Tufts Health Care Institute Program on Opioid Risk Management

How Industry Uses Root Cause Analysis to Manage Risk and Linkage to REMS Intervention

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All Industries Face Problems

- Davis-Besse crack in nuclear reactor vessel; recent fatalities at Japanese nuclear plant
- West Pharmaceuticals plant explosion
- NASA Challenger and Columbia
- Boston Big Dig plans forgot Fleet Center
- BP Texas refinery fire, Alaska pipeline leaks
- Worldcom and Enron
- Mortgage securitization and the recession

Example: Fall From Roof

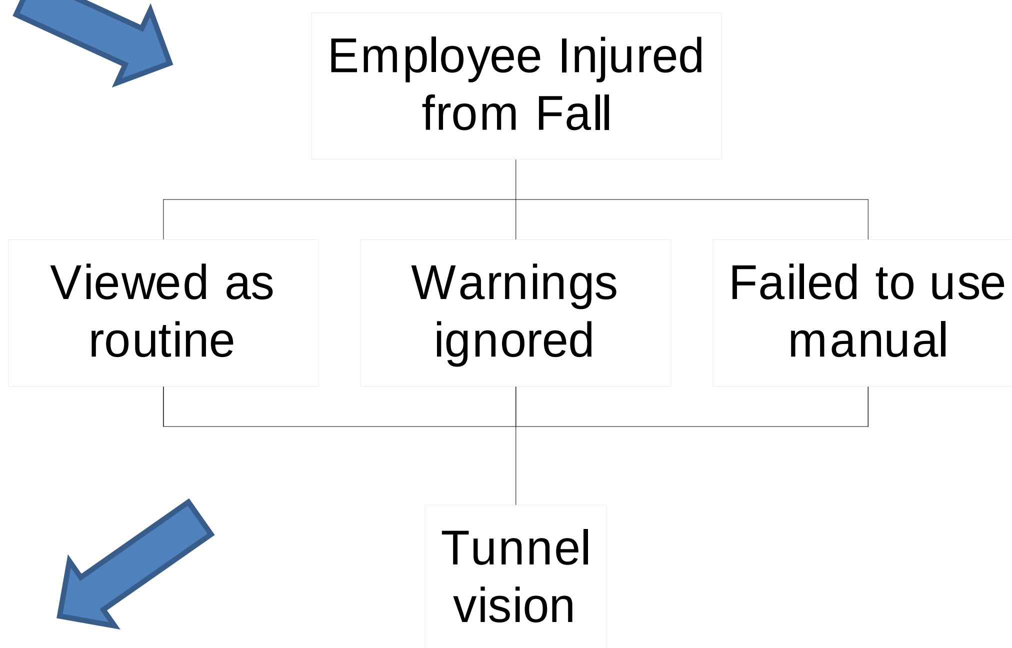
Joe Smith, a new electrical maintenance worker, climbed onto the thin roofing of a shed inside the hot machine shop, an area used to decontaminate equipment with radiological residue. His goal was to replace burned-out fluorescent lights. Joe was advised by other workers to stay on the 1.5” steel frame of the shed. As he crawled on the roof, his hand slipped through a Plexiglas skylight, but he caught himself and continued. He then slipped again off the steel frame and fell through the roof to the floor 10 feet below. His injuries included 5 fractures and severe lacerations. Joe had been counseled two months before for failing to use fall protection while painting.

Root Cause Analysis

- For decades, industries have collected reports of problems in order to learn and improve
  - E.g., airline SRS, black boxes, NTSB investigation
- Those reports are analyzed to extract lessons, especially the "***root cause***" of serious events
  - It is natural to blame "human error": Joe did the wrong thing and is at fault (easy in hindsight)
  - "Root cause analysis" tries to go "deeper": Why did Joe do what he did? What is wrong with the "system" around Joe?

Incident Investigation

<u>Root Cause Team of 8</u>:
analyst-leader, union officer, environ coord, manager of equipment services, 2 HR consultants, etc.



