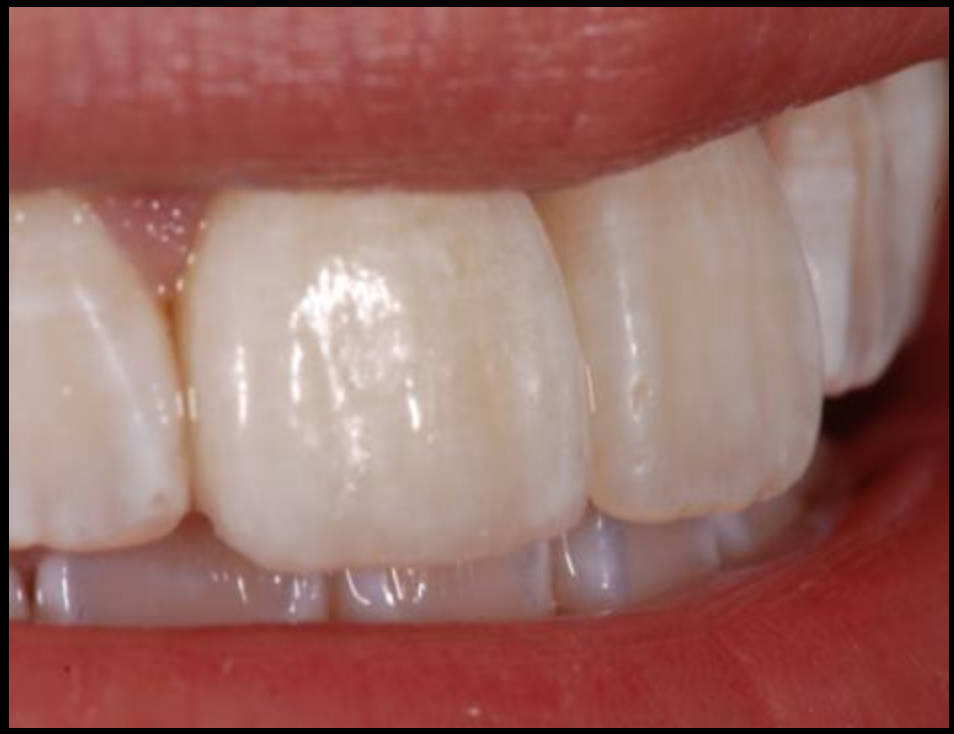
Grey Market Dental Supplies

"The Perils and Pitfalls of using Non-Approved Materials in Your Dental Practice"

Trevor Laingchild
R.D.T. A AACD

What Is A Registered Dental Technologist…..
And
Why Do We need them



As an RDT Lab Owner it is my responsibility to adhere to the rules and the regulations as noted by the:

Regulated Health Profesions Act 1991
Dental Technology Act 1991

Governed by

College of Dental Technologists of Ontario
"CDTO"

College Of Dental Technologists Of Ontario Mission:

Fulfill its mission to serve and protect the public interest in a variety of ways.

Ensures academic and practice standards for those seeking registration as an RDT

College Of Dental Technologists Of Ontario

Statutory Standing Committees
Executive
Registration
Complaints
Discipline
Fitness to practice
Patient relations
Quality insurance

College Of Dental Technologists Of Ontario

Establishes and enforces practice standards
Promotes quality practice
Encourages continuing competency in Dental Technology
Holds all Dental Technologists accountable for conduct and practice

College Of Dental Technologists Of Ontario

Licensed Laboratory

Obtain recognized certification of Practice Maintaining the License from recognized legislature

College Of Dental Technologists Of Ontario

License Laboratory

Open to professional reviews
Have appropriate Errors, Omissions and Liability insurance

College Of Dental Technologists Of Ontario

License Laboratory

Complete continuing education
Asepsis courses
Jurisprudence courses
Full and complete record maintenance

