

Challenges & Rewards of Implementing the FDA Retail Program Standards

A Mostly Successful Story

 Minnesota
Department of Health
Food, Pools and Lodging Services Section

I just want to add a little footnote to my bio in context of this talk. I'm going to be sharing some lessons learned from Minnesota's experience with implementing elements of the FDA Voluntary Retail Program Standards into a NON-voluntary program evaluation process. I'm speaking to you from the perspective of someone who has worked at two of the locally delegated agencies that have been evaluated, as well as someone who was on the evaluation team for four years. As of last year, I supervise the evaluation team, and as of very

recently, I'm also co-chairing a workgroup that will be developing the next phase of our evaluation process. So I'm speaking to you today while wearing several different hats.

Objectives

- **Minnesota Department of Health's approach to the *Standards***
- **Minnesota's challenges with implementing the *Standards***
- **Minnesota's success stories**
- **"Next steps" for the *Standards***
- **Lessons learned**

MDH

My objectives today are to share the Minnesota Department of Health's experience and approach to the Voluntary National Retail Food Regulatory Program Standards (the "Standards"), I'll share some of the challenges that we've encountered with our process, as well as some of our success stories. I'll finish it up by sharing where we are heading with the Standards, and leave you with a few of our lessons learned.

Minnesota Department of Health (MDH) Approach



So let's start by talking a little bit about MDH's approach to the Standards.

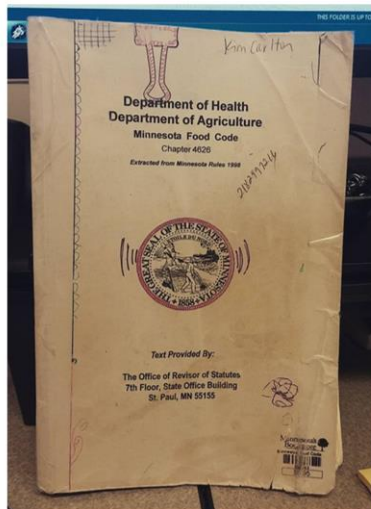
Retail food regulatory structure

- **MN Dept. of Health (“eat onsite”)**
 - Restaurants, schools, caterers, food trucks, etc.
- **MN Dept. of Agriculture (“eat offsite”)**
 - Groceries, c-stores, bakeries

MDH

In Minnesota, retail food regulation is located at the state level. Statutory authority is split between the Department of Health (who I will refer to as MDH) and the Department of Agriculture (which I will refer to as MDA), and the simplest way to describe it is “eat onsite” vs “eat offsite.” Very generally speaking, the department of health regulates things like restaurants, schools, caterers, and food trucks while the department of agriculture regulates things like groceries and delis, convenience stores, and bakeries.

Minnesota Food Code



MDH

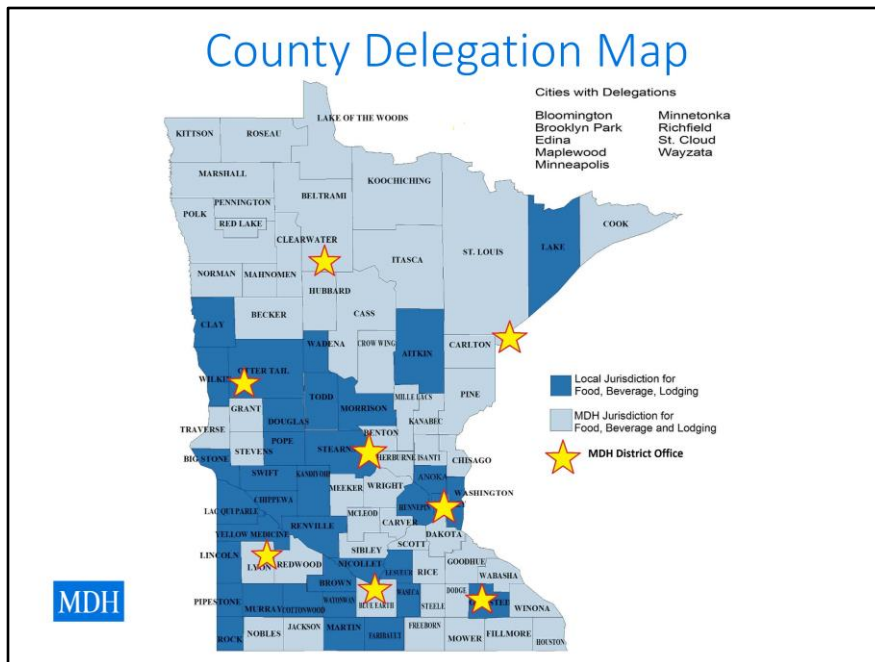
Both state agencies follow the Minnesota food code, which is based on the FDA model food code, and we will talk a little more about that later.