<u>Corrective Actions</u>:

Reinforce expectations

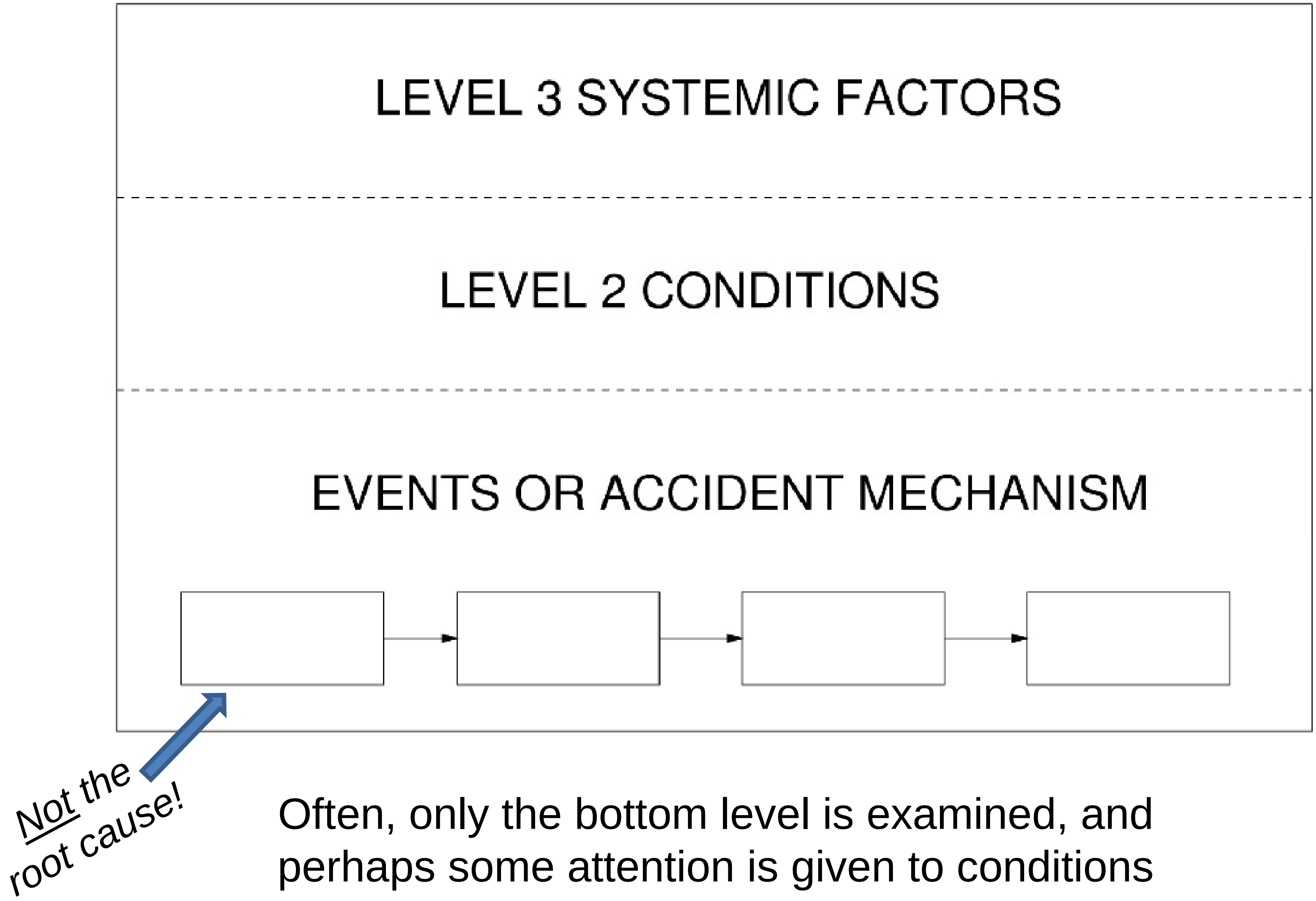
Detail/training on working aloft

Counsel workers involved

Blaming the "Sharp End"