College Of Dental Technologists Of Ontario

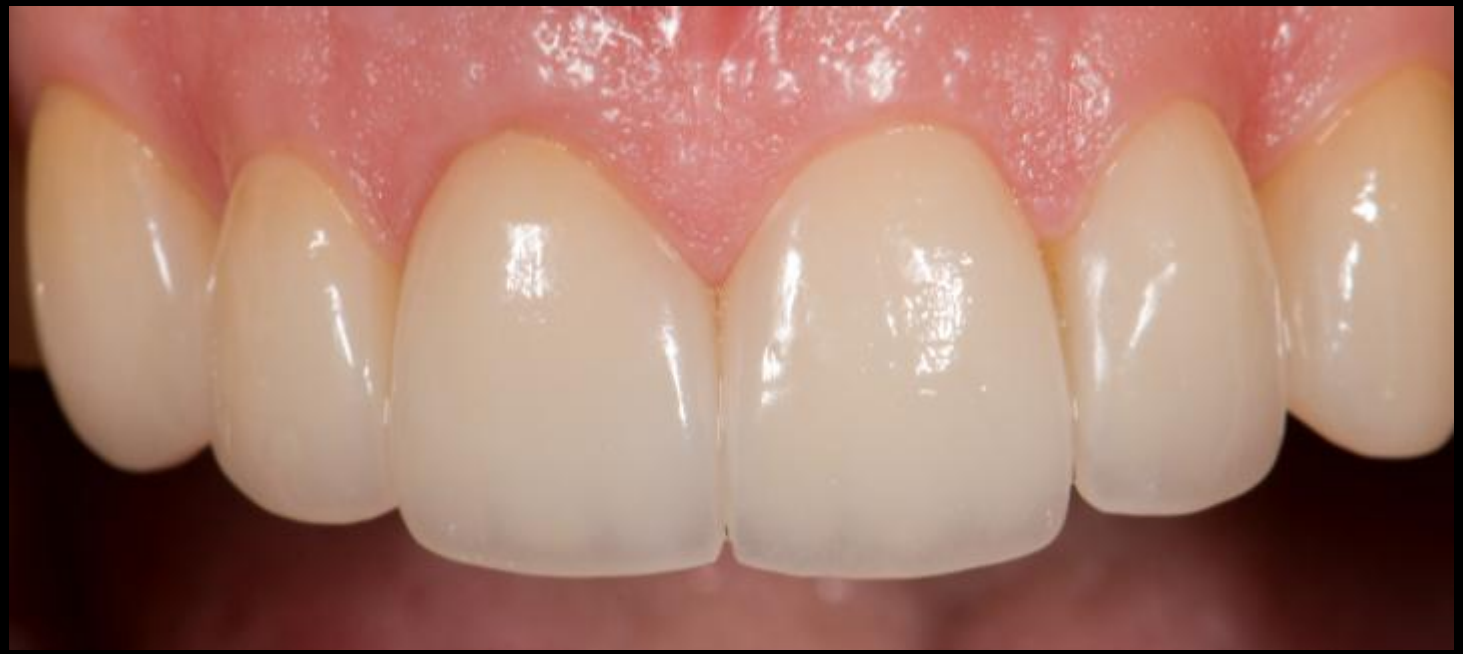
License Laboratory

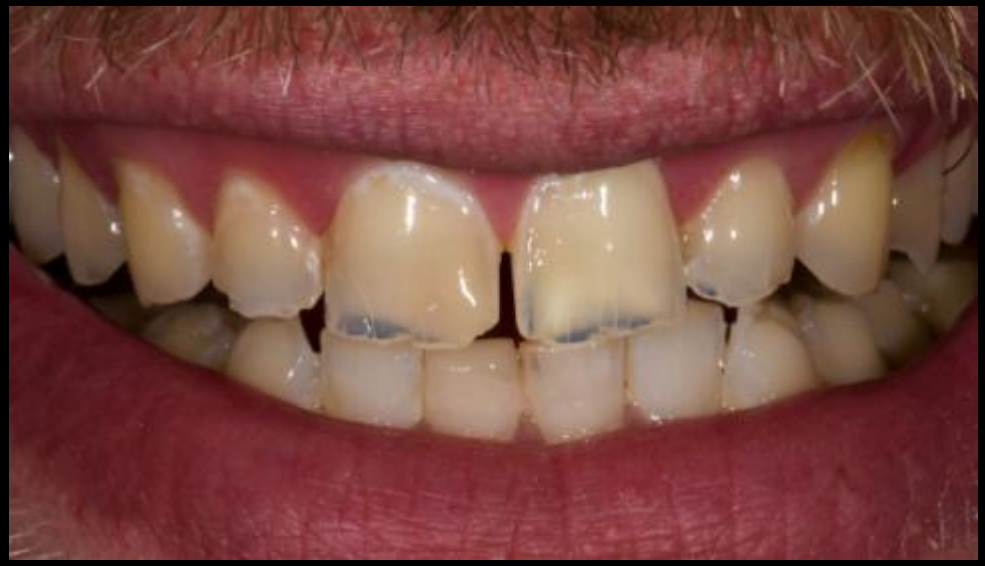
Open to professional reviews
Have appropriate Errors, Omissions and Liability insurance

