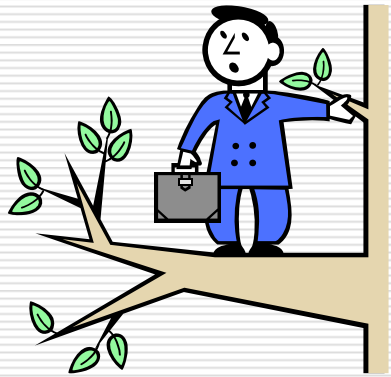
Risk Based Inspections

In Food Safety



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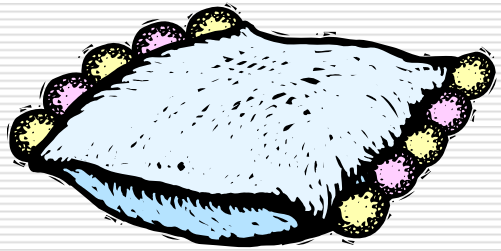
President Environ Health Associates, Inc.



Perspective

- I have conducted over 10,000 inspections of food and related facilities

Perspective

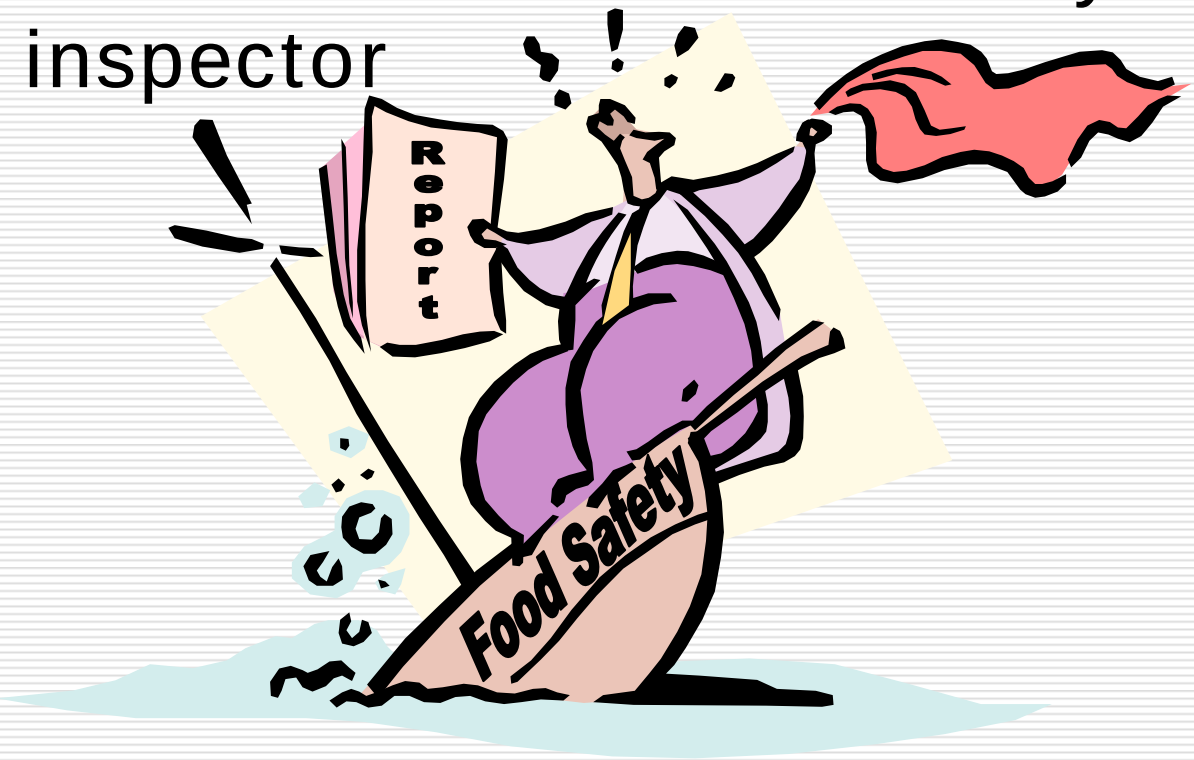
- My one most important finding is

Inspection does not work

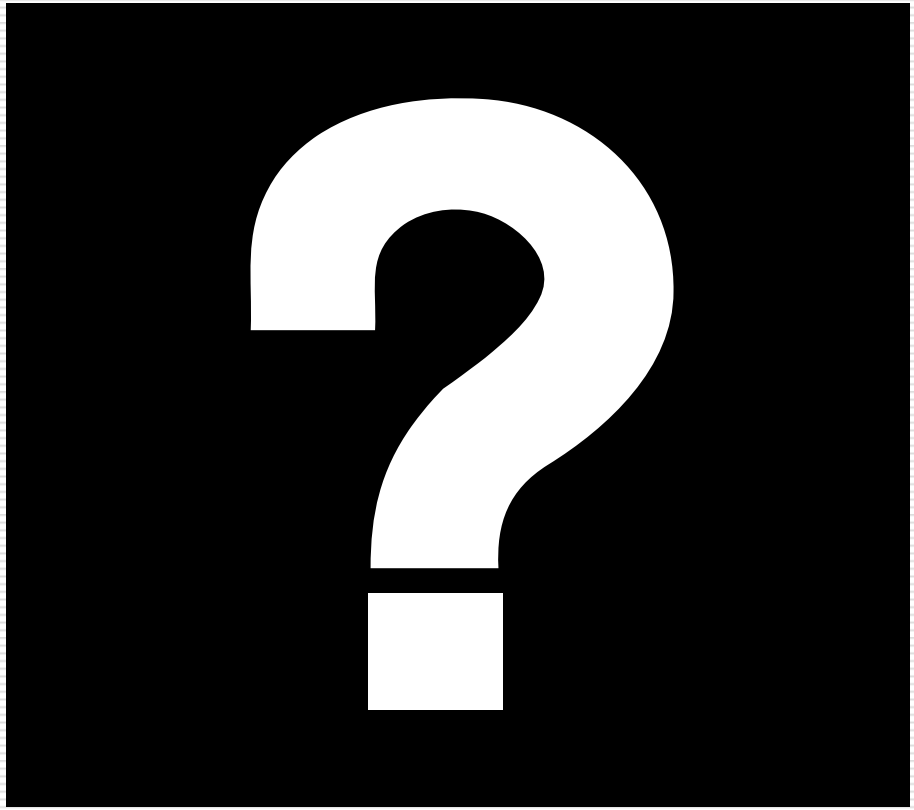
- Inspection does not work!

When inspection does not work…

- This causes a serious dilemma if you are an inspector



What's the problem?



Inspection do not work

- Defining the Problem