- Organizations typically respond to problems by making more rules, increasing monitoring, and punishing the guilty
- What happens when we blame the pilot, the control room operator, or the doctor? (or Joe)
- First, reports of problems dry up (Tamuz, SRS) and the units with fewer reports of problems may be the worst ones (Edmondson)
- Second, we punish, exhort, and retrain people with only temporary success: problems keep emerging
- Third, we erode trust between workers and managers, and reduce managers' knowledge, which creates new long-term vulnerabilities

Hierarchical Models of Cause



Often, only the bottom level is examined, and perhaps some attention is given to conditions

Industry Still Learns Slowly

- Tendency to look for a single “root cause”
- Heroes fix problems: “It’s against the culture to talk about problems unless you have a solution”
- “Good managers have no problems”
- Learning = training, or a staff function
- Even if we think we know the causes, that doesn’t tell us what to do to improve!
- Blame the operator who misused the software rather than the design and testing. No one in engineering is “singularly responsible” for the design.
- Stockholm (Shell Chemicals) estimates that 30% of problems are caused by prior fixes!

A Learning Failure at NASA

- What was learned from Challenger (1986)?
  - Pressures for production outweighed expertise
  - Normalization of risk (accepting known problems)
- What happened with Columbia (2003)?
  - Back to business as usual; “didn’t get it”
  - More production pressure
  - Leadership that tolerated no dissent
  - Lack of independent voice for safety
  - Safety/quality people are promoted: message?

(From Columbia Commission report, 2003 and Leveson et al, 2004)

The Hidden Value of Incident Investigations

- Investigations are an opportunity to build relationships
- External function of teams (Ancona): getting access and resources, building credibility, managing upward
- Reports are negotiated or sold to managers who then take action (delegated participation, Nutt, 1999)
- “If top level managers aren’t willing to listen to the people doing the work, and respond to their findings, it all becomes a waste!” […or if teams don’t know how to persuade managers!]
- At chem co., the goal of problem investigations is to “educate managers” who are collectively responsible for setting the conditions of performance and change

Accelerating Learning

- Incident investigation is basically reactive, so:
- Get more data: industry-level incident reports, benchmarking, audits, peer reviews
- Model/simulate: Probabilistic Safety Analysis
- Enlist more participation: heedful interrelating, questioning attitude from all
- Encourage doubt and inquiry, talk to outsiders
- Use your imagination
- Look for new approaches (e.g., next slide)

Process Safety Engineering

(*Leveson, MIT*)

- Safety is an emergent (system) property
- Accidents are not simply an event or chain of events
  - Involve complex, dynamic processes
  - Arise from interactions among humans, machines and the environment (not just component failures)

"~~prevent failures~~"

?