Delegation of authority

- **MN Statutes allow state agencies to delegate authority to local entities**
- **MDH: 31 delegation agreements with city, county, or multi-county agencies**
- **7 of the 31 have agreements with MDA – dual delegations**

MDH

Minnesota statutes allow both of the state agencies to delegate their authority to a local entity via a delegation agreement. The agreement allows the locals to issue licenses, collect license fees, perform inspections, and proceed with enforcement activities when needed. MDH currently has 31 delegated agencies made of city, county or multi-county community health boards. 7 of those 31 also have a delegation agreement with the MDA, so we consider them dually delegated.



To give you an idea of the delegation breakdown for MDH, there are 87 counties in Minnesota. The lighter shade of blue shows counties that are under MDH jurisdiction. We have 8 district offices across the state, that our 50 or so inspectors work out of, and those are marked with the stars on the map. The darker shaded blue counties are locally delegated, and some of those counties (such as Hennepin county) might have multiple city delegations within it. The entire population of Minnesota is about 5 and a half million people, and

about 3 and a half million of those live in the twin cities metro area. In these four blue-shaded counties alone, we have 12 different delegation agreements. So about 1/3 of our 31 delegated agencies are located right here in the metro area. The delegated agencies are very diverse in size, resources, geography, and program focus. As an example, the City of Minneapolis has 18 inspectors who cover 58 square miles. On the other end of the spectrum, Countryside Public Health has 2 inspectors to cover five counties or 3400 square miles.

Delegation agreement language

- **MN Statute:**
 - *The agreement must list criteria the delegating authority will use to determine if the designated agent's performance meets appropriate standards and is sufficient to replace performance by the delegating authority.*

MDH

The statute that allows MDH to grant delegation agreements specifically states: “The agreement must list criteria the delegating authority will use to determine if the designated agent's performance meets appropriate standards and is sufficient to replace performance by the delegating authority.” So what are those criteria?

2007 - Delegation agreement advisory council

- **Updated agreements**
 - Separation of “operational” and “statutory” language
 - Creation of a “best practices” manual
 - Creation of a workgroup to define program evaluation and develop a uniform evaluation process

MDH

In 2007, an advisory council was convened in order to rewrite the delegation agreements. They developed the new document based on the FDA standards, which included minimum criteria for evaluation. Aside from a new agreement, the advisory council had three main recommendations, including the separation of operational and statutory language, the creation of a best practices manual, and the creation of a workgroup specifically to define program evaluation and develop a uniform evaluation process.

Program evaluation

- **“To ensure that minimum program standards put forth in Minnesota Statutes, Rules and the Delegation Agreement are in place and maintained, in order to protect public health.”**

MDH

From 2008 into 2009, a dedicated workgroup of MDH and locally delegated staff worked together to develop an evaluation protocol. The agreed-upon goal of the evaluation was to ensure that minimum program standards were in place and maintained, in order to protect public health.

Evaluation foundation

- **Based on FDA Retail Program Standards**
- **Food, Swimming Pools, Lodging, Recreational Campgrounds and Manufactured Home Parks, Youth Camps**

MDH

The workgroup decided not to entirely re-invent the wheel, so they developed an evaluation process based on the latest version of the FDA Retail Program standards. However, since MDH's delegation agreements covered more than just food programs, the standards and evaluation process were expanded to cover swimming pools, lodging, recreational campgrounds, manufactured home parks, and youth camps in addition to the food programs.

Evaluation criteria

- **FDA *Standards* modified by workgroup**
- **Elements added / subtracted**
 - Statutory requirements
 - Delegation agreement requirements
 - Resource limitations
 - Field component

MDH

The eight standards were modified by the workgroup - and we'll come back to that in a minute - but essentially, certain items that are specifically required by MN statute or the delegation agreements were added, and things that were seen as overly burdensome due to agency resources and capacity were removed or made optional. We also added a field component.

Evaluation Team

- **Evaluations done by FDA standardized food safety inspection officers**
- **Team of 3 evaluators**
 - 2 per evaluation

MDH

The evaluations were done by a dedicated team in the Partnership and Workforce Development Unit. The unit is unique, having been created specifically to sustain and expand Food, Pools, and Lodging Services (FPLS) Section activities, local partnerships, and collaborations. The unit is funded in part by a Statewide Hospitality Fee of \$35 annually which assessed to each

MDH or MDH-delegated food, beverage and lodging facility in the state of Minnesota.

The evaluators themselves were FDA standardized food safety inspection officers. The team consisted of 3 people, who would rotate through, with 2 people on each evaluation.

