

SURVIVING INSPECTION in TML

PREPARING FOR, UNDERGOING AND FOLLOW-
UP

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Saskatchewan
Health Authority

SHA Mission

VISION

Healthy People, Healthy Saskatchewan

MISSION

We work together to improve health and well-being. Every day. For everyone.

VALUES

- **SAFETY: *Be aware.*** Commit to physical, psychological, social, cultural and environmental safety. Every day. For everyone.
- **ACCOUNTABILITY: *Be responsible.*** Own each action and decision. Be transparent and have courage to speak up.
- **RESPECT: *Be kind.*** Honour diversity with dignity and empathy. Value each person as an individual.
- **COLLABORATION: *Be better together.*** Include and acknowledge the contributions of employees, physicians, patients, families and partners.
- **COMPASSION: *Be caring.*** Practice empathy. Listen actively to understand each other's experiences.

PHILOSOPHY OF CARE: Our commitment to a philosophy of Patient and Family Centred Care is at the heart of everything we do and provides the foundation of our values.



SURVIVING INSPECTION

Objectives

- Who performs inspections/accreditation
- What are the elements of the inspection process (preparation, inspection, reports)
- Managing the outcome



INSPECTION DAY IS COMING



REMAIN POSITIVE

- Inspections are opportunities
 - Input and review from peers
 - Meet professionals in your field
 - Share information



Inspections in Transfusion Medicine

Who, What?



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WHO ARE WE INSPECTED BY?

- Health Canada
- Ministry of Health – performed by:
 - CPSS
 - CAP
- Other: CNSC, OHS

WHAT WILL THEY BE LOOKING FOR?

- **Inspect and assess**
 - compliance to standards and regulations
 - quality management system
 - Look at all aspects of lab services (collection of blood product to administration)
- **Utilize checklists or inspection standards**
 - customized for each facility
 - Note: CPSS general standards (WCDAA) apply

Blood Components and Products

Inspection of Administration

- Completed by CPSS and CAP inspectors
- Includes
 - Administration of blood components and products
 - Administration records
 - Adverse events
 - Training and competency
 - Equipment used



Inspection Agencies

Overview



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HEALTH CANADA

Background

- In 1997 the final report provided Commission of Inquiry on the Blood System in Canada (Krever Commission Report)
 - Recommendations for improvement of blood safety
 - One recommendation: regular monitoring by regulator
- October 2014 Blood Regulations came into effect
- HC inspects facilities to verify that processes will not pose a risk to human safety
- Have been inspecting in Saskatchewan since 2016

HEALTH CANADA

When, Who, What

- Announced or unannounced
- Inspectors who collaborate nation wide
- Focus on blood safety
- Findings provided
 - Evidence required with target date
- Inspection frequency no less than every 3 years



CPSS

Background

- Lab Licensing Act and Regulations came into effect March 1996 (Ministry of Health)
- MOH Contracts CPSS Lab Quality Assurance Program ensure compliance to Lab Licensing Act and Regulations
 - Use of WCDAA was implemented 2017
- Any licensed facility is subject to CPSS inspection



CPSS

When, Who, What

- Announced
- Inspectors are peers with experience in related division
- Focus on ‘continuous quality improvement and optimum performance’
- Findings – a report is provided
 - Evidence approved by LQAP PMC
- Inspections occur every 4 years

CAP

Who, When, What

- Inspecting agency for sites who are CAP accredited
- Unannounced after initial inspection, occur annually
- Inspectors are peers in the field
- Focus on management and lab operations
- Findings provided at completion of inspection

Inspection Agency Summary

	Health Canada	CAP	CPSS
Notice given	Announced or unannounced	Unannounced	announced
Duration of inspection	Varies	1-2 days	Varies
Frequency	2-3 years (minimum)	Annually (alternating on site and self inspection)	4 years (minimum)
Evidence submissions	20 working days	30 days	30 or 60 days

Inspection Summary

	Health Canada	CAP	CPSS
License/registration required	√ (processing/transformation facilities)	√ (license required by MOH)	√ (license required by MOH)
Quality management	√	√	√
Donor screening	√		
Processing (donor suitability, collection, testing, preparation)	√ (donor)	√ (not including donor suitability/collection)	√ (not including donor suitability/collection)
Storage and distribution	√	√	√
Administration		√	√
Error and Accident/Adverse event	√ (as its related to component/product)	√	√



Inspection Preparation



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Be prepared

If you're always ready, you
don't have to get ready.

Will Smith

“ quote fancy



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Preparation

How can I prepare?

- *Documents and records
- Review inspection checklist/standards
- Review past deficiencies
- Perform mock inspections
- Review:
 - General safety
 - Lab processes – pre-examination, examination, post-examination
 - Training and competency
- Get all staff involved

Preparation

Behind the scenes

- Provide for inspecting agencies
 - Test menu
 - Staff listing
 - Logistics (meeting rooms etc.)
 - Pre-assessment forms
- Request signed
 - Confidentiality agreements (local)
 - Safety forms



Inspection Day

- Opening meeting and lab tour
- Interviews (directors, manager, physicians)
- Inspectors will work around daily activities
 - Observe, ask to show them, follow specimen/product, read, ask questions, look at items previously deficient, high risk, high or low volume, new equipment or process
- Indicate when deficiencies identified
- Closing meeting followed with a report

Report received

- Accreditation received

OR

- Deficiencies identified
 - Required evidence outlined
 - Deadline given
 - Track and submit



Handling Responses

- Develop a plan to resolve deficiencies (PDCA)
 - Consult with staff (clinical, technologist, stakeholders)
 - Track progress (action log, progress)
 - Complete evidence submission by required date
 - Revisit to check that change is sustained



Inspection Completed



END SLIDE

For more information, visit
saskhealthauthority.ca.



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