PROVINCIAL DENTAL BOARD
OF NOVA SCOTIA

Nova Scotia Provincial Blood Coordinating Program
Provincial Dental Board of Nova Scotia

Toolkit for Allograft Usage In Dental Practice

September 29, 2017

A. Preamble

This document has been developed by the Nova Scotia Provincial Blood Coordinating Program in conjunction with the Provincial Dental Board of Nova Scotia to support compliance by dentists practicing in Nova Scotia to the Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations. As described within this toolkit, establishments other than source establishments that discover an unexpected adverse reaction has occurred must report the information to the source establishment or the importer (if applicable) for all suspected or known unexpected adverse reactions associated with a tissue without delay.

This document is divided into sections according to responsibilities the user has:

- Determining whether or not a distributor or manufacturer is licensed by Health Canada;
- Signs and symptoms of an adverse reaction;
- Example cases of adverse reactions to tissues used in dental settings;
- Who to report adverse reactions of transplanted tissue to; and
- How to report adverse reactions.

Table of Contents

B. Reporting Allograft Usage Data: What Dentists Need to Know

Since 2016 dentists have been required to report the number of human allograft tissues transplanted in practice each year to the Provincial Dental Board of Nova Scotia.

Human allograft tissues are commonly used in dental practice today. In 2009, the Health Products and Food Branch Inspectorate of Health Canada adopted the *Guidance Document for Cell, Tissue, and Organ Establishments – Safety of Human Cells, Tissues, and Organs for Transplantation.* This document was published to assist establishments in complying with Health Canada's *Safety of Human Cells, Tissues, and Organs for Transplantation Regulations*, which came into force in 2008.

The Canadian Dental Association published its *Guidance Document for Dentists Providing Human Allogeneic Transplants* in 2010. This document outlines the specific requirements that pertain to dentists using human allograft tissue products in their practice. The main requirements for dentists utilizing these products in their practice are as follows:

1. To ensure that any human allograft tissue products utilized in practice are obtained from Source Establishments that are registered with Health Canada
2. To ensure that recordkeeping practices capture all of the information required (donor identification code, description of the transplanted tissue, the Health Canada registration number of the source establishment, the notice of exceptional distribution, if applicable, information that allows for identification of the recipient, and documentation of any suspected errors, accidents, or adverse reactions and their investigation) for ten years
3. To ensure that there are procedures in place for reporting suspected errors, accidents and adverse reactions

The Provincial Dental Board of Nova Scotia has a mandate to protect the public interest in matters related to the delivery of dental care. The Board does this by ensuring that only properly trained, licensed individuals provide treatment and that the treatment is of a reasonable standard. The Provincial Dental Board is responsible for the administration of the *Dental Act* and the Regulations pursuant to the *Act*. With the privilege of self-regulation comes the responsibility of responsible action.

Part of the responsible action is ensuring that practitioners in Nova Scotia are aware of the regulatory requirements and are adhering to regulations and standards. As such, dentists must provide to the Board, as part of annual license renewal, the number of human allograft tissue products transplanted in practice in the previous calendar year. This is done for the safety of Nova Scotians by ensuring that transplanted tissue products are obtained from Health Canada registered source establishments, and that recipients are easily identifiable in the event of a recall.

Additionally, the number and type of human allografts transplanted by dentists will be shared with the Nova Scotia Provincial Blood Coordinating Program (NSPBCP). The Program collects data on tissue usage in Nova Scotia as part of their participation in the National Cells, Tissues, and Organs Surveillance System.

What products are included in the project?

Below are some examples to help you identify the type of products that fall within this scope:

1. Demineralized bone (Raptos by Citagenix; PentOs Ol Fill by Citagenix, Straumann AlloGraft)
2. Mineralized bone (Mineralized cancellous powder by Synthes)
3. Demineralized bone strips (PentOs Ol Fec by Citagenix)
4. Demineralized bone putty (PentOs Ol Putty by Citagenix, DBM Putty by Synthes, AlloOss Putty with demineralized bone chips by ACE Surgical)
5. Injectable bone morphogenetic protein (INFUSE Bone Graft by Medtronic)
6. Particulate allograft (Puros by Zimmer)
7. Extracellular dermal matrix (DynaMatrix by Citagenix)
8. Acellular dermal matrix (NeoDerm by Citagenix, AlloDerm Regenerative Tissue Matrix by LifeCell; DermanMatrix Acellular Dermis by Synthes)
9. Placental allograft membrane (BioXclude by Citagenix)
10. Any other product that contains human cells

These are some examples of the products that are in scope. If you have other products and are unsure whether they should be counted, you can contact the Nova Scotia Provincial Blood Coordinating Program at (902) 487-0504.

