

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

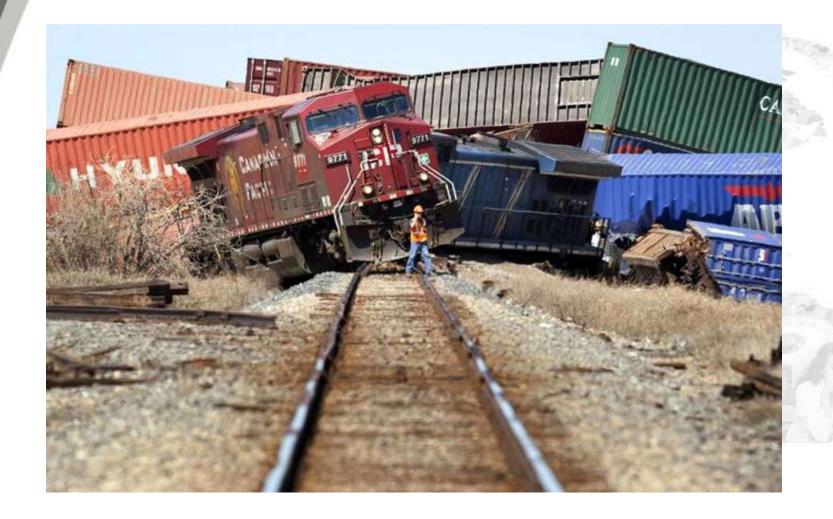
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A Crisis in the Making...1980s





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.





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













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

Z316.7-12

- ☐ 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

Primary sample collection facilities and medical laboratories — Patient safety and quality of care — Requirements for collecting, transporting, and storing samples





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





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







ISO 15189*Plus*™

Centre for Accreditation

Engagement Rigour



ISO 15189 *Plus*™ Non conformances









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.





Contact Information



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