  - Repetitive non compliance issues
  - Stiff handed inspection approach vs. easy going manner doesn't matter much
  - Fines don't work
  - Education during inspection doesn't work
  - Too many judgment calls
  - Responsible person not involved

Inspection does not work

- Analysis of problem
  - Rarely see same people twice
  - Inconsistencies in the inspection program and between territories
  - No industry management support for regulatory compliance issues
  - No political support for public health protection

Inspections do not work

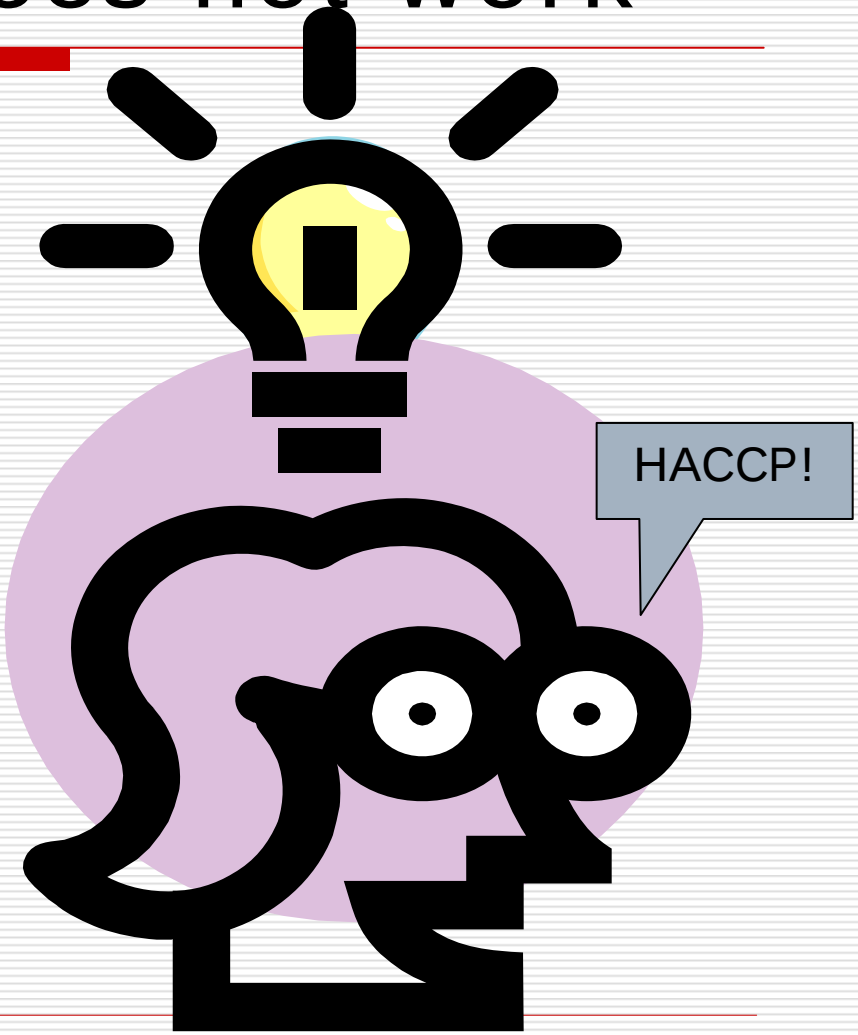
- All of this leads to failure and requires us to ask why is this so?