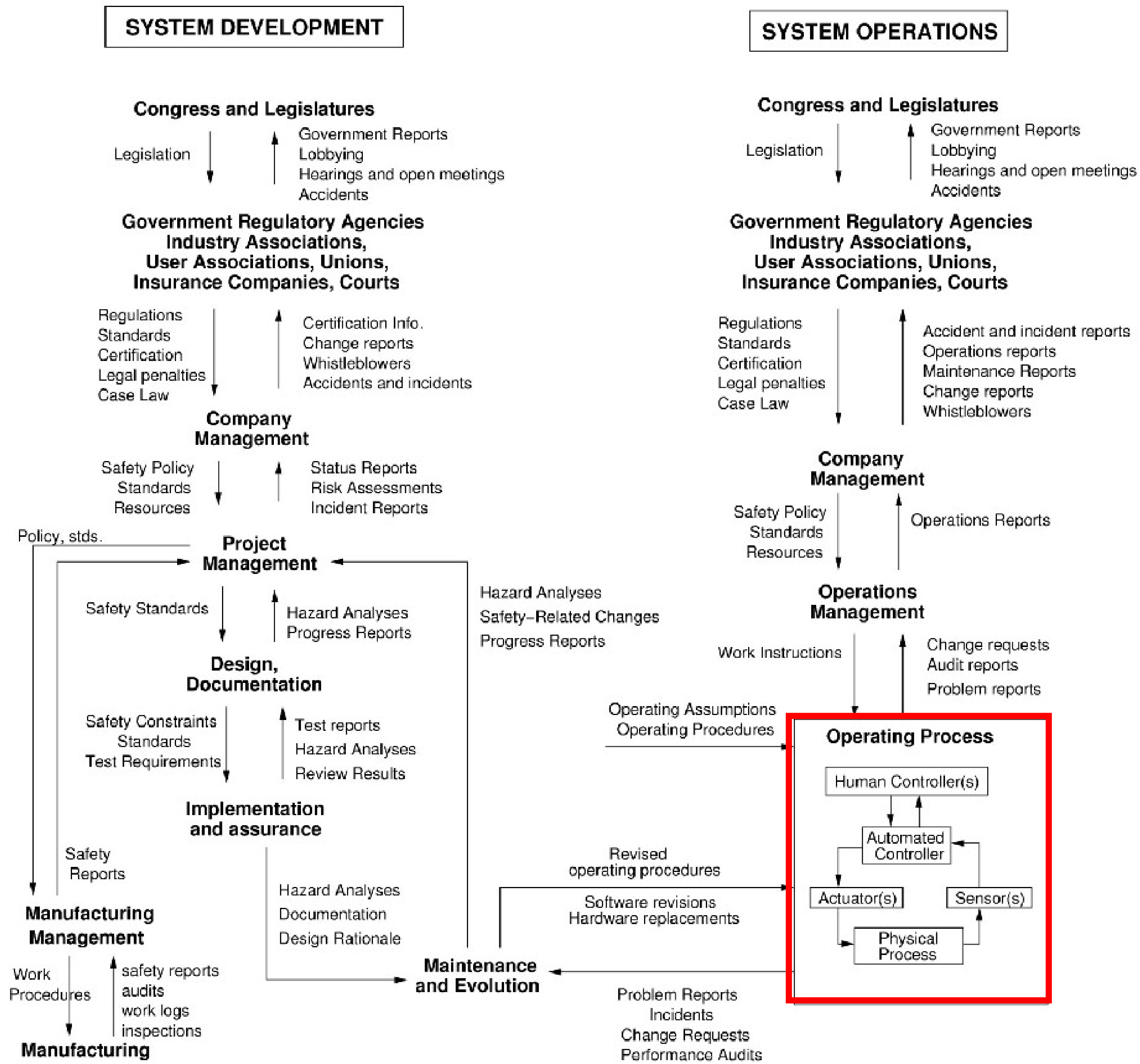
"enforce safety constraints on system behavior and component interactions"

- "Safety constraint" = requirements among system variables or components that bound safe system states
- Goal of process safety engineering is to identify the safety constraints & enforce them in system design & operations

