Change Control Management in a University Environment

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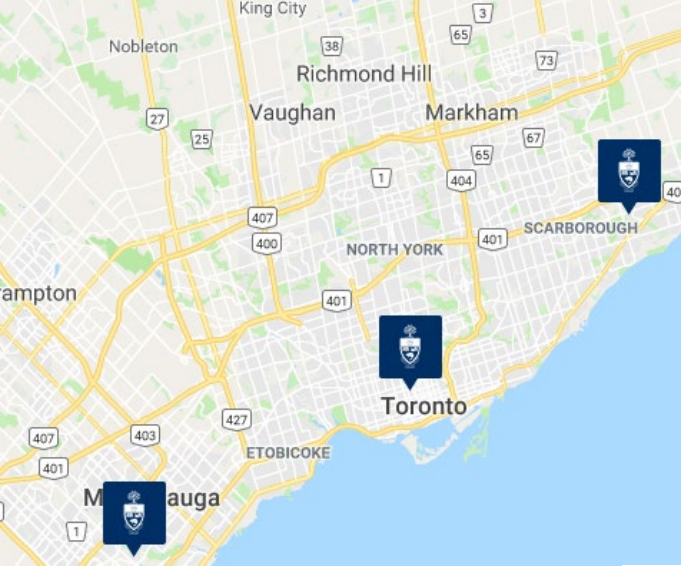
UNIVERSITY OF TORONTO

Notice to Minister Before Making Changes

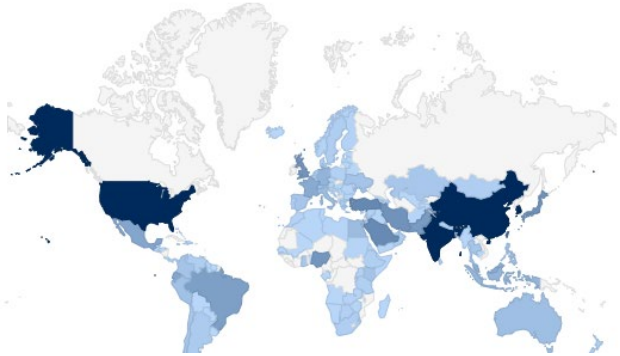
HPTR 6 (1)

A licence holder must — if their licence authorizes controlled activities in respect of a human pathogen that falls into Risk Group 3 or Risk Group 4 or in respect of a prescribed toxin — notify the Minister before they make any change to the physical structure of the facility, to any equipment or to the standard operating procedures that could affect biocontainment.



U of T has international students from 157 countries and regions

The top five countries/regions of origin are China, India, United States, South Korea and Hong Kong.



Country/Region	Students
China	12,571
India	1,276
United States	883
Korea (South)	609
Hong Kong	344
Taiwan	307
Turkey	224
Saudi Arabia	220
Japan	198
Iran	196

Faculty & Staff (Fall 2017)

14,434 **Faculty Members excludes Research Fellows**
5,606 **Teaching Assistants**