Why Inspection does not work

- Inspections:
  - Do not accurately identify risk
  - Cannot directly prevent risk
  - Do not “allow” the operation to prevent risk
  - Do not reduce risk on behalf of the public

Why inspection does not work

- Then, the light went on in 1992
  - When I read Dr. Peter Snyder's work on Industry Self Control- and
  - when I read Dr. Frank Bryan's work on HACCP



Changing paradigm

- I realized:
  - the operator is the responsible party for food safety;
  - inspectors can only evaluate compliance; and
  - both operator and inspector must change roles

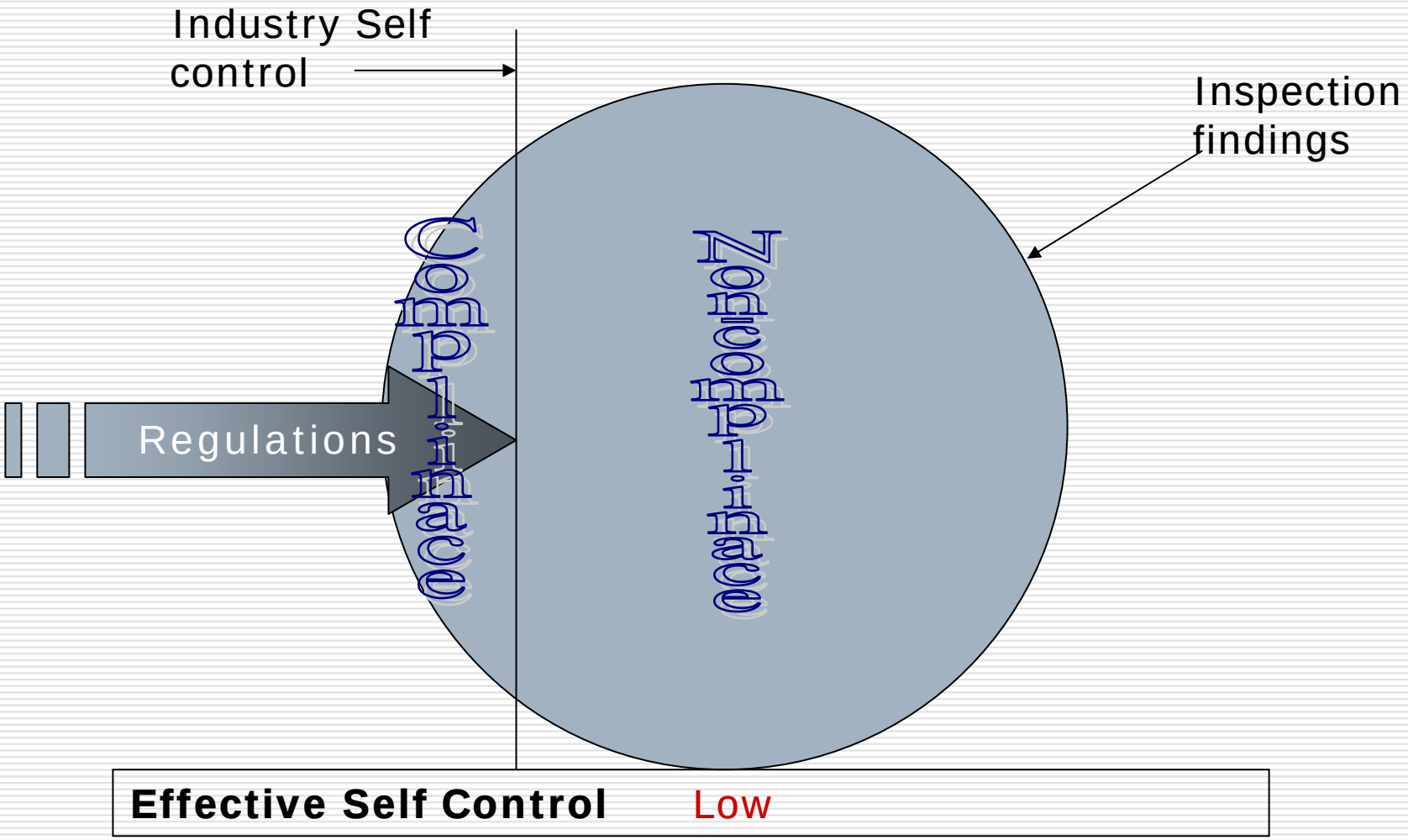
Changing the paradigm

- The operator himself must be empowered to take the authority and responsibility over food safety
- Operator ***must*** have a food safety system