Evaluation implementation

- **Components:**
 - Agency self-assessment
 - Desk audit of submitted materials
 - Field review
 - Onsite record review
 - Reports

MDH

The evaluation itself consisted of several components. First, the agencies were required to submit a self-assessment along with supporting documentation 30 days in advance of their scheduled evaluation. This would include things like ordinances, org charts, a list of licensed establishments, written policies and procedures, staff credentials and things of that nature. The evaluators would review those items in advance so they could get an idea of what the agency looked like before showing they showed up to do the field

evaluation. The field portion took about a week to a week and a half on average. On the first day, they would meet with agency management and staff to go over some of the materials that already had been submitted and reviewed. Then they would draw the random sample of establishments that would be visited by the eval team with everybody watching so there would be no question of bias. The team would then hit the field with their list of establishment for the next several days to do brief pop-in non-regulatory inspections. The purpose was to get a general idea of what the establishment really did. For example, if an agency had a place licensed as a low-risk bar, the team would assess if that's true or if in reality they're actually doing weekly prime rib dinners and running a catering operation out of the back. The field portion was also used to assess trends in risk factors. After that was done, the team would return to the agency's office for a couple of days of record review. They'd review the previous four inspection reports for the establishments that were visited, as well as examples of HACCP plans, plan reviews, the complaint log, et cetera. After that, the team would head back to the office where they'd have 60 days to write a draft report which

would be sent to the agency, the agency would have 30 days to comment and make corrections, and then the evaluation team would have another 30 days to submit the final report back to the agency.

Evaluation timeline

- **Original schedule: 5 year cycle**
 - 34 agencies to be evaluated
 - ~6 months to complete an evaluation
 - Weather & geography
 - One per month, April-October

MDH

The original evaluation timeline was scheduled to take five years. Again, we had 34 agencies to evaluate. And a process that realistically took six months for each one to be completed. So they were scheduled so that a new one would start every month.

As I mentioned earlier, the evaluation team was made of three people who would rotate through on each one. The cycle was to lead one, assist one, and then take one month off to finish writing the report for the evaluation you started 2 months ago, or do a

standardization, or do any of your other job duties. Also in Minnesota, we have winter which not only can make travel hazardous, but since the evaluations encompassed all of the program areas, seasonal facilities like outdoor pools and campgrounds couldn't be evaluated in the winter months, so they were originally only scheduled from April through October.

Evaluation Tool

- **Describes program elements to be evaluated**
- **Weighted according to statute, rule, and delegation agreements**
 - Essential “orange”
 - Required “yellow”
 - Value-added “white”

MDH

The evaluation tools were the worksheets that were used for scoring. The exact same tools were used for an agency’s self-assessment as for the formal evaluation.

The individual items were weighted into a three-tier system, according to statute, rule and delegation agreement requirements.

An Example of an “essential” item would be something like adopting ordinances granting regulatory authority.

An Example of a “required” item would be correctly categorizing establishments according to risk
And Example of a “value added” item would be enrollment in the FDA program standards

The essential and required items were the only ones that were actually required to be scored. The only time that the “value-added” items were calculated into the overall score is when an agency fell into the overall “acceptable” category. They became like extra credit.

Scoring

- Each item scored 0-2

Program Element	Value
Acceptable (little or no improvement needed)	2
Needs Improvement	1
Unacceptable	0

MDH

Each item on the evaluation tool was given a score of 0 to 2. This was a deviation from the FDA standards, in that it allowed an agency to get partial credit for something, versus an all-or nothing system where you either meet it or don't meet it.

Delegation agreement status

- **Aggregated score = status**
 - *Acceptable – exceeds minimum*
 - Acceptable (“A”)
 - Acceptable – needs improvement (“B”)
 - Conditionally acceptable (“C”)
 - Unacceptable (“D”)
 - Subject to termination (“F”)

MDH

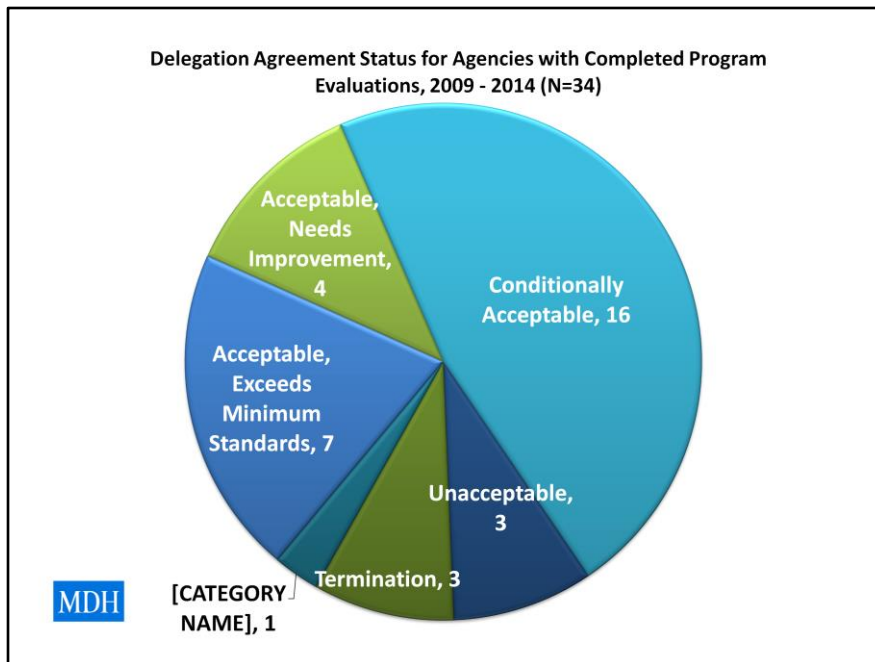
Once the scores had been assigned, the numbers for all of standards and all of the various program areas were plugged into an incredibly complicated scoring matrix that I would be happy to attempt to describe offline, but we’d be here for an extra hour if I were to try to do it justice right now.