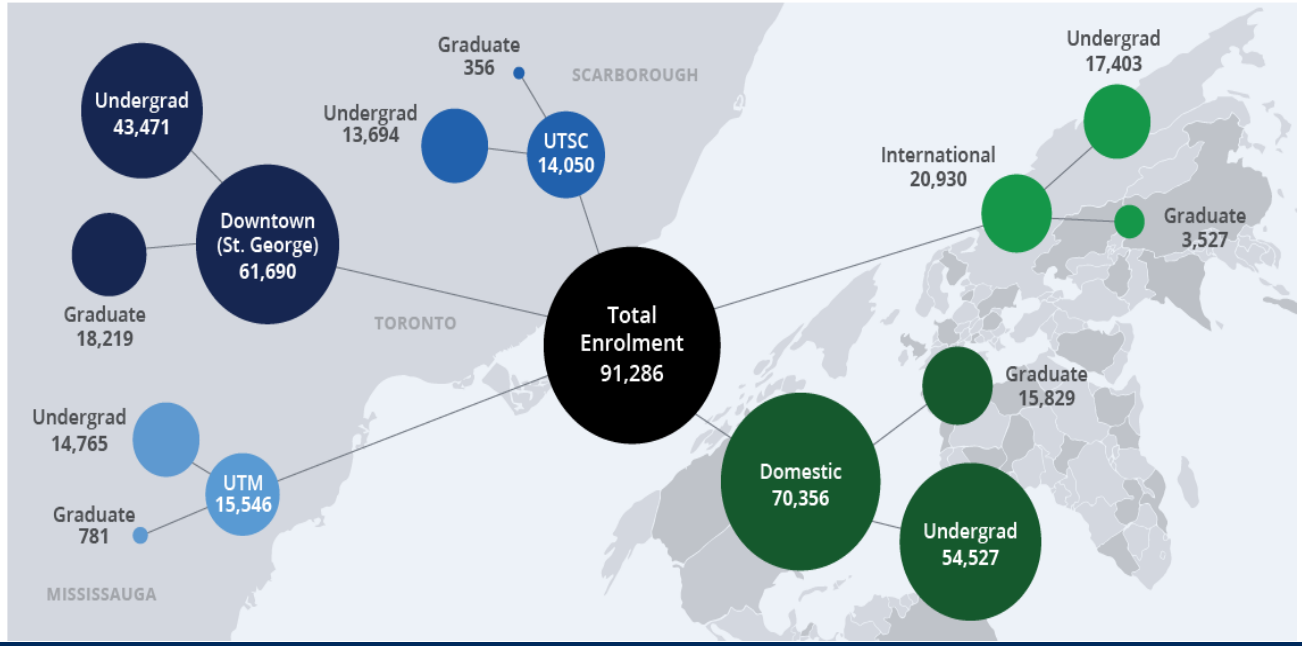
7,198 **Staff**

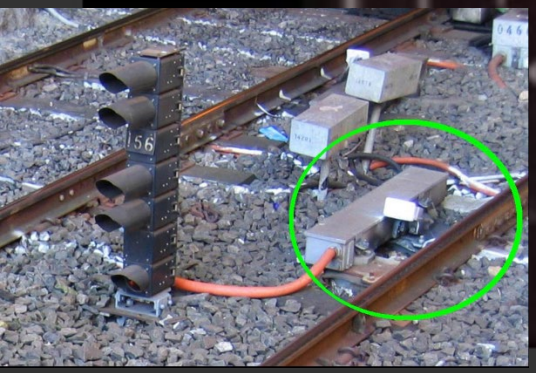
156 **Librarians**
44 **Libraries**

over 591,904 **Alumni**

Student Enrolment (Fall 2018 – 19)

Operating Budget is $2.7 billion





The scene inside the subway car after the worst crash in TTC history on Aug. 11, 1995.

Global News

The jury produced 18 recommendations

- An updated Operations Training Centre to include a **suitable subway simulator**.
- **Improved communication** within the organization.
- Emergency response exercise every five years with "everybody". Yearly reviews by the Safety department
- **Improved predictive and preventative maintenance** with computer assist where applicable.
- Review of **equipment procurement** with respect to **quality control**.
- Traceable design criteria and standards for track, signal and subway cars. **No modifications without approval of design review authority.**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Change Control Management

A written procedure that describes the action to be taken if a change is proposed

(a) to facilities, materials, equipment, and/or processes or

(b) that may affect the operation of the quality or support system.

Provide for ongoing process optimization and a continuing state of control.

- All stakeholders have an opportunity to participate
- All Health, Safety, Regulatory, Compliances and Performances including up and down stream processes are assessed, verified, validated and approved
- All recipients are made aware of any changes that occur and its implications
- There is an audit trail from request to closing

Terms of Reference

- Objective
- Stake Holders
- Composition of **C**hange **C**ontrol **C**ommittee
- Roles and Responsibilities
- Process and Procedures
- Change Request form
- Change Owner
- Approval
- Verification/Validations
- Finalization
- Communications
- Documentation

Change Request Form

Change Types

- Physical Change
- Operational change

Ask for

- What
- Where
- Why
- How
- Who
- Projected outcome

SUBMITTER - GENERAL INFORMATION				
CR#				
Submitter Name				
Brief Description of Request				
Date Submitted				
Date Required				
Priority	☐ Low	☐ Medium	☐ High	☐ Mandatory
Reason for Change				
Other Artifacts Impacted				
Assumptions and Notes				
Attachments or References	☐ Yes	☐ No		
	Link:			

INITIAL ANALYSIS		
Hour Impact		
Duration Impact		
Schedule Impact		
Comments		
Recommendations		