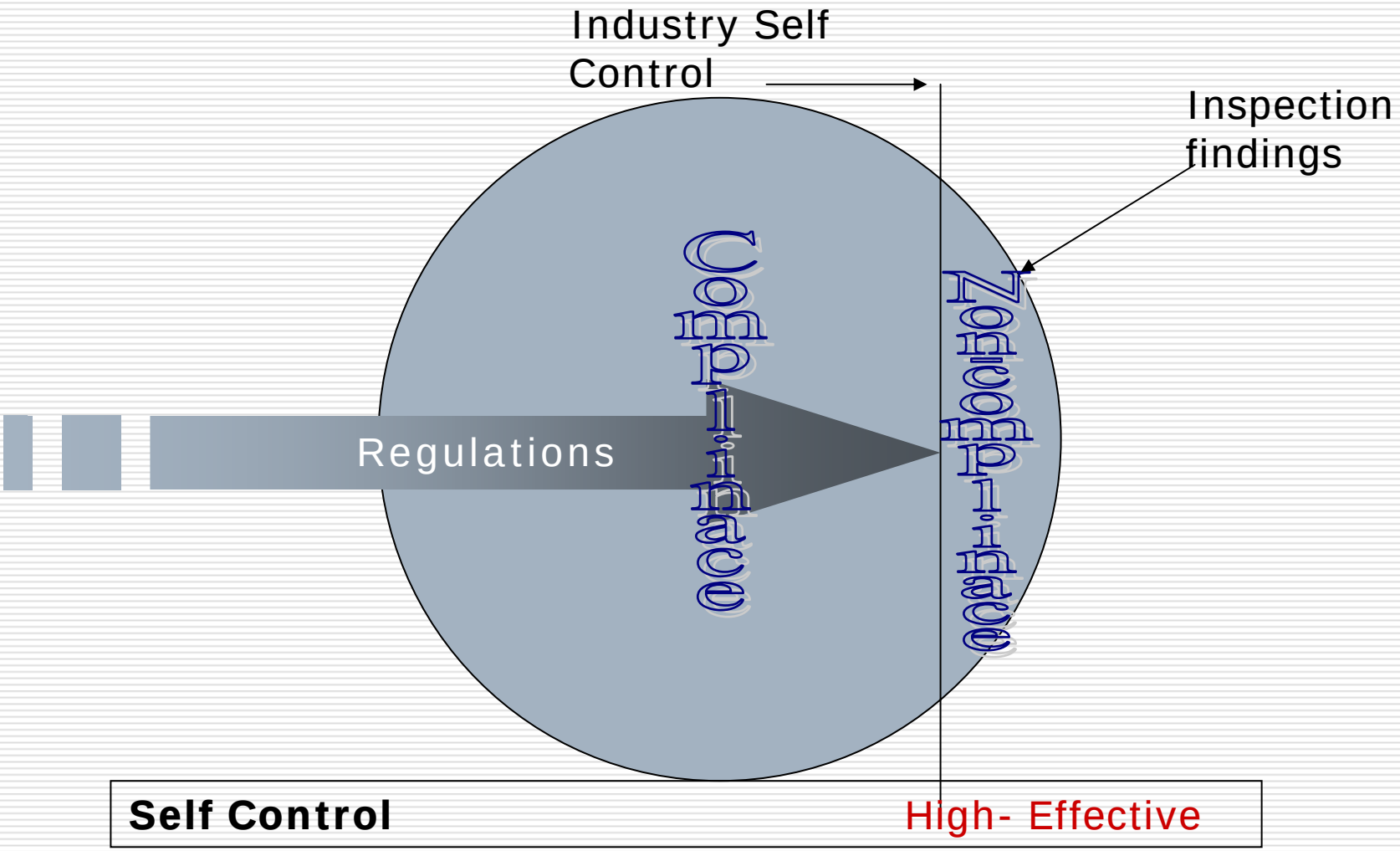
Changing the paradigm

- Make science the driver for regulatory compliance
- The operators own scientific controls become the lever to move regulatory compliance forward
- Training is of paramount importance