Ultimately each delegated agency would be given a status, as defined in the delegation agreements. We sort of looked at these like a grading scale in school, from A to F.

“Acceptable – exceeds minimum” is a fake category, which isn’t actually in the delegation agreement, but it was created to describe agencies with “extra credit” from scoring high on all of the essential and required items, in addition to having additional “value added” points.

Basically, If you got anything with “acceptable” in the name, your agency would be expected to come up with an improvement plan to correct the items that didn’t score a “2,” put it into place, and make improvements within an agreed-upon timeframe. If you were “Unacceptable,” your agency would be subject to more rigorous follow-up, including potentially further evaluation.

And if you were “Subject to termination,” MDH would be required to terminate the delegation immediately with duties reverting to MDH.



So when everything was said and done, at the end of the last cycle, the overall picture of programs in Minnesota looked like this. We had 7 that were in the A+ “extra credit” category of exceeding minimum standards, we had 4 that fell into that “B” category of acceptable with improvements needed, and just about half fell into the “conditionally acceptable” or what we would consider “C” or “average” category. Thankfully there were only a few that fell into unacceptable and termination categories. And I will talk about the conditional

agreement in a little bit.

Standard 1: Regulatory Foundation

- **Removed regulatory requirement for the most current edition of the FDA *Food Code***
 - MN Code is based on 1995 – nobody would meet it
- **Requires ordinances consistent with state statutes and rules**

MDH

I want to just real briefly share some of the modifications that MDH made to each of the standards. If you'd like to know more about specifics or the gory details of the scoring matrix, we can talk about it later. I'm happy to share the whole protocol and tools if anybody would like them.

For standard 1, we took out the part about the most current edition of the FDA food code because although Minnesota's code is based on the FDA code, the last time it was updated was 1998, and it's

based on the 1995 model food code - so nobody in the state would meet it.

Instead, standard 1 requires the agencies to have adopted ordinances that are consistent with state statutes and rules.

Standard 2: Trained Regulatory Staff

- **Standardization is “value added”**
 - Offered to each delegated agency
 - MDH has 2 FDA standardized food safety inspection officers
- **RS/REHS credential is mandatory**

MDH

For standard 2, we made standardization a value added item. We currently have 2 FDA standardized food safety inspection officers, and we do offer standardization to each delegated agency but it is not currently required. That being said, 20 of our 31 delegated agencies do have standardized staff. Also, in Minnesota the RS/REHS credential is mandatory within two years of hire, so we added that in here.

Standard 3: Risk-based inspection program

- **“Value-added”**
 - In/Out/NA/NO inspection form
 - Documented procedure for long-term control of risk factors
 - Documented procedure for HACCP plans

MDH

In standard 3, we made some of the documentation items value-added, such as the CFP-style inspection form, procedures for long-term controls of risk factors, and procedures for reviewing HACCP plans.

Standard 4: Uniform inspection program

- **Less emphasis on internal quality assurance program and documentation**
- **No statistical analysis of QA program**
- **Added plan review and license requirements**

MDH

In standard 4, we placed less of an emphasis on an agency's internal quality assurance programs and documentation. We also removed the statistical analysis piece, but added plan review and licensing requirements.

Standard 5: Illness & injury investigation and response

- **Outbreaks are coordinated at the state level; emphasized utilization of *Foodborne Outbreak Protocol***
 - Recalls, traceback, etc. coordinated by MDA
- **Removed data review & analysis**
- **Added requirement to transmit illness complaints to MDH in 1 business day, and follow up on complaints in 1 business day.**

MDH

In standard 5, since outbreaks are coordinated at the state level, we emphasized the utilization of the MDH Foodborne Outbreak Protocol. We have a very robust system for outbreak response in Minnesota, and we work closely with the MDA for recalls and traceback activities, so we don't place that responsibility with our delegated agencies. We did add in the requirement for an agency to transmit illness complaints that they receive to MDH within one business day, and also added the requirement to follow up on foodborne illness complaints within

one day.

