

# **How did the challenge of ISO 15189 arise and why applies to Blood Banks?**

**Linda Crawford**  
**Executive Director, Programs**  
**IQMH, Canada**

# A Crisis in the Making...1980s



# Contributing Factors



# Human Immunodeficiency Virus

In February 1982, the Laboratory Centre for Disease Control, which conducted disease surveillance on behalf of the Government of Canada, received the first report of a case of AIDS in Canada. By the end of December 1982, the Centers for Disease Control in Atlanta believed it had strong evidence that AIDS was transmissible by a blood-borne agent.

More than 1,000 persons in Canada were infected with HIV through the blood supply, and some unknowingly infected others.

By the early 1990s, there was a growing recognition of the extent and gravity of the contamination of the blood supply.

# Hepatitis C

In the period 1986 to 1990, approximately 28,600 persons might have been infected by HCV through blood transfusion.

As many as 70% of hemophiliacs were infected with Hepatitis C through blood products.





## Canada's worst-ever preventable public health disaster

# The Investigation



# Facts - Tainted Blood Scandal Inquiry

- ❑ Led by Justice Horace Krever
- ❑ Four+ years (1993 – 1997)
- ❑ \$16 million
- ❑ 244 days of public hearings
- ❑ 353 witnesses
- ❑ 50,000 pages of testimony
- ❑ Three-volume report
- ❑ 50 recommendations





# Canada's worst-ever preventable public health disaster

*“In the pages that follow, an account is given of a public health disaster that was unprecedented in Canada, and if we have learned from it, one that will never occur again.”*

*“When there was reasonable evidence that serious infectious diseases could be transmitted by blood, the principal actors in the blood supply system in Canada refrained from taking essential preventative measures until causation had been proved with scientific certainty. The result was a national public health disaster.”*

Mr. Justice Horace Krever  
Commission of Inquiry on the Blood System in Canada  
Final Report 1997

# Findings - Tainted Blood Scandal Inquiry

***“The operator of the blood supply system and the Health Protection Branch must not wait for scientific certainty about the spread of a transfusion or infusion-associated disease and the effectiveness of particular risk reduction measures before they act to reduce risks.”***

Mr. Justice Horace Krever

## ***RECOMMENDATIONS***

- Compensation to those infected**
- Revised governance**
- New national blood service**
- Regulatory reform**
- Public health protection**

# Compensate those infected





# Fix the system



# Findings - Tainted Blood Scandal Inquiry

*“Major systemic problems contributed to the contamination of the blood supply in Canada during the 1980s. Only by analysing these problems can one appreciate the reforms that are necessary to prevent similar events from occurring in the future.”*

Mr. Justice Horace Krever  
Commission of Inquiry on the Blood System in Canada  
Final Report 1997

# Reforming the blood supply system

**New agencies implemented**  
*Héma-Québec & Canadian Blood Services*

**National blood safety standards written**  
Canadian Standards Association  
*Z902 Blood and Blood Components (2004 & 2010)*

**Federal legislation enacted**  
*Food & Drug Act - Blood Regulations (2013)*

# A new national standard – 2004

- ❑ **“Vein to vein” CSA Z902-2010 *Blood and Blood Components***
- ❑ All aspects of transfusion, ranging from selection of donors through administration of blood or blood products
- ❑ **Technical requirements**
- ❑ **Quality system**
  - Quality manual, designated specialist
  - Processes and procedures
  - Document control and record management
  - Organizational structure, sufficient staff
  - Personnel training and competency assessment
  - Corrective action, error and incident management
  - Management review, internal and external audits
  - Proficiency testing
  - Process control, validation





# New blood regulations - 2013

## Health Canada Food and Drugs Act *Blood Regulations*

- Effective October 2014**  
Applies to all blood components (not manufactured blood products)
- Licensure, registration, reporting adverse reactions to government**
- Technical requirements**
- Quality Management**  
Organizational structure, responsible person  
Processes and procedures  
Document control and records management  
Personnel training and competency assessment  
Corrective, preventive action  
Regular review  
Proficiency testing  
Process control and improvement, validation

# Restore Public Confidence



# Breach of Trust

***“The current lack of confidence in the blood supply system affects donors of blood, consumers of blood components and blood products, and the public at large. It is integral to the success of any new blood supply system that it have the confidence, trust, and commitment of the public.”***

**Mr. Justice Horace Krever  
Commission of Inquiry on the Blood System in Canada  
Final Report 1997**



Trust

# ISO 15189 – Ensuring a Foundation of Trust

- ❑ **Technical requirements**
  - Personnel
  
- ❑ **Quality Management**
  - Organization and management
  - QMS
  - Document control
  - Service agreements
  - Advisory services
  - Resolution of complaints
  - Identification and control of nonconformities
  - Corrective, preventive action
  - Continual improvement
  - Control of records
  - Proficiency testing
  - Evaluation and audits
  - Management review



# ISO 15189 Accreditation in Canada





# Engagement

# Rigour

A large, faded, light-colored world map is positioned in the background on the right side of the slide, showing the continents.

# ISO 15189 *Plus*<sup>TM</sup> Non conformances





# Summary




# Summary – Challenges Faced

A person is rappelling down a dark rock face on the right side of the image. The background shows a vast landscape with a city, a bay, and mountains under a blue sky. The person is in silhouette, wearing a harness and holding ropes.

**1980s – Tainted blood caused a public health disaster and triggered widespread reform to increase safety and public trust.**

# Summary – Facing the Challenge with ISO 15189 Accreditation



Provides the tools to demonstrate

- Quality management
- Ongoing competence
- Preventive risk measures

It is an effective tool to ensure reforms stay in place, and to increase public trust.



# Confidence. *Elevated.*

# Contact Information



Institute for Quality  
Management in Healthcare  
Centre for Accreditation

**Linda Crawford**  
**Executive Director, Programs**  
**Institute for Quality Management in Healthcare (IQMH)**  
**1500 – 393 University Avenue**  
**Toronto, Ontario M5G 1E6 CANADA**  
**Email: [lcrawford@iqmh.org](mailto:lcrawford@iqmh.org)**  
**Telephone: 1.416.323.9540 ext.246**

Confidence. *Elevated.*