Regulations lack impact when self control is marginal

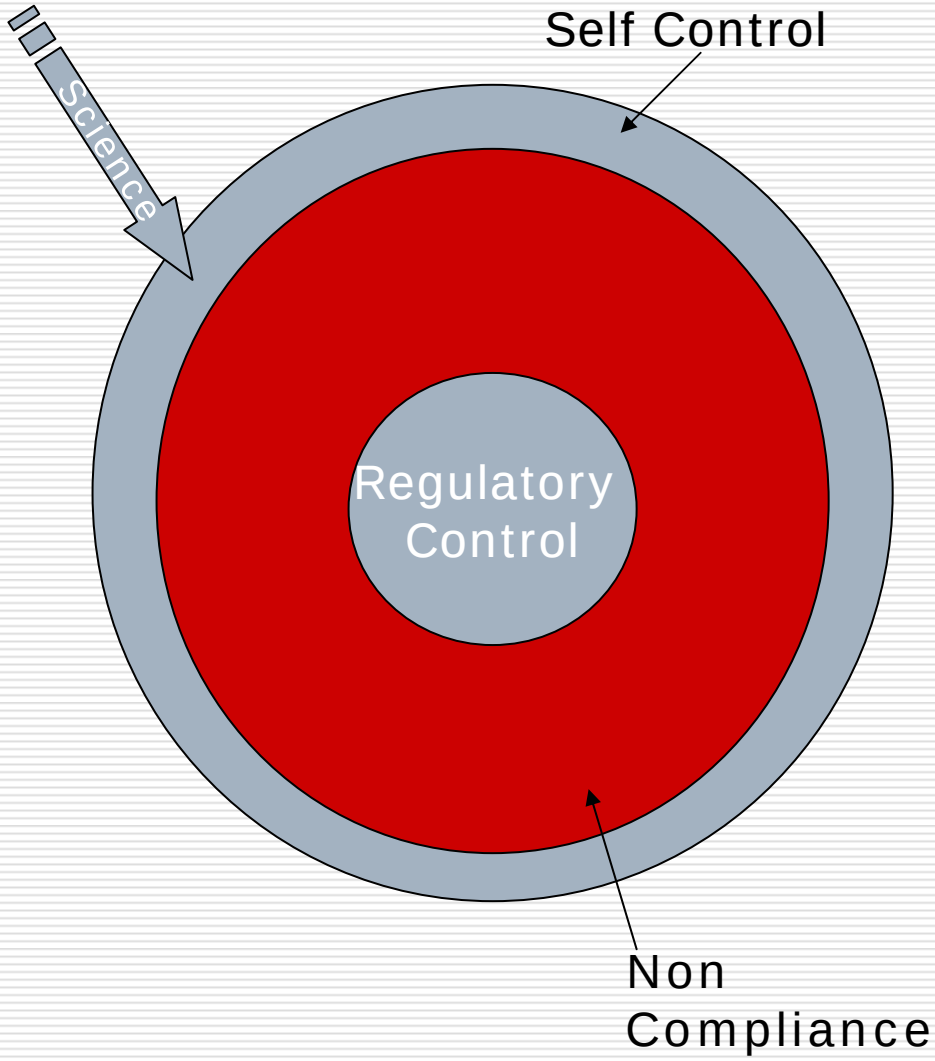


Regulations effective when self control is



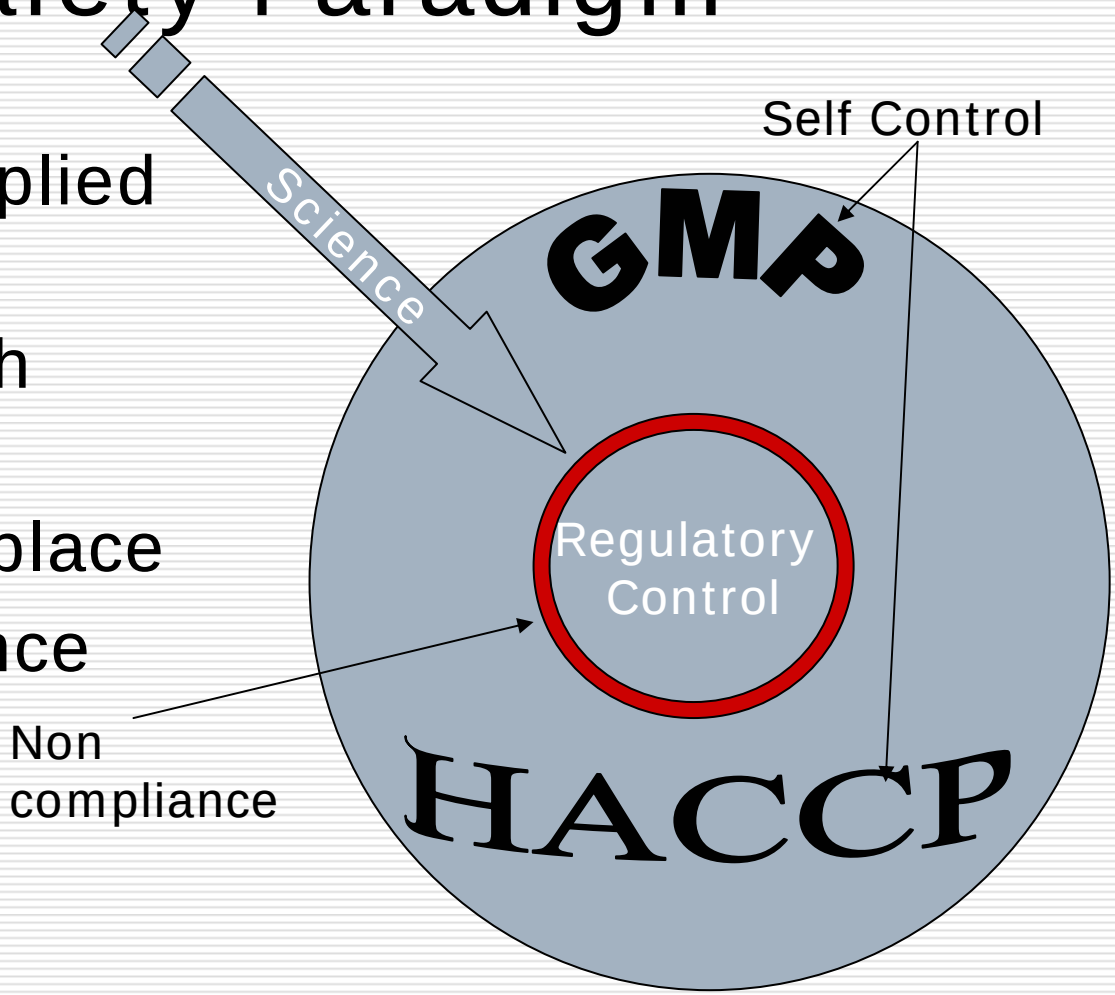
Old Food Safety Paradigm

- Regulations occupy the center of compliance
- Industry self control is marginal
- Non compliance is high
- Little penetration of science