Standard 6: Compliance & Enforcement

- **Addition of records retention policy**

MDH

In Standard 6, we added a requirement for a records retention policy.

Standard 7: Industry & Community Relations

- **Less documentation required**

MDH

Standard 7 is essentially the same as the FDA standards, but without a defined documentation requirement.

Standard 8 – Program resources

- **All agencies have duties in addition to food. Staffing levels not mandated**
 - Lodging, pools, manufactured home parks, youth camps, public health nuisances, drinking water, septics, hazardous waste, etc.
- **Added safety training**

MDH

Standard 8 – staffing levels was considered a value-added item, because all of our agencies have duties beyond just food. We also included an item for individual safety training.

Standard 9 – Program Assessment

- **Not included**

MDH

Challenges

MDH

So we have our process and protocol in place – great!

What could go wrong? Well, turns out – lots of things!

Timeline Immediately Modified

- **New CHB delegation agreements**
- **Flooding**
- **State government shutdown**
- **Staffing issues**

MDH

Right out of the gate, that five year timeline was immediately modified. One of the first agencies on the schedule gave back their program before they were even evaluated. There were a few scenarios where new community health boards were formed, so evaluations of their existing county components were had to be done in order to make sure they were prepared to take on additional counties, and that impacted the schedule. One of the counties had massive flooding and so they requested a deferment to later in the schedule. In 2011, there

was a state government shutdown that lasted a few weeks, so that took the evaluation team offline for awhile. And then finally we had some staffing issues with members of the evaluation team being reassigned to other duties, so we couldn't keep up with the every month schedule, and changed it to an every-other-month system.

	2009	2010	2011	2012	2013	2014	2015
Feb							
March							
April		Faribault/ Martin	Wabasha	Brooklyn Park	Moorhead		
May		Wadena	Hopkins	St. Paul	Maplewood		
June		Ramsey	Clay-Wilkin	LLMP	Stearns		
July	Goodhue	Minneapolis	Douglas/Pope	Washington	LeSueur/ Waseca		
Aug	Kandiyohi (pilot)	Nobles/Rock	Lake	Winona	Countryside		
Sept	Aitkin	Bloomington/ Richfield	St. Cloud	Olmsted	Redwood/ Renville		
Oct	Minnetonka/Wa yzata	Morrison/ Todd	Brown-Nicollet	Edina	Anoka		
Nov		St. Louis Park	Hennepin				

	2009	2010	2011	2012	2013	2014	2015
Feb			St. Louis Park				
March	Anoka (pilot)			Brown-Nicollet	Edina	LeSueur/Waseca	
April		Faribault/ Martin		Hennepin			
May		Wadena	Hopkins	Brooklyn Park	Wabasha	Countryside	SWHHS Re-eval
June		Douglas-Pope	Clay-Wilkin	St. Paul			
July		Minneapolis		SWHHS	Maplewood		Clay Wilkin Re- Eval
Aug	Kandiyohi (pilot)	Nobles/ Rock	Ramsey				Hennepin Re-Eval
Sept	Aitkin	Bloomington/ Richfield	Lake	Washington	Stearns		Minneapolis Re- Eval
Oct	Minnetonka/Wayz ata	Morrison/ Todd	St. Cloud	Winona			
Nov				Olmsted			

I don't expect you to read this slide, but it shows how the schedule got drawn out. The top table is the original schedule which was very tightly packed. The lower table shows what actually ended up happening, with the dates much more spread apart.

Self-assessments: Honor system

- **Intended to be annual**
 - Not required to submit until evaluation
- **Some agencies chose to do them at the last minute**
 - No opportunity to identify gaps and make improvements

MDH

Another challenge was that although an annual self-assessment was supposed to be the cornerstone of the process, they weren't necessarily being done. There was no requirement for the agencies to submit their self-assessment until 30 days before their evaluation. And it was evident that several of the agencies didn't do them until right before they had to turn them in. That really defeated the purpose of having the self-assessment, since agencies didn't give themselves an opportunity to identify gaps in their programs and more

importantly to make improvements.

Lack of standardized measuring tools

- **How do you get a 0-1-2?**
 - 2 – “little to no improvement needed”
 - 1 – “needs improvement”
 - 0 – “unacceptable”
- **“Has the Board developed a documented procedure for xyz?”**
 - This is a yes/no question
 - Binary/quantitative vs. qualitative

MDH

One of our biggest challenges was a lack of standardized measuring tools, especially since we offered partial credit for scoring. There was no rubric for how to give partial credit vs full credit for something. For example, when it came to correctly assigning risk categories, and let’s say you had 20 establishments in a sample, how many would need to be correctly assigned in order to get full credit? The unwritten rule of thumb was that you could get one or two wrong and still get full credit, but what if you had three? Four? On the flip side, what if you

got 4 or 5 right but got 15 of them wrong? Is that still partial credit? As a side note, we called that unacceptable.

