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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### 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 hand pieces**      **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 <b>Validation Report</b> 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 documentation will be examined:

- **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
- Department of Health regulations may be viewed [here](#).
- Dental Council guidelines (see Section 4) can be viewed [here](#).

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- **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 contractor.
- Further details regarding the regulations are available in the National Hazardous Waste Management Plan [here](#).
- Dental Council guidelines (see Section 4.2.2) can be viewed [here](#).

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- **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 by all staff members, and it must be readily accessible to all workers 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 [here](#).
- Dental Council guidelines (see Section 5) may be viewed [here](#).

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- **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.”*
- Dental premises must be compliant with these regulations. The premises owner should produce on the day of the practice inspection any report or certification received from a qualified fire safety expert.
- Further details on the regulations may be obtained from this link to the [Health and Safety Authority](#).

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- **Up to date X Ray Licence including Schedule 2 and 3**

- Schedule 2 gives the details about each machine covered by the license.
- Schedule 3 gives the name of the Radiological Protection Advisor and the date of the last Quality Assurance (QA) report for this license.
- The date of the QA report must be within 2 years of the day of the DTSS practice inspection date.
- The Dental Council code of practice may be viewed [here](#).
- The EPA regulations may be viewed [here](#).

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- **Emergency Medical Care**

- 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
  - The oxygen cylinder must be accessible at all times that the dental practice is open.

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- **Decontamination (physical inspection)**

- The surgery must be visibly tidy, cleanable, and must support good infection control practice.
  - For example, there must be sufficient space for zoning clean and dirty areas, the work surfaces must be cleanable and cleaned adequately, etc.
  
- Dental instruments and materials must be properly treated for infection control purposes according to Dental Council guidelines. For example:
  - Hand washing of instruments alone will not be acceptable.
  - Dental hand pieces must be cleaned and oiled according to manufacturer's instructions.
  - Instruments must be cleaned in either a suitable ultrasonic bath using an enzymatic cleaner, or (preferably) a washer-disinfector.
  - Any instruments not for immediate use must be bagged prior to autoclaving.
  - The autoclave must be suitable for sterilising bagged and Hollow A (narrow lumened) instruments, such as dental hand pieces. 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.
  - Please note that all new dental premises opened after 1<sup>st</sup> 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 must be properly managed according to SARI guidelines, which can be viewed [here](#). 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
  - Hand washing poster visible at the hand washing sink

See Dental Council guidelines, Section 2.3 (“Elements of Standard Precautions”) [here](#).

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- **[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.
  
- 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 hand piece. 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. 134°C for at least 3 minutes) should be verified.

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**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.