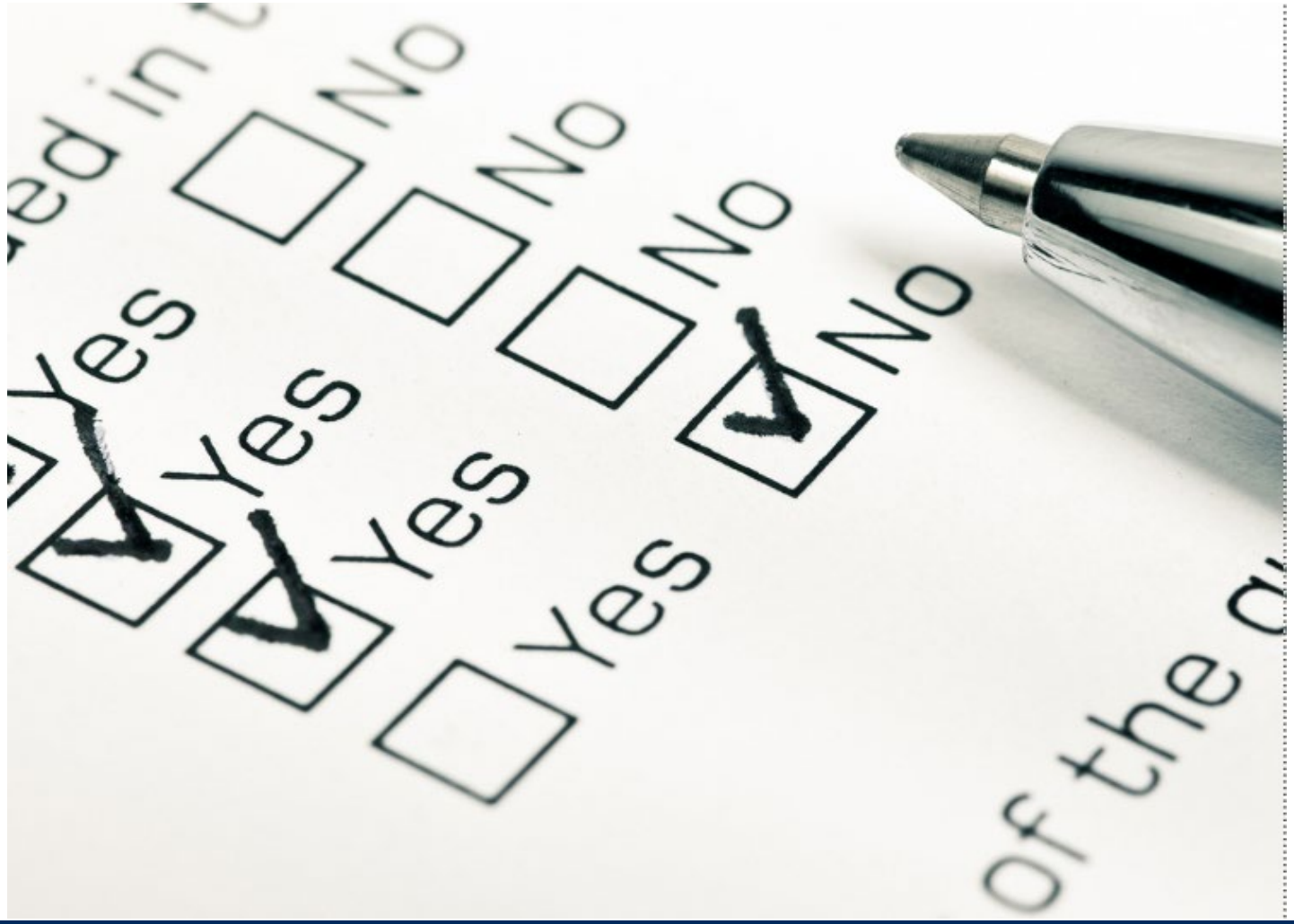
CHANGE CONTROL COMMITTEE - DECISION				
Decision	☐ Approved	☐ Approved w/Conditions	☐ Rejected	☐ More Info
Decision Date				
Decision Explanation				
Conditions				

Technical and Regulatory Review

- Justification
- Impact
- Implications
  - Health and Safety
  - Operations
  - Regulatory
  - Performance
  - Contractual
  - Training
- Sign off process

Approval Process

Implement and Validate Technical and Regulatory Conformity



Close Change

- Successful
- Partially Successful
- Unsuccessful- Not Backed Out
- Unsuccessful- Backed Out
- Cancelled
- Rejected

Documentation

Document retention

29 (1) Documents that are required under the Act to be prepared must be maintained for five years after the day on which they are prepared and must be provided to the Minister on request.

Exception — incidents

(2) Despite subsection (1), the retention period is 10 years for documents that contain information that relates to the following incidents:

(a) an incident that is described in subsection 12(1) or (2), or section 13 or 14, of the Act; and

(b) any incident that results in a failure of or compromise to biocontainment.

https://www2a.cdc.gov/cdcup/library/templates/CDC_UP_Change_Management_Plan_Template.doc

https://www2a.cdc.gov/cdcup/library/templates/lite_templates.htm

Yale University Change Management Process Guide