There was also a difference in interpretation of the items related to how they were written. On the evaluation tools, many of the questions asked a yes/no question. For example, “has the Board developed a documented procedure for follow-up activities.” Technically this is a yes or no question. Some agencies scored themselves with full credit for having a procedure for something – as in “yes we have a procedure so we should get a 2,” but the evaluation team generally scored these items based on the quality or content of these procedures. So in this example, the evaluation team would want to actually see an effective follow-up procedure based on severity of violations, number of violations, timeframe, repeat violations, and things like that – rather than a procedure that says “we do follow-up inspections as needed.”

Length of Evaluation Cycle

- **Turnover in evaluators**
 - Multi-year, evolution, personalities
- **Precedent**
 - “X county got a “1” here, Y county should too...”
- **5+ years is a long time to keep a status**

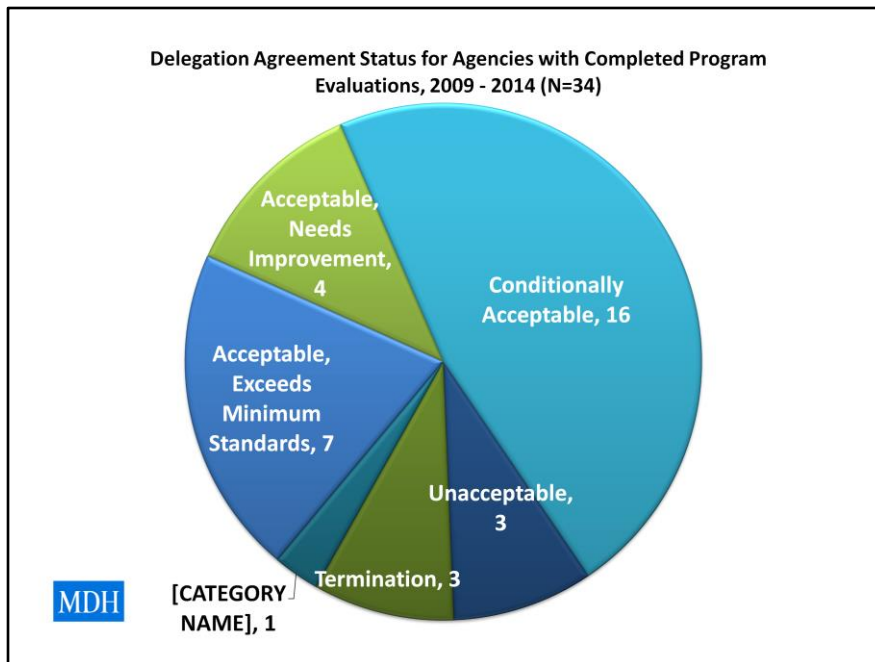
MDH

The length of the evaluation cycle itself proved to be a challenge. There was some turnover during those five (which actually was seven) years, so the team who evaluated the first few agencies was completely different from those who did the last ones. Myself, I came on during year 4 of the 7-year cycle.

Precedents were definitely set along the way. If one agency had scored a certain way on something, the next one to have a similar situation would be scored

the same way. But without standardized scoring tools, if something new happened, the scoring could inevitably be subjective to the evaluator.

Also, if you are an agency that was dissatisfied with your status, you have to keep it until your next evaluation. With the exception of the ones who were in the “unacceptable” category, nobody has had a chance for an upgrade in their status.



I'll just show you this distribution of statuses again – we had 16 out of 34 agencies that fell into the “conditionally acceptable” or “average” or “C” category.

Nobody wants to be average!



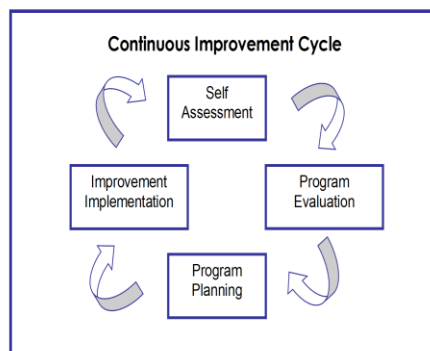
MDH

The problem with that is that we come from Minnesota. And although Lake Wobegon is a fictional place, when it comes to Minnesotans? Quite literally – all the women are strong, all the men are good looking, and all the children really are above average!

So to give an agency an “average” rating really didn’t sit well with a lot of folks.

Continuous Improvement

- **The theme of the program evaluation workgroup and protocol...**
- **...but the mechanism was not created by the workgroup**



MDH

Continuous improvement was the foundation that the evaluation system was built upon.