New Food Safety Paradigm

- Science is applied
- Industry self control is high
- Food safety programs in place
- Non compliance contracts



Regulatory Implications of Industry Self Control

- Regulators must strengthen industry controls through verification of food safety systems through risk based inspection
- Clear guidelines are needed for industry to follow
- Industry must accept responsibility for control
- Self control must prove its benefit
- Compliance must be verifiable

IOWA: Quick analysis of transport can save problems at processing plants

…It can also be the beginning of the line for the spread of pathogenic Salmonella, if processors don't take note of whether incoming hogs are bringing the bacteria with them or developing it at the lairage.

The key is finding out early enough in the process at the lairage. That has led Food Safety Consortium researchers at Iowa State University to look for a way to determine within a few hours whether transport vehicles or lairage facilities have a minimal infective dose of Salmonella.

They are trying to do so by using a polymerase chain reaction (PCR), a technique for amplifying specific fragments of DNA sequences for ready laboratory analysis.

"We can get a sample in and we use our PCR kit on it," explained Stephen Gaul, an ISU researcher who assisted D.L. (Hank) Harris, professor of animal sciences. "It takes about two hours to do the extractions, depending on how many samples we do at one time. Then running the PCR is another four hours."

About six hours after the sample was obtained, Gaul said, "you'd know if it's positive for Salmonella and, hopefully, with the standard controls in there you can find out exactly how much there is in that fecal sample."

Once the results would be known, lairage operators would have time to implement sanitation procedures that would bring any Salmonella infection levels down to minimal level, if necessary.

US: Beef recall raises worry on industry oversight

This weekend's announcement of the largest meat recall in U.S. history raises new doubts about the Department of Agriculture's ability to adequately monitor the nation's meatpacking facilities.

Lawmakers and consumer advocates again are calling for tighter oversight and regulation of the nation's meat supply after Hallmark/Westland Meat Packing Co., Chino, Calif., issued a recall of 143 million pounds of beef products, some of which were for school-lunch programs. Mike Taylor, a former Agriculture Department food-safety official said, "The failure of the inspection program to stop the company's egregious behavior is just another sign of how USDA's thousands of meat inspectors are locked into a rigid, antiquated form of inspection..."

Tom McGarity, a law professor at the University of Texas, said, "This is a very big deal. The fact that downer cows are getting into the food supply is very disturbing and indicates a problem with the inspection process at slaughterhouses."

Michael Doyle, director of the Center of Food Safety at the University of Georgia, said,..."I think it's inappropriate to put emphasis on BSE [mad cow disease], simply because it's so, so rare in this country,"...the animals lay in their waste, so it gets on their hide, and hide contamination is the primary reason why the carcass gets contaminated"

Bill Marler, Seattle attorney, said, "I think the risk is really low. ... There are inspectors, USDA inspectors, were in that plant. I think one of the real difficult questions the USDA has to answer is where were they? What were they looking at when cattle were being picked up by forklifts?"

What is a risk-based inspection?

- A risk based inspection uses verifiable evidence to support the safety of the food production system
- A risk based inspection provides a valid determination of present, passed and future food safety performance-or the probability of a hazard occurring

Risk Based Inspection Model

- Must answer the following
  - How is risk defined?
  - Who will conduct the risk assessment?
  - How is risk assessed?
  - How will progress in reducing risk be measured?

Definitions of risk

- Risk is the probability a hazard will occur and its significance
- Risk= Likelihood of occurrence of a hazard x severity of symptoms
- Risk relies upon epidemiological findings for public health significance