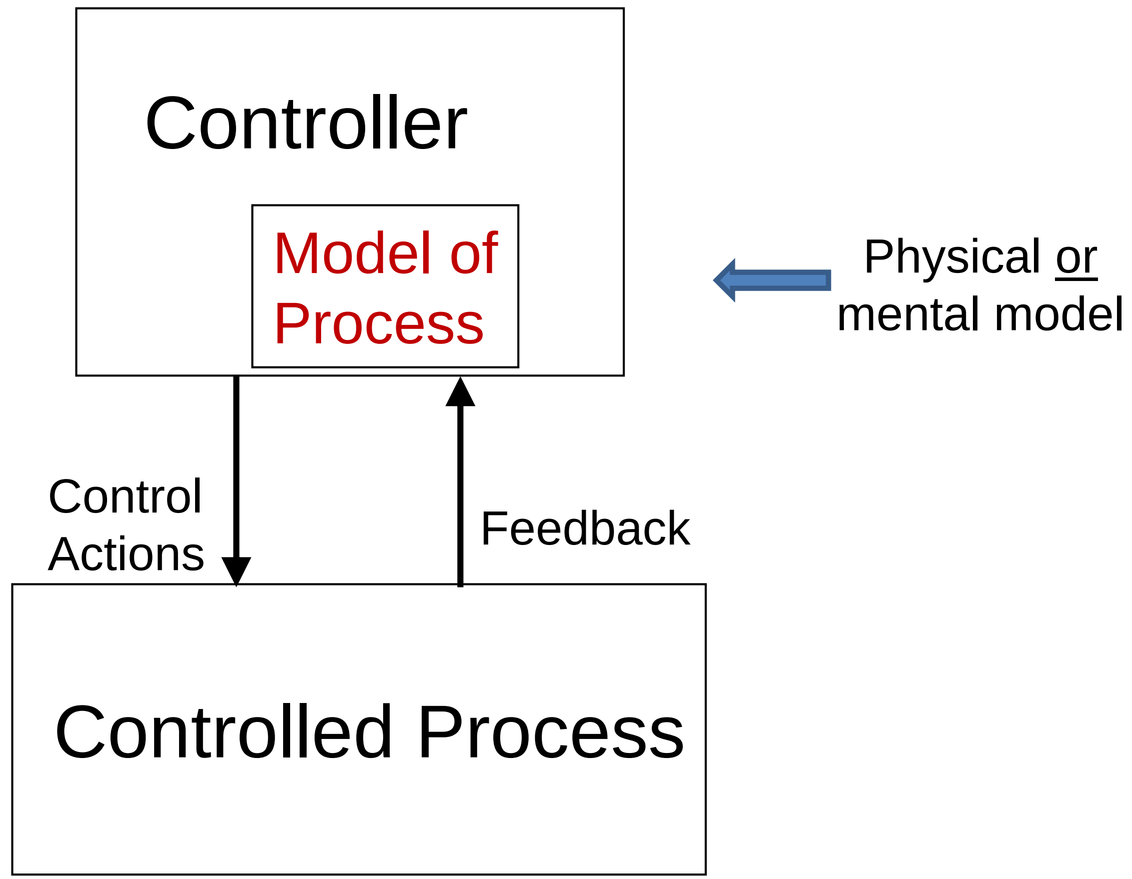
Changing Systems and Human Error

- A socio-technical system is dynamic, continually *adapting* to achieve its ends, reacting to internal and external changes
- Systems and organizations *migrate* toward accidents (states of high risk) under cost and productivity pressures
- Human error is a symptom, not a cause (a learning-ful start!)
- All behavior is affected by context (system):
  - Design of equipment
  - Usefulness of procedures
  - Existence of goal conflicts and production pressures
  - Dynamic work process and continual adaptation

Example Control Structure



Controlling and managing dynamic systems requires a model of the controlled process