C. List of Registered CTO Establishments

In accordance with the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations), all source establishments and establishments that distribute or import for further distribution, cells, tissues and organs (CTO), must register with Health Canada. *The List of Registered CTO Establishments* should be used as a reference tool to identify those establishments that have registered with Health Canada prior to requesting tissues from suppliers.

The List of Registered Cells, Tissues and Organs Establishments can be found at:

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/cells-tissues-organs/list-registered-cells-tissues-organs-establishments.html

Commonly used registered establishments in Nova Scotia include:

- BioHorizons

- Citagenix
- Zimmer BioMet
- Nobel BioCare
- Straumann
- Musculoskeletal Transplant Foundation

Medical devices establishment licences held with Health Canada can be determined by entering the appropriate information in this website: https://health-products.canada.ca/mdel-leim/index-eng.jsp

Commonly used licensed medical device establishments include:

- Dentsply
- Depuy

D. Adverse Reactions to Tissues

Establishments, other than source establishments, that discover an unexpected adverse reaction has occurred must report to the source establishment and the importer (if applicable) all suspected or known unexpected adverse reactions associated with a tissue without delay as well as the NSPBCP.

Upon receipt of the notice above, an importer of tissue is required to notify the source establishment of the adverse reaction.

An **unexpected** adverse reaction following the transplantation of a tissue includes the **unintended** and **unforeseen** transmission of any bacterial, viral or fungal infection (infection disease or disease agents), as well as malignancies or any other disease/disorders (e.g. genetic disorder, immunological disorder, etc.) that is suspected to originate from the donor.

Signs and Symptoms include but are not limited to:

- Chills
- Fever
- Localized tenderness
- Abscess formation
- Osteonecrosis
- Rash