As an RDT/Lab owner my responsibility is to the prescribing Doctor and ultimately to the patient.

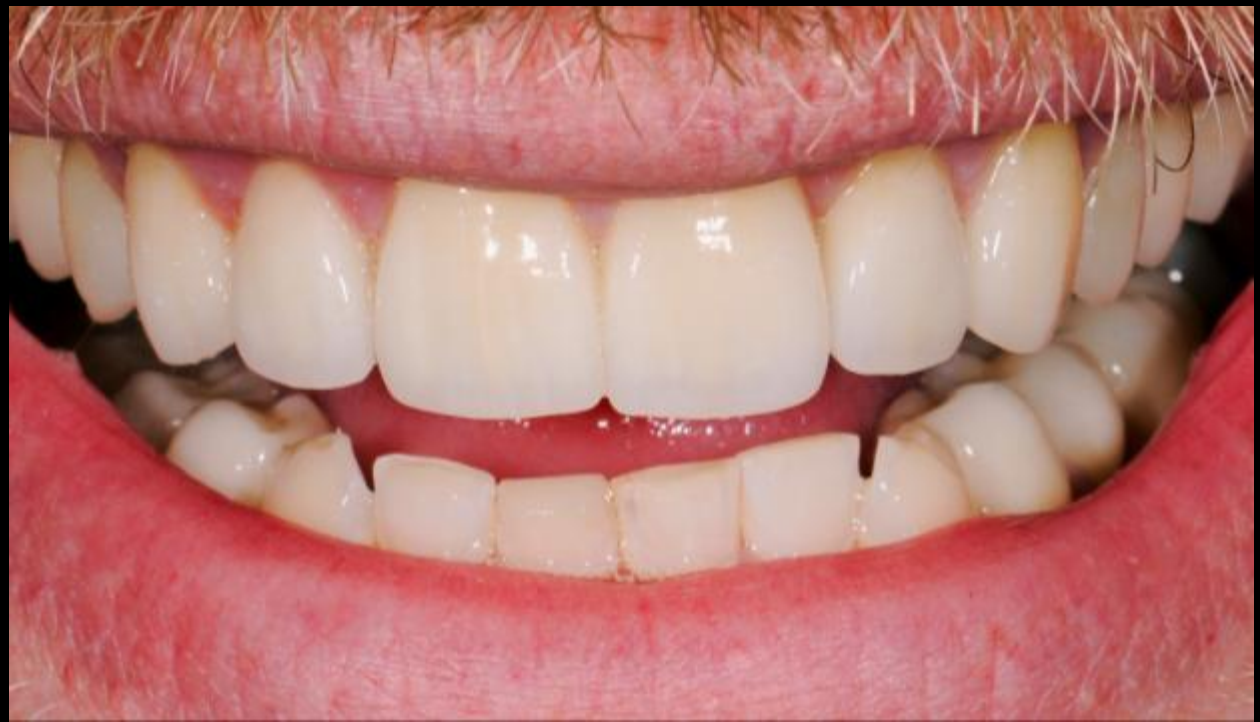
Responsibilities to the Doctors and Patients