Accidents often occur when that model is wrong

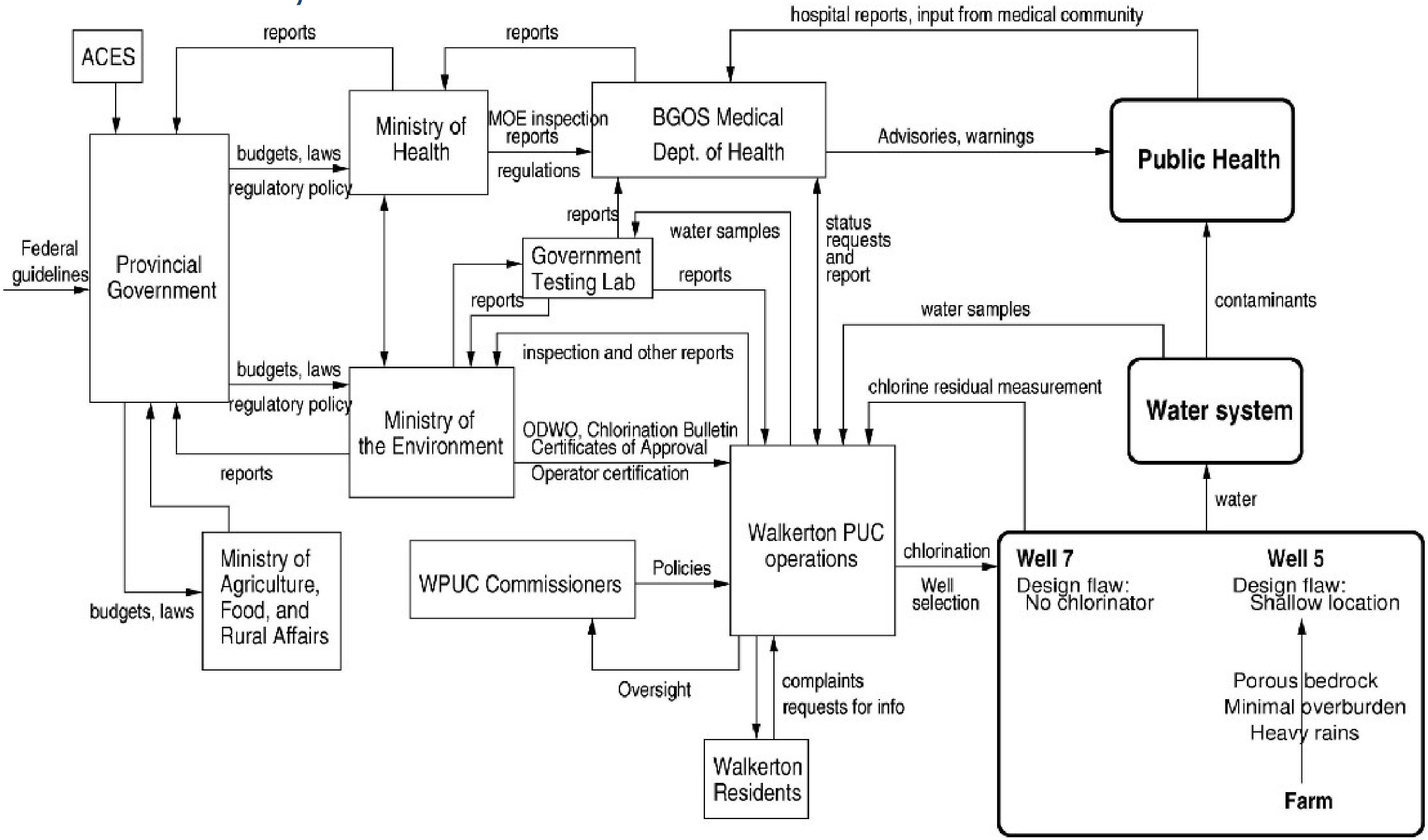
System Hazard: Public is exposed to E. coli or other health-related contaminants through drinking water.

System Safety Constraints: The safety control structure must prevent exposure of the public to contaminated water.

(1) Water quality must not be compromised.

(2) Public health measures must reduce risk of exposure if water quality is compromised (e.g., notification and procedures to follow)

Walkerton, Ontario Water Contamination Event



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Walkerton PUC Operations Management

Safety Requirements and Constraints:

- Monitor operations to ensure that sample taking and reporting is accurate and adequate chlorination is being performed.
- Keep accurate records.
- Update knowledge as required.

Context in Which Decisions Made:

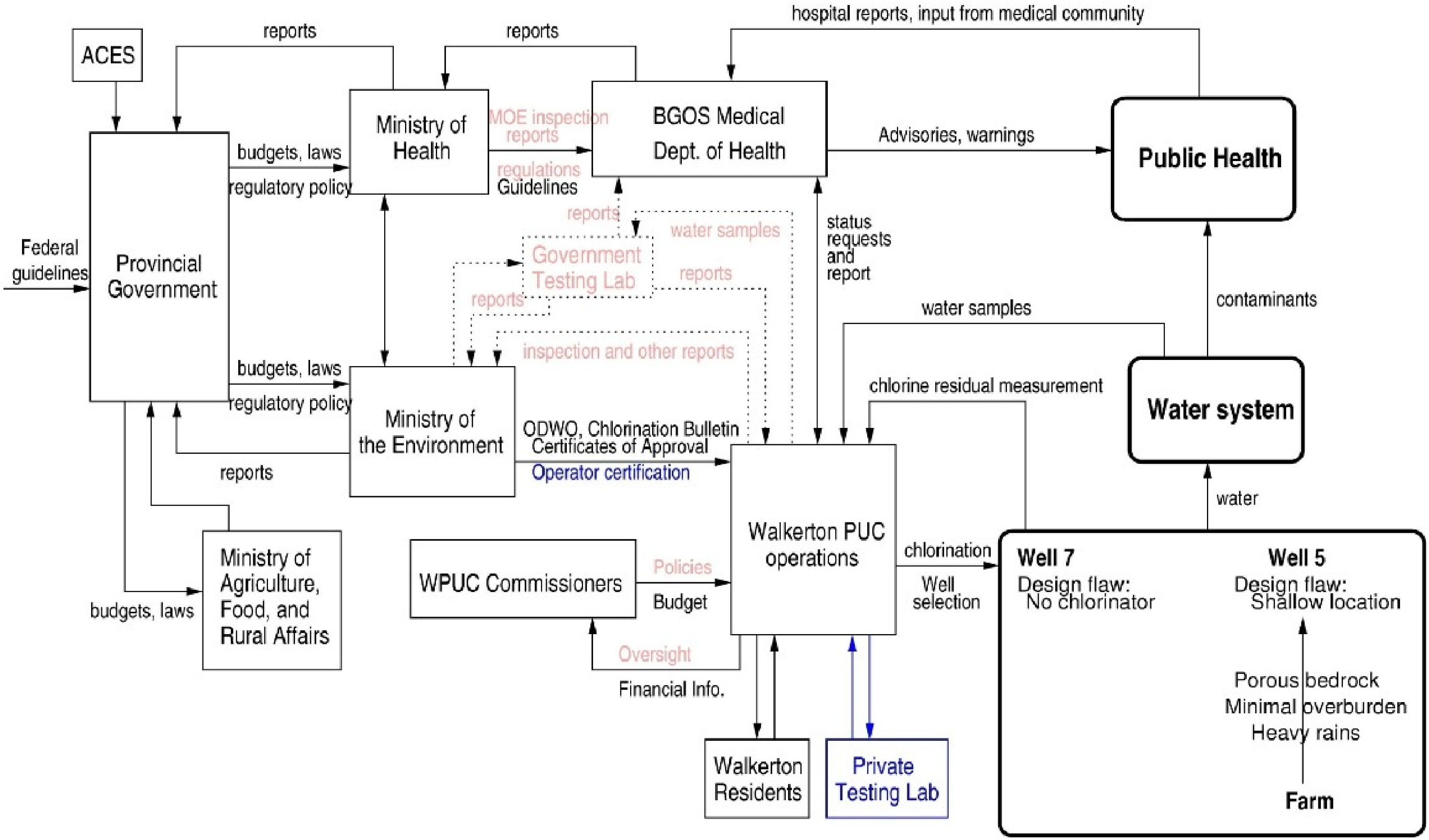
- Complaints by citizens about chlorine taste in drinking water.
- Improper activities were established practice for 20 years.
- Lacked adequate training and expertise.

Inadequate Control Actions:

- Inadequate monitoring and supervision of operations
- Adverse test results not reported when asked.
- Problems discovered during inspections not rectified.
- Inadequate response after first symptoms in community
- Did not maintain proper training or operations records.

Mental Model Flaws:

- Believed sources for water system were generally safe. .
- Thought untreated water safe to drink.
- Did not understand health risks posed by underchlorinated water.
- Did not understand risks of bacterial contaminants like E. coli.
- Did not believe guidelines were a high priority.



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Linkage to REMS Intervention

- Risk Evaluation and Mitigation is a “control strategy” based on a model (explicit or implicit) of the system and its risks
- You don’t have all the answers!
- You will continue to collect data to analyze why there are still deaths and trends either up or down
- It is very hard to know what to do and how to implement change
- It is hard to see the system in its full structure, culture, and stakeholder interests: the goal of root cause analysis is to update your mental models and build collaborative relationships for collective learning

Summary

- All industries struggle to avoid accidents and other undesirable events
- Such events are "gifts of failure" or opportunities to learn
- Root cause analysis is a set of techniques for identifying cause but it is not magic!
- Most RCAs do not go very deep, and more system-oriented analyses are emerging
- This is difficult, but there is great opportunity