Definitions of risk

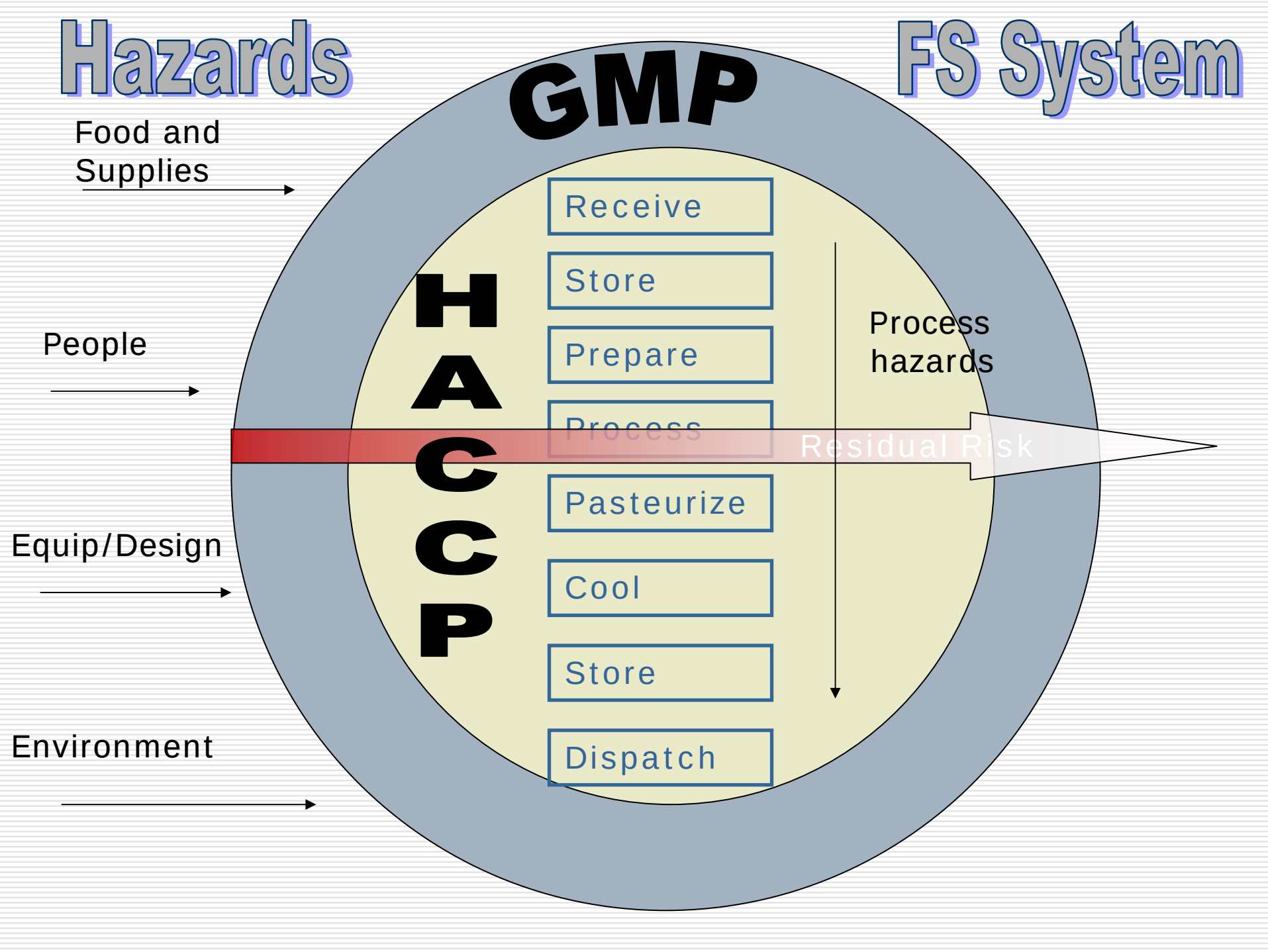
- Clinical risks are expressed in terms of infectious dose and susceptibility
- There are risks associated with inputs
- There are risks associated with the process
- There is a risk associated with certain procedures
- There are risks from behaviors
- There are risks in the way the food safety system is managed
- There is residual risk

Qualitative Risk Matrix

HAZARD	CONSEQUENCES			
	Low	Moderate	High	Very High
Very Low	Very Low	Low	Low	Moderate
Low	Low	Low	Moderate	High
Moderate	Low	Moderate	High	Very High
High	Moderate	High	Very High	Very High

Understanding Food Safety Hazards

- Hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption
- Where do hazards originate? People, food, water, soil
- How does contamination happen


Hazards
FS System
Food and Supplies
People
Equip/Design
Environment
GMP
HACCP
Receive
Store
Prepare
Process
Pasteurize
Cool
Store
Dispatch
Process hazards
Residual Risk

Basis for a Risk Based Inspection

- An operator must first identify and assess his hazards
- When a food safety system is implemented by an operator to control hazards, it becomes possible to assess risk in a comprehensive and meaningful way
- Without a food safety system there cannot be a valid risk based inspection
- The results of the inspection will be flawed

Basis for a Risk Based Inspection

- It makes much more sense to look at the way an operator controls risk to determine how much residual risk is left in the system
- The goal of a risk based inspection is to identify risk, reduce risk and protect the public

Making the transition to a risk based inspection model

- It is up to the operator to define risks
- Training is paramount
- Guidelines that facilitate the integration of standards into procedures are critical
- Management must be committed
- Management must have assets
- Management must have good communications

Risk Based Inspections are Two Sided

Verify the basis for risk control procedures

Verify those procedures are carried out

Risk

Making the transition to a risk based inspection model

- Verify Sanitation Standard Operating procedures-SSOP
  - Confirm that the operator has an effective cleaning and sanitizing program in place
    - Documented procedures and records
    - Documented training
    - Demonstration of procedures-tests
    - Demonstration of knowledge-tests
    - Procedures describe what to clean, who will clean, and who will verify cleanliness
    - SSOP records properly verified by management

Making the transition to a risk based inspection model

- Verify SSOP
  - Evaluate facility and equipment cleanliness and sanitation
    - Visual inspection
    - Tests