At the end of their evaluation, non-failing agencies were supposed to create their improvement plan, and then implement it. And hopefully that's been happening.

But without a formal mechanism for re-evaluation or affirmation that the improvements have been made, most of the agencies have had to live with their status assignments for several years.

Conditional Delegation Agreements

- **“Subject to Termination” = second chances**
- **Terminated original agreements**
- **New agreements with increased oversight**

MDH

Conditional agreements were implemented in 2012 and 2013. In those years, there were three evaluations that were subject to termination. Our division management decided that through the appeals process, they would implement a new type of agreement that wasn't originally spelled out in the delegation agreements or the evaluation protocol, called a “conditional delegation agreement” (which is not to be confused with being conditionally acceptable – because remember, that's average).

The agencies' original delegation agreements were terminated, per the agreement language, but they were given a second chance and a new agreement that had very specific criteria to meet, including increased oversight from MDH. The oversight ranged from reports being required to be submitted and reviewed on a regular basis, to actually having an MDH staff person physically located in their office to try to bring the program into compliance.

Resources

- **State oversight during conditional status**
- **Delegation agreement states the authority reverts to the state if an agency fails**
- **Additional inspection staff hired**

MDH

As you might imagine, resources became something of an issue. There was an increased burden on the evaluation team for overseeing the conditional agreements, in reviewing reports, doing standardization, and other hands-on assistance. But 2 of the three conditional agreements also ultimately ended in termination because the agencies just couldn't make the improvements that were needed. For those, since the delegation agreements state that a program will revert MDH, we ended up having to absorb them. We had to hire

and train several new inspection staff, which was an outcome that I don't think anybody would have predicted.

Politics

- **City of St. Paul**
 - “Subject to termination”
 - Conditional agreement with state oversight, terminated
 - MDH & MDA were sued

MDH

The City of St. Paul - the capitol city of Minnesota, with a population of about 300,000 – was evaluated in 2012. The evaluation resulted in a “subject to termination” status.

To give you an idea of the types of deficiencies that a program in this category would have to have, their inspection frequency was well below acceptable rates, with many establishments being 3 or more years overdue for an inspection. The numbers worked out to an average of 8 inspections being done per employee per month. Their staff wasn't

provided with adequate training. They had interns performing inspections that were required to be done by registered sanitarians. Their inspection reports were seriously inaccurate – citing incorrect orders, and misinterpreting the code.

However, City officials didn't agree that their program should be terminated, and they fought it all the way to Governor Mark Dayton's office. After a lot of back-and-forth between the City and the state, the City of St. Paul was the first delegated agency to be offered one of those conditional agreements.

The City agreed to heavy oversight – including our unit's supervisor being physically relocated to their office to oversee their improvement efforts. They hired 6 additional staff, a new manager, they restructured so that they had two new supervisors who MDH standardized, all of their reports were reviewed, and they all received additional training. Ultimately though, the improvements weren't enough. St. Paul also had a delegation agreement with the department of agriculture. MDA did their own evaluation of their program during all of this, which had a similar outcome. The two state agencies ultimately terminated their delegation agreements with the City in the summer of 2013, which was

about a year after MDH's original evaluation. The city sued both state agencies, filing a temporary restraining order, a temporary injunction and a permanent injunction. Their arguments were that since St. Paul had a home rule charter, the state had no authority to remove their powers, they argued that MDH & MDA hadn't done evaluations according to the frequency stated in their delegation agreements, they argued that they were in the process of making improvements, and they argued that their performance was no better or worse than the state's.

The lawsuit was dismissed. **HOWEVER...**

Increased attention

- **Division management, commissioner's office, governor's office *and media***
- **Two additional agencies "subject to termination"**
 - Conditional agreements
- **Abrupt halt to evaluations**
 - 2 agencies and MDH left un-evaluated

MDH

Now we had people's attention. Our division management, the commissioner's office, the governor's office, and even the media were now interested in what we were doing.

Unfortunately, after St. Paul the very next agency that was evaluated was also subject to termination. Since precedent had been set, we offered them a conditional agreement as well, but without the onsite oversight because quite frankly we didn't have the resources for it. The St. Paul city office was literally six blocks from the MDH home office, and

this next agency's office was four hours away. After that, we had a string of "conditionally acceptables," – or "averages," one "acceptable – exceeds minimum standards," and then another "subject to termination."

By this point, the decision-makers in MDH had heard just about enough complaints about the process. They put an abrupt halt to the evaluations, leaving two delegated agencies without a full evaluation, in addition to MDH not being evaluated. One of MDH's district offices was a pilot site before the evaluations started, but the plan was to finish the cycle with an evaluation of the entire MDH system as well – and due to all of the turmoil, it didn't happen.

