

## **Notice to Stakeholders – Blood Regulations come into force**

Health Canada is pleased to announce that the *Blood Regulations* and consequential amendments under the authority of the *Food and Drugs Act*, published in *Canada Gazette*, Part II (<http://www.gazette.gc.ca/gazette/home-accueil-eng.php>) come into force **October 23, 2014**.

The *Blood Regulations* contain safety requirements with respect to blood for transfusion or for further manufacture and apply to all establishments who handle blood.

The final **Guidance Document: Blood Regulations** is effective on October 23, 2014. Please find attached the Guidance Document which interprets the *Blood Regulations* for all establishments who perform any of the regulated activities. The *Establishment Licence Application Form* and *Registration Application Form* are also attached. Please send any questions regarding these application forms to [blood\\_sang\\_questions@hc-sc.gc.ca](mailto:blood_sang_questions@hc-sc.gc.ca).

Furthermore, the following three documents are also available:

- The *Inspection Strategy for Blood Establishments* (POL-0039) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/pol-0039\\_eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/pol-0039_eng.php)) document is intended to provide information on Health Canada's approach to inspections of all blood establishments regulated under the *Blood Regulations*.
- The guidance document entitled: *Risk Classification of Observations made during Inspections of Blood Establishments* (GUI-0061) (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/gui-0061-eng.php>) is an administrative tool to inform blood establishments on how observations noted during inspections regulated under the *Blood Regulations* are classified by Health Canada.
- *Blood Regulations - Error or Accident Investigation Preliminary Report Form* (FRM-0337) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/frm-0337\\_eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/frm-0337_eng.php)) is intended to facilitate the submission of error and accident reports that are required to be submitted to Health Canada within 24 hours, as per section 107 of the *Blood Regulations*.

If you have any questions or concerns regarding the requirements of the *Blood Regulations* or its Guidance Document please email them to [bgtd.opic@hc-sc.gc.ca](mailto:bgtd.opic@hc-sc.gc.ca).

Sincerely,

Dr. Robert Cushman  
Director General