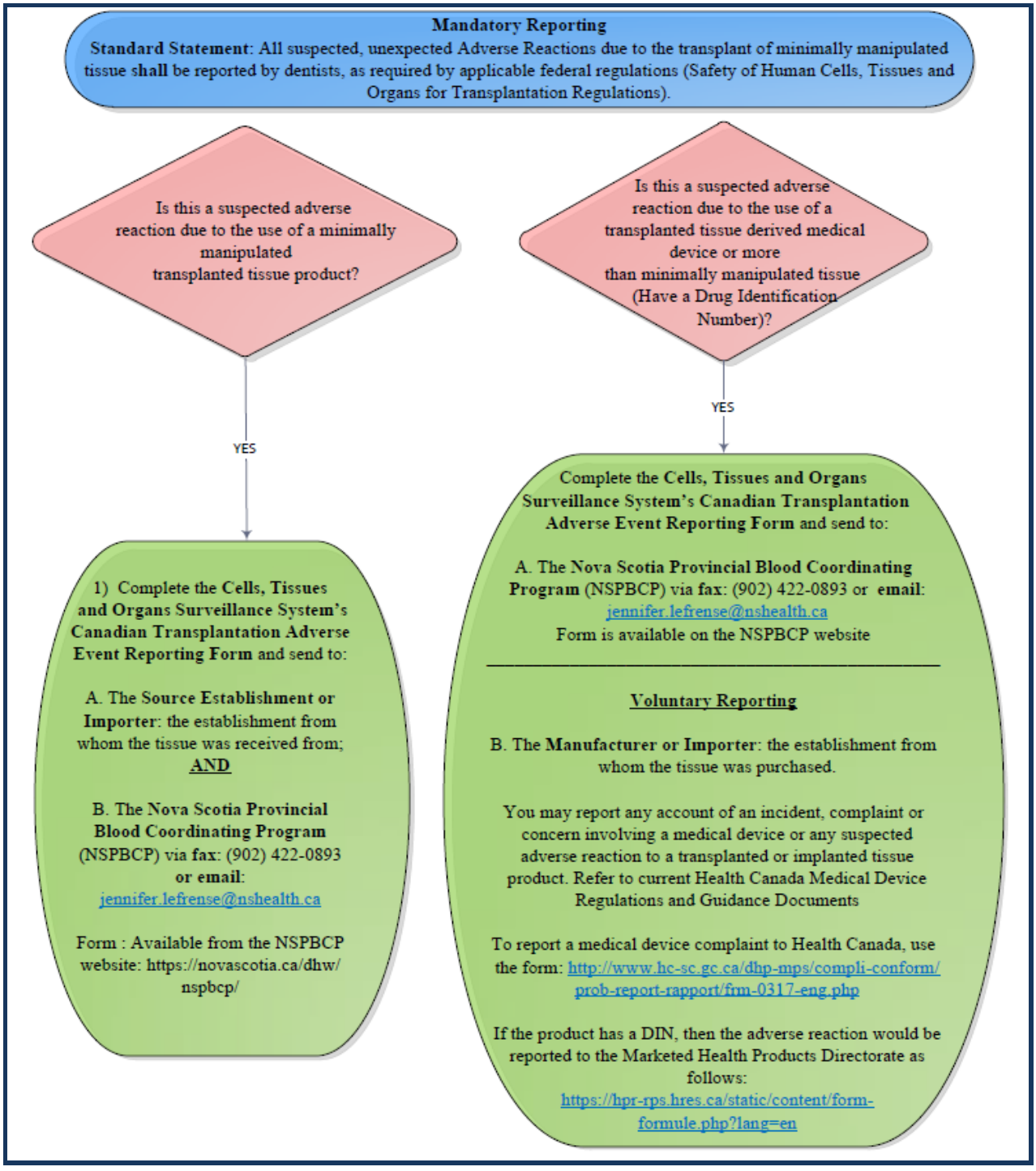
- Pain
- Swelling
- Dry socket
- Bleeding

If the infectious agent was a virus such as HBV or HIV etc., the presentation would of course differ depending on the disease and may be a positive screening test in an asymptomatic patient.

E. Example Cases

Tissue	Adverse Reaction(s)
Mineralized cortical powder	Jaw ache/pain, dry socket and premature loss of sutures
Cortical bone demineralized and dental pericardium	Rash
AlloDerm	Peri-implantitis, infection of the AlloDerm membrane
Mineralized allograft cortical/cancellous bone granules	Failed osteointegration of a bone allograft possibly due to a post-operative infection of the graft site
AlloDerm (acellular human skin graft)	Swelling and bleeding

F. Algorithm for Reporting Adverse Reactions to Transplanted Tissues by Dentists

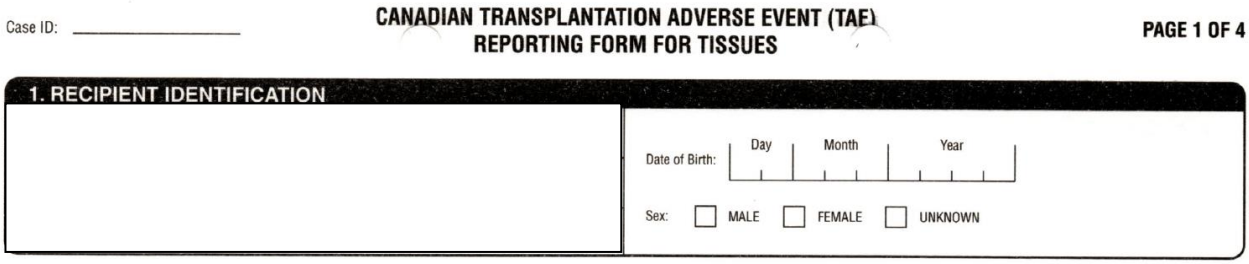


G. Canadian Transplantation Adverse Event (TAE) Reporting Form for Tissues

The TAE Reporting Form for Tissues can be obtained by calling The NSPBCP at 902-487-0504 or on the NSPBCP website: https://novascotia.ca/dhw/nspbcp/

Instructions for Completing the Canadian Transplantation Adverse Event (TAE) Reporting Form for Tissues are as follows:

1) Complete the Date of birth and sex fields.