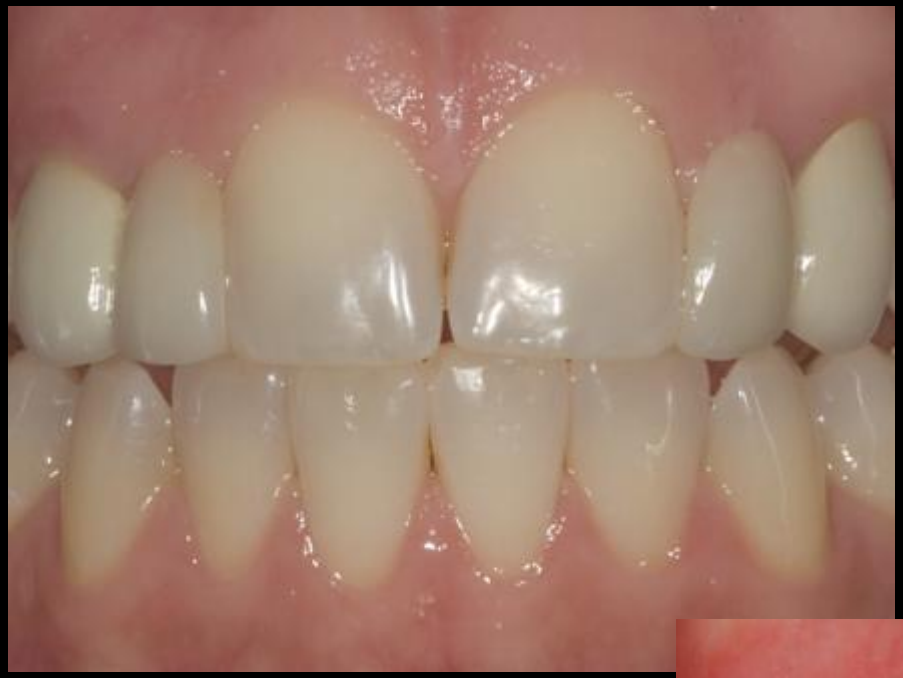
Follow procedures and exceed Standards of Practice from CDTO





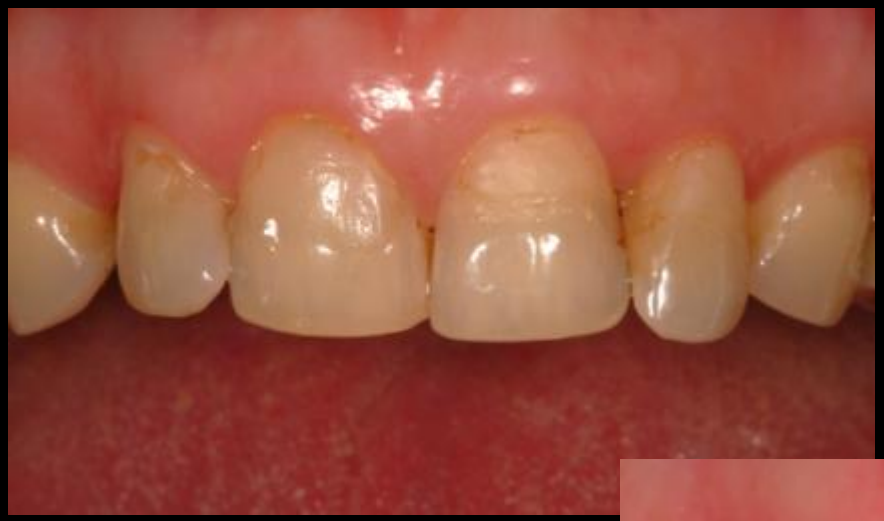
Responsibilities to the Doctors and Patients