Making the transition to a risk based inspection model

- Verify GMP
  - Evaluate facility design and maintenance
    - Evidence of plan review and prior approvals
    - Records of potable water and testing
    - Documented preventive maintenance procedures
    - Records of preventive maintenance
    - Documented maintenance procedures
    - Effectiveness of procedures; describe what to clean, who will clean and who will verify cleanliness
    - Internal GMP audits carried out

Making the transition to a risk based inspection model

- Verify GMP
  - Evaluate facility design and maintenance
    - Visual inspection
      - Sound exterior structure
      - Sound internal structure
      - Plumbing maintained and waste water safely disposed
      - Solid waste disposed properly
      - Premises maintained
      - Equipment maintained functional according to the plan

Making the transition to a risk based inspection model

- Verify GMP
  - Assess Employee Health and Hygiene
    - Evidence of a health policy with exclusions for ill workers and restrictions
    - Evaluate personal hygiene training records
    - Documented personal hygiene procedures
    - Effectiveness of procedures; describe when to wash, how to wash, where to wash and who will verify hygiene
    - Internal GMP audits carried out

Making the transition to a risk based inspection model

- Verify GMP
  - Assess Employee Health and Hygiene
    - Observe for ill employees, cuts and infectious lesions
    - Question employees about health rules
    - Question employees about hand washing procedures
    - Operation of hand washing stations
    - Demonstrate procedures; when to wash, how to wash, where to wash and who will verify hygiene
    - Employee practices conform to procedures

Making the transition to a risk based inspection model

- Verify a Food Safety System is in place
  - Determine
    - The system is planned, organized and controlled
    - Leadership supports the system
    - The plan is written and documented and communicated to all
    - The operator understands and has documented process, his hazards and controls
    - The plan is effective at controlling risks
    - Employees are carrying out procedures developed
    - Monitoring is occurring at frequencies required
    - Critical limits are met and when not met a corrective action is taken and documented
    - Employee practices conform to procedures

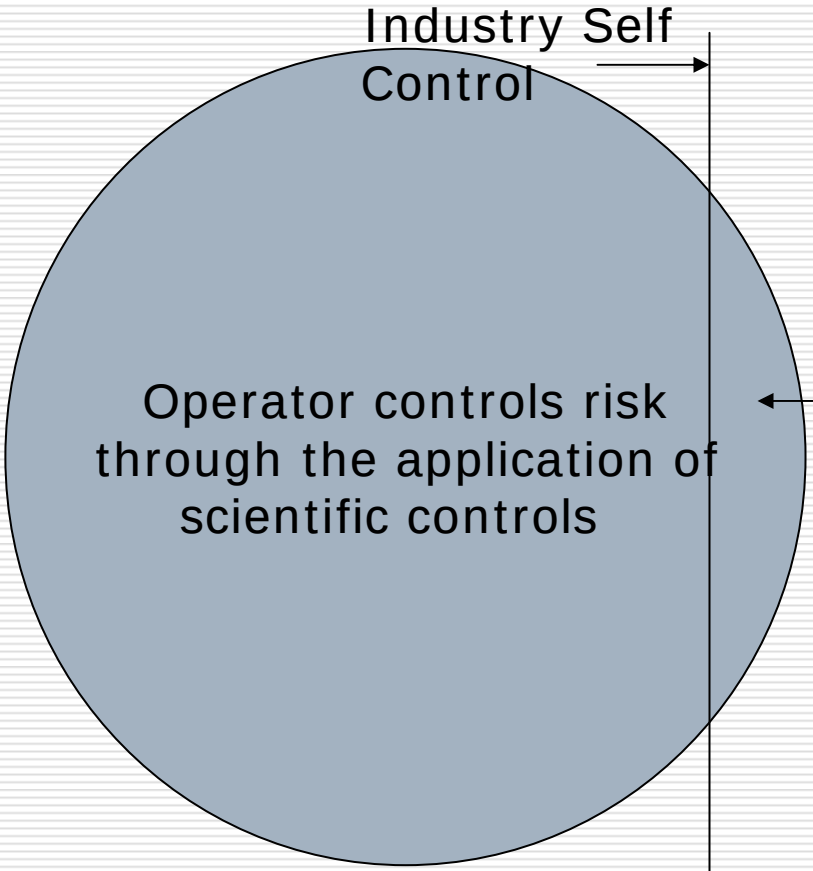
Making the transition to a risk based inspection model

- Verify a Food Safety System is in place
  - Determine
    - The operator conducts a verification of his GMP-SSOP-HACCP system at prescribed frequencies
    - Records are kept, they are available for review and reviewed by management on a periodic basis
      - Documents describe all of systems procedures
      - Records describe compliance with all procedures
      - Records are of monitoring are completed as monitored

Making the transition to a risk based inspection model

- Verify the qualifications, training, knowledge and experience
  - Determine
    - The operator has the knowledge to carry out the food safety procedures
    - The inspector has the necessary training and qualifications and knows how to assess procedures
      - Has scientific regulations
      - Understands how to audit records
      - Can identify lapses in procedures

Control of Risk



- The balance of risk controlled by operator
- Regulatory risk assessment more effective when the operator controls risks

Thank You.

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