Case ID: _____

CANADIAN TRANSPLANTATION ADVERSE EVENT (TAE) REPORTING FORM FOR TISSUES

PAGE 1 OF 4

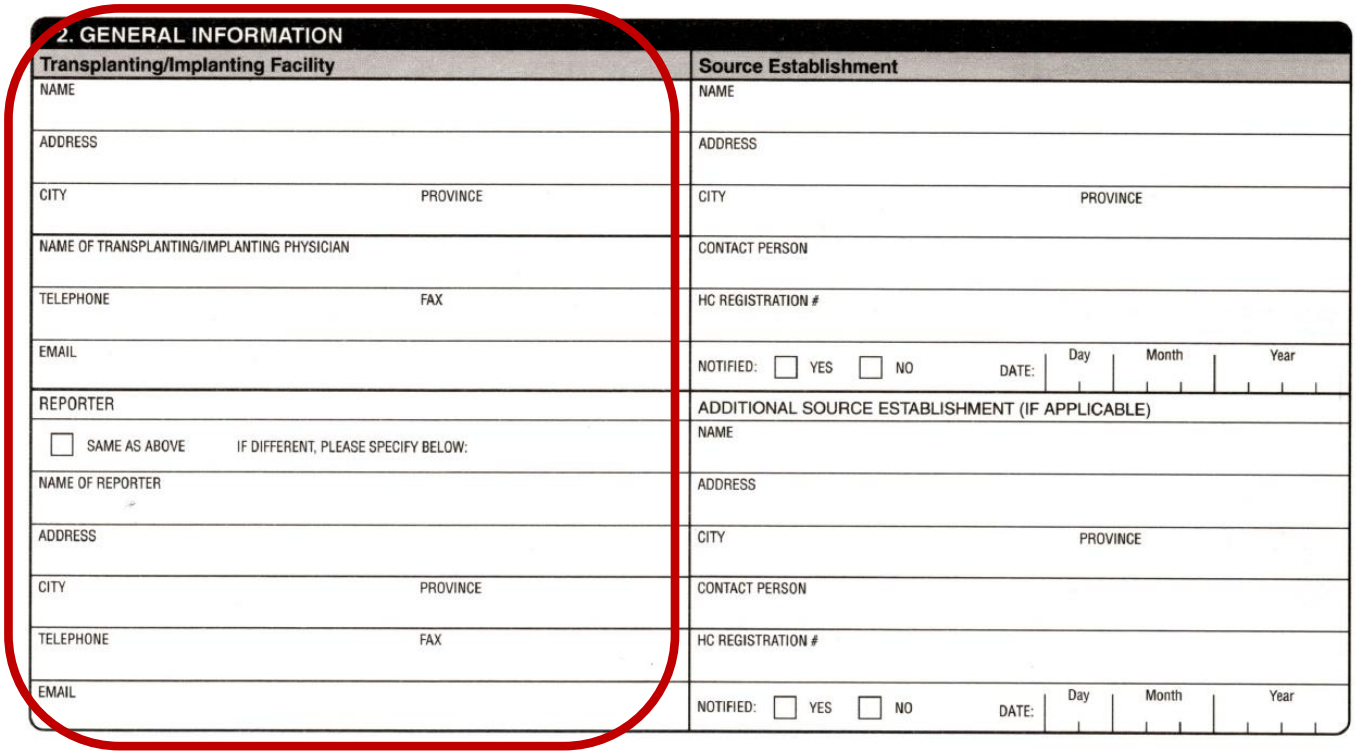
1. RECIPIENT IDENTIFICATION

Date of Birth: Day Month Year

Sex: ☐ MALE ☐ FEMALE ☐ UNKNOWN

2) Complete the information in regards to your facility. This includes:

- Name of facility
- Address
- Name and contact information of the transplanting dentist
- Name and contact information of the individual completing the form if different from the transplanting dentist

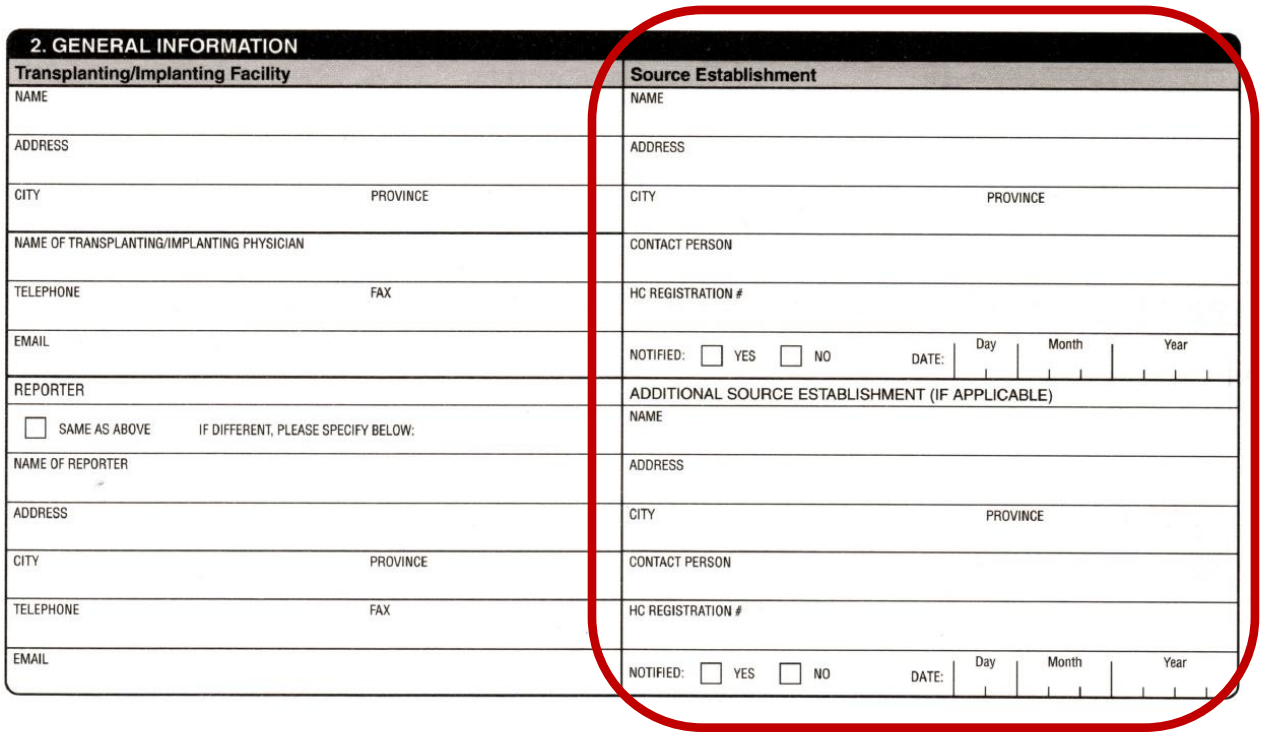


2. GENERAL INFORMATION

Transplanting/Implanting Facility	Source Establishment
NAME	NAME
ADDRESS	ADDRESS
CITY PROVINCE	CITY PROVINCE
NAME OF TRANSPLANTING/IMPLANTING PHYSICIAN	CONTACT PERSON
TELEPHONE FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day Month Year
REPORTER	ADDITIONAL SOURCE ESTABLISHMENT (IF APPLICABLE)
☐ SAME AS ABOVE IF DIFFERENT, PLEASE SPECIFY BELOW:	NAME
NAME OF REPORTER	ADDRESS
ADDRESS	CITY PROVINCE
CITY PROVINCE	CONTACT PERSON
TELEPHONE FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day Month Year

3) Complete the information in regards to the Source Establishment. This includes:

- Name
- Address
- Contact Person and Health Canada registration number, you must also indicate if they were notified