Environmental Health Continuous Improvement Board

- **New board chartered by Local Public Health Association and MDH to advance state-local partnerships**
- **Re-evaluation process for lowest-status programs implemented**
- **New evaluation workgroup chartered**

MDH

So shortly after the termination of the conditional St. Paul delegation agreement in the summer of 2013, concerns about the relationships between local public health entities and the state were expressed to the commissioner of health. As a result, a new board was chartered by the Local Public Health Association and MDH in order to formally commit to improving the state-local partnerships related to the food, pools and lodging programs, as well as to better integrate environmental health into the statewide public

health system.

One of the first outcomes of the Board was a re-evaluation process, which was offered to the 3 agencies who were sitting with an “Unacceptable” status, as well as the one who successfully made it to the end of their conditional agreement. Two were upgraded to “Acceptable,” and two made it to “Conditionally acceptable.”

Most recently, the board chartered a new workgroup to work on the next iteration of the program evaluation process.

Successes

MDH

So... we had some challenges, but let's switch gears and talk about some of the successes of the evaluation process.

Added Resources

- **Evaluation results used to justify resources**
 - People
 - Training
 - Equipment
 - Enforcement
 - Updated ordinances

As a result of their evaluation statuses, several agencies were able to show tangible proof to their administration, whether it was city council or a county board, that they needed resources to beef up their programs.

In certain cases, agencies were able to add people, they were able to provide training opportunities for their staff, they were able to upgrade or acquire equipment that they needed, they were able to justify strengthening their enforcement procedures, and in several cases they were able to update their

ordinances. In one unique situation, we identified a multi-county agency that had been operating without ordinances for swimming pool regulation, although they'd been doing it forever. Passing an ordinance became a quick priority when the state came in and temporarily took over their swimming pool program... (and then gave it back once ordinances were passed).

Success story - Minneapolis

- **“Unacceptable” 2010**
- **Support from mayor & city council**
- **Justify license fees to support program resources**
- **Complete restructuring of program**
- **10 inspectors & 1 support staff to 18 inspectors & 3 support staff**
- **Re-evaluation: “Acceptable” 2015**

The City of Minneapolis is one of our success stories. They were evaluated in 2010 and received an “Unacceptable” status. Like most government agencies at the time, they’d gone through a few years of recession fallout with dwindling resources, dwindling support, as well as having upper management with little to no experience in environmental health, and they had basically been running in subsistence mode for awhile. They were able to use this evaluation to clearly show the mayor and the city council that they needed

additional support. They were able to justify additional license fees, and they completely restructured their inspection program. They went from having 10 inspectors and one support staff, to 18 inspectors and 3 support staff. After their 2015 re-evaluation, they'd upgraded to "Acceptable."

Success story – Southwest Health and Human Services

- **“Subject to Termination” status 2012**
- **Conditional Agreement**
 - Standardization
 - Report review
 - Training
- **Re-evaluation: “Acceptable” 2015**

Another of our biggest success stories is Southwest Health and Human Services, which is a 4-county agency in southwestern MN, near the South Dakota border. They were subject to termination, and were one of the recipients of a conditional agreement. As part of their conditional agreement, MDH required their staff to be standardized, they were required to submit their inspection reports for us to review and comment on, and we provided basic training and input on their policies and procedures. They received a re-evaluation at the end of their

conditional agreement in 2015, and also as part of their efforts to onboard 2 additional counties. That evaluation gave them an “Acceptable” status.

I can honestly say that they are now one of our best partners. They frequently participate as trainers in trainings that we give, on subjects that are outside the realm of our comfort zone – such as campground plumbing. We call on them to provide testimony to the benefits of the evaluation process, because they’ve had first-hand experience of the worst and the best of it. As a matter of fact, they’ve become so invested in the process that the manager of the program is now my co-chair on the new workgroup to revise the evaluation system.

Public Health Protection

- **Self-assessments identified gaps and corrections were made**
- **Worst-performing agencies had agreements revoked**
- **Public health accreditation**

In terms of overall public health protection, the evaluation process provided a somewhat standardized approach for the state to look at our programs. The agencies that did their self-assessments had an opportunity to identify gaps and make corrections, whether it well in advance of their evaluation, or as part of a continuous improvement process.

I hate to say that agencies having their delegation agreements revoked is a success. I don't want to gloss over the fact that my former coworkers and

friends lost their jobs. The evaluation team was essentially shunned by other inspectors for being traitors, and by some in our own department for being troublemakers. But in those very extreme cases, the communities that were entrusting those delegated agencies to provide public health services were not being adequately protected, so as hard as it was, I do believe that reverting those programs back to the state is a success for the people living in those communities.

Just as a side note, 7 of our delegated agencies have received PH accreditation. I know it's not directly related to their evaluations, but it's something to be noted and celebrated.

Conformance with *Standards*