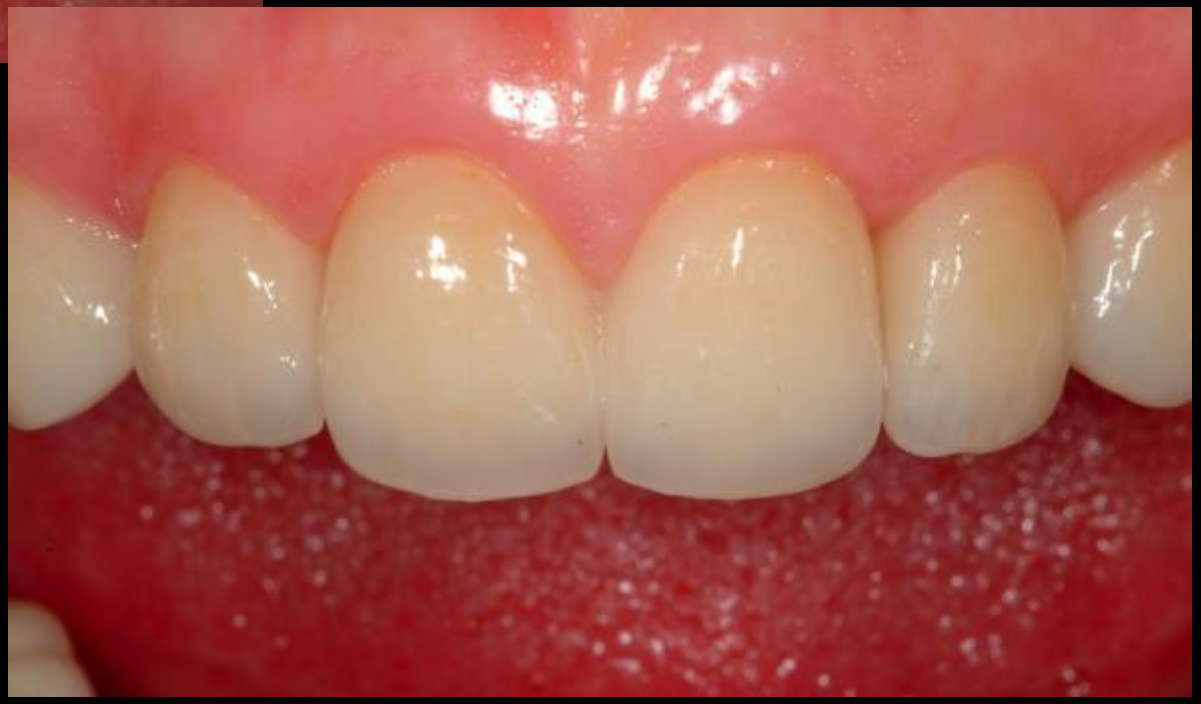




Responsibilities to the Doctors and Patients

Responsibilities to the Doctors and Patients





Responsibilities to the Doctors and Patients

Use materials that are approved for use by Health Canada

Responsibilities to the Doctors and Patients

Use certification of approved materials
For example:

- *Ident-alloy*
- *Implant components*
- *Ceramic materials*
- *Zirconium materials*
- *Acrylic materials*
- *Composite materials*

Responsibilities to the Doctors and Patients

Responsibilities to the Doctors and Patients

Implants

Variety
Confusing
Clones
Fakes
Original Parts

Responsibilities to the Doctors and Patients

CAD/CAM

Not original parts
Is it original screw ?
Possible warranty/ legal ramification
for non original part manufacturers
Health Canada approval

Responsibilities to the Doctors and Patients

CAD/CAM

Offshore milling infrastructures using non health Canada approved materials Zirc, Ti, etc….

Responsibilities to the Doctors and Patients

Invoice:

- *Transparency of fabrication protocols*
- *Materials used*
- *Certification of materials*
- *RDT Stamp (including registration #)*

Responsibilities to the Doctors and Patients

Lab Prescription, Invoice and related information

Kept for a period of 10 years

Possible CDTO , RCDS review of records

Peer review

Patient

Deserving of optimum care and use of materials

Health Canada approved materials

Prosthesis fabricated by a licensed Laboratory or individual

US Statistics of Dental Device Imports and FDA Requirements

By

Warren H. Rogers

Dental Device Imports - US

NADL estimates based on US International Trade Commission statistics

- Up to 35% of total units may be imported devices
- Up to 24% of revenue may be from imported devices

US Customs custom's value statistics indicate an overall growing trend in the past five year period

2008 – 7.4%
2009 – 1.7%
2010 – 7.9%
2011 – 13.7%
2012 – 9.9%

Dental Device Imports - US

Based on statistics from the US Department of Commerce and the US International Trade Commission, the following our the top six import countries of dental devices and their % share of all imported dental devices