2. GENERAL INFORMATION

Transplanting/Implanting Facility	Source Establishment
NAME	NAME
ADDRESS	ADDRESS
CITY PROVINCE	CITY PROVINCE
NAME OF TRANSPLANTING/IMPLANTING PHYSICIAN	CONTACT PERSON
TELEPHONE FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day Month Year
REPORTER	ADDITIONAL SOURCE ESTABLISHMENT (IF APPLICABLE)
☐ SAME AS ABOVE IF DIFFERENT, PLEASE SPECIFY BELOW:	NAME
NAME OF REPORTER	ADDRESS
ADDRESS	CITY PROVINCE
CITY PROVINCE	CONTACT PERSON
TELEPHONE FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day Month Year

4) Complete the information in regards to the transplantation adverse event. This includes:

- Date and location of the event
- Tissue type
- Product code
- Supplier name
- Donor ID code
- Expiry date
- Quantity
- Dates of Transplant, Pre-Transplant and Post-Transplant.

3. DATE AND LOCATION OF THE TAE

DATE OCCURRED:	Day	Month	Year	DATE REPORTED:	Day	Month	Year

LOCATION WHERE THE TAE WAS RECOGNIZED:

- ☐ HOSPITAL WHERE GRAFT TRANSPLATED/IMPLANTED;
- ☐ OTHER FACILITY, E.G. WALK-IN CLINIC, HOME _____
- ☐ OTHER HOSPITAL;
- ☐ MEDICAL OFFICE OF PHYSICIAN/SURGEON WHO PERFORMED TRANSPLANTATION/IMPLANTATION
- ☐ MEDICAL OFFICE OF OTHER PHYSICIAN WHO RECOGNIZED THE TAE.

4. SUSPECTED TRANSPLANTED/IMPLANTED TISSUE(S)

(NOTE: PRE AND POST TRANSPLANT/IMPLANT CULTURE DATES AND RESULTS ARE TO BE COMPLETED BY SOURCE ESTABLISHMENTS ONLY)

TISSUE TYPE	PRODUCT CODE	SUPPLIER NAME	DONOR ID CODE	EXPIRY DATE	QUANTITY TRANSPLANTED	DATE OF TRANSPLANT/ IMPLANT	PRE-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT	POST-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	Day Month Year

COMMENTS (INCLUDING TYPE OF PATHOGEN AND COLONY COUNT):

5) Complete the clinical history section of the form with as much information as possible.

5. CLINICAL HISTORY

TYPE OF GRAFT: ☐ MUSCULOSKELETAL ☐ OCULAR ☐ CARDIAC ☐ VASCULAR ☐ SKIN ☐ OTHER: _____	ANTIBIOTIC PROPHYLAXIS: ☐ YES ☐ NO DESCRIBE:
UNDERLYING DIAGNOSIS/INDICATION FOR TRANSPLANT/IMPLANT: DESCRIBE:	CONCOMITANT MEDICATION:
DESCRIBE/SPECIFY THE PROCEDURE PERFORMED:	IMMUNE COMPROMISED: ☐ YES ☐ NO IF YES, DESCRIBE:
ADDITIONAL COMMENTS:	OTHER CLINICAL HISTORY: ☐ YES ☐ NO

6) Complete the Clinical Signs section providing as much information as possible.

6. CLINICAL SIGNS

CLINCAL SIGNS AND SYMPTOMS:

☐ FEVER (Describe): _____ ☐ SHOCK ☐ DEHISCENCE
☐ CHILLS/RIGORS ☐ WOUND REDNESS/SWELLING ☐ DEATH
☐ URTICARIA ☐ PUS ☐ OTHER (Describe): _____
☐ OTHER SKIN RASH ☐ PAIN (Location): _____

6A. RELEVANT TESTS/LABORATORY RESULTS

LABORATORY TEST	DATE SPECIMEN TAKEN			RESULTS		
	DAY	MONTH	YEAR	NORMAL	ABNORMAL	DETAILS
				☐	☐	
				☐	☐	
				☐	☐	
				☐	☐	
				☐	☐	
				NEGATIVE	POSITIVE	
BLOOD CLUTURE				☐	☐	
WOUND CULTURE (POST-TRANSPLANT)				☐	☐	

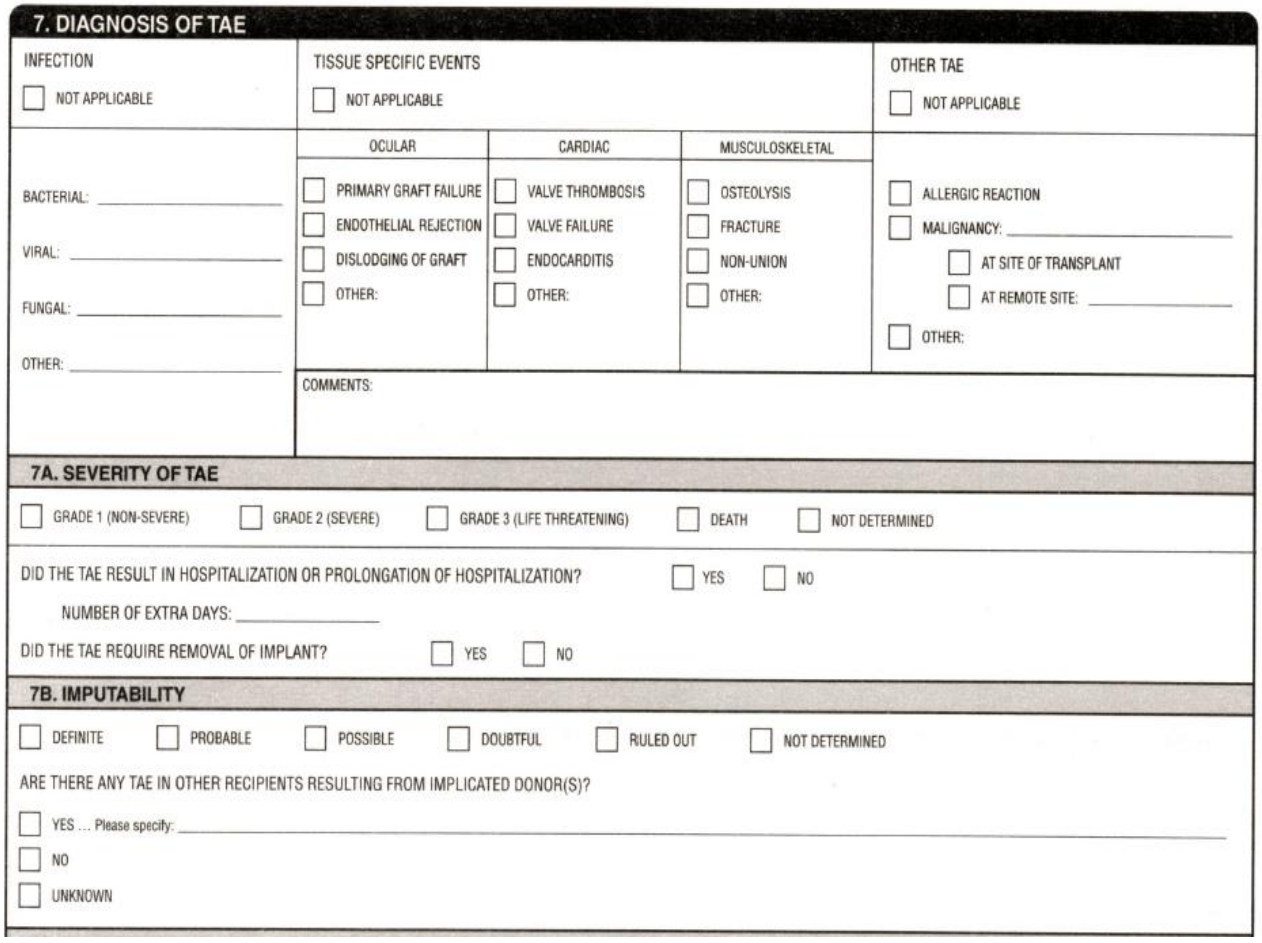
X-RAY RESULTS:	COMMENTS:

6B. DESCRIPTION OF TAE AND ACTION TAKEN

DESCRIBE:

7) Complete the diagnosis of TAE section. This includes details on:

- the specific event
- severity
- imputability
- outcome
- status of the investigation



7. DIAGNOSIS OF TAE

INFECTION
☐ NOT APPLICABLE

BACTERIAL: _____
VIRAL: _____
FUNGAL: _____
OTHER: _____

TISSUE SPECIFIC EVENTS
☐ NOT APPLICABLE

OCULAR	CARDIAC	MUSCULOSKELETAL
☐ PRIMARY GRAFT FAILURE	☐ VALVE THROMBOSIS	☐ OSTEOLYSIS
☐ ENDOTHELIAL REJECTION	☐ VALVE FAILURE	☐ FRACTURE
☐ DISLODGING OF GRAFT	☐ ENDOCARDITIS	☐ NON-UNION
☐ OTHER:	☐ OTHER:	☐ OTHER:

OTHER TAE
☐ NOT APPLICABLE

☐ ALLERGIC REACTION
☐ MALIGNANCY: _____
☐ AT SITE OF TRANSPLANT
☐ AT REMOTE SITE: _____
☐ OTHER:

COMMENTS:

7A. SEVERITY OF TAE

☐ GRADE 1 (NON-SEVERE) ☐ GRADE 2 (SEVERE) ☐ GRADE 3 (LIFE THREATENING) ☐ DEATH ☐ NOT DETERMINED

DID THE TAE RESULT IN HOSPITALIZATION OR PROLONGATION OF HOSPITALIZATION? ☐ YES ☐ NO

NUMBER OF EXTRA DAYS: _____

DID THE TAE REQUIRE REMOVAL OF IMPLANT? ☐ YES ☐ NO

7B. IMPUTABILITY

☐ DEFINITE ☐ PROBABLE ☐ POSSIBLE ☐ DOUBTFUL ☐ RULED OUT ☐ NOT DETERMINED

ARE THERE ANY TAE IN OTHER RECIPIENTS RESULTING FROM IMPLICATED DONOR(S)?

☐ YES ... Please specify: _____
☐ NO
☐ UNKNOWN

7C. OUTCOME

☐ MINOR/NO CONSEQUENCE ☐ MAJOR CONSEQUENCE ☐ DEATH ☐ NOT DETERMINED

IF DEATH OCCURRED, DESCRIBE THE CIRCUMSTANCES RELATED TO THE DEATH:

IMPUTABILITY OF DEATH:

☐ DEFINITE ☐ PROBABLE ☐ POSSIBLE ☐ DOUBTFUL ☐ RULED OUT ☐ NOT DETERMINED

7D. STATUS OF INVESTIGATION

INVESTIGATION BY:

☐ SOURCE ESTABLISHMENT ☐ TRANSPLANTATION/IMPLANTATION FACILITY ☐ OTHER

☐ IN PROGRESS ☐ CONCLUDED (please specify): _____

☐ CANNOT BE CONDUCTED, REASON _____

DATE: Day Month Year

SIGNATURE: _____

8) Complete the conclusion section. The transplanting dentist would sign off on all information documented verifying its accuracy as well as providing a contact number and date/time the report was completed.

8. CONCLUSION (TO BE COMPLETED BY THE HOSPITAL WHERE THE TRANSPLANTATION/IMPLANTATION OCCURRED OR WHERE TAE WAS TREATED)

DATE REPORT RECEIVED: Day Month Year

DATE INVESTIGATION INITIATED: Day Month Year

HOSPITAL REPORTING PERSON:

SIGNATURE:

TELEPHONE NUMBER:

DATE AND TIME: Day Month Year Time (hh:mm)

Once complete, the TAE Reporting Form should be forwarded to the source establishment or importer (if applicable) as well as the NSPBCP by fax at 902-422-0893 or email to jennifer.lefrense@nshealth.ca.

The source establishment or importer and the NSPBCP may contact you for further information not captured on the form if the situation requires it.

Documentation of submitting the form to the source establishment or the importer as well as the NSPBCP should be kept in the patients file to prove compliance to the regulations.