China –	29%
Spain –	14%
Germany –	13%
Canada –	8%
Costa Rica –	5%
Italy –	5%

Dental Device Imports - US

US Food and Drug Administration (FDA) requirements relative to imported devices

- All foreign made devices must be registered with FDA
- Every dental laboratory that receives a device from a foreign source and relabel's and or repackages is considered a Repackager/Relabeler and must be registered with FDA

Although most all foreign made devices are in registration compliance, it is estimated that only 50% or less dental labs are a registered Repackager/relabeler and in compliance

Dental Device Imports - US

US Food and Drug Administration (FDA) recent initiatives relative to imported devices

- Registration annual fee for repackager/relabeler is now over $2,000 from no fee
- All foreign entities selling in the US must report to FDA; the name, address, contact, phone number of all US customers in the supply chain

IRS implemented Medical Device Excise tax where all foreign made, FDA registered devices are subject to a 2.3% tax

- US made devices (except sleep apnea) are not classified and do not require a excise tax

Canada Import estimates and regulatory requirements

Estimates and evaluation for dental devices in Canada

Canada's import and export business is up overall and has recovered from 2009

The dental laboratory products segment is estimated between C$800M and C$1B

Despite the worldwide economical downturn, Canada medical and dental device business is doing well and expected to continue to grow

The economy growth is predicted to be 2% for the next five years and an expectation to have a surplus in the economy by 2015

Canadian dental device imports

Dental instruments and appliances make up the top 10 segments of imports for the medical devices category with a 3% share

50% of all medical devices is imported from the US and China and Germany round out the top three

Canada imports more than C$3.5B in medical devices each year

Canadian dental device imports

Based on current statistics in the US, the current Canadian import statistics on medical devices and the Canadian dental health system dynamics, it is estimated that dental device import revenue make up 12% - 14% and 17% - 20% of units.

It is estimated that up to 50% of dental devices are imported from the US

Based on research of the Health Canada active license listing, it is estimated that less than 5% of US dental labs are registered

Dental Device regulatory requirements when importing into Canada

Dental devices are classified; class II, class III for removable and fixed devices

Foreign manufacturer must have quality management system certified by an accredited Standards Counsel of Canada (SCC) third party auditor, must meet all criteria outlined by Canadian Medical Device Conformity Assessment System (CMDCAS) – ISO 13485

All devices, labels and packaging must meet all requirements outlined by Health Canada

All products must be registered and approved by Health Canada including patient contact material elements

Health Canada – Registration of device requirements

Cover Letter

Executive Summary

Device Description

General Description

License Amendments

Drugs

Design Philosophy

Indications for Use and/or Intended Use and Contraindications

Device Labels, Package Labeling and Documentation

Marketing History

Incident Reports and Recalls

Health Canada – Registration of device requirements

- Safety and Effectiveness Studies
  - Standards
  - Preclinical Studies
  - Physical and Mechanical Bench Tests
  - Software Verification and Validation
  - Biocompatibility Tests
  - Pyrogenicity
  - Animal Studies
  - Clinical Studies
- Sterilization
  - Sterilization Validation
  - Residual Toxicity
  - Packaging
  - Shelf Life Validation
  - Shelf Life of the Product
  - Shelf Life of the Packaging
  - Bibliography

Health Canada – Registration of device requirements

Registration is required for each device or family of device

- All Ceramic devices
- Ceramic to Alloy devices
- All metal devices
- Full Acrylic dentures
- Partial acrylic dentures
- Partial resin dentures
- Partial metal/acrylic dentures

Health Canada – Registration of device requirements

Estimated cost for foreign entity to legally meet all Canadian regulatory requirements

ISO 13485 Certification (assuming entity does not have)

- Management time appropriation (1-Yr) $100,000
- Outside QSM counseling $ 10,000
- QSM analysis and auditing $ 14,000

Registration Process

- Professional services/registration $ 8,000
- Health Canada application fees $ 17,000
- Packaging/Translation changes $ 12,000
- Licensure $ 1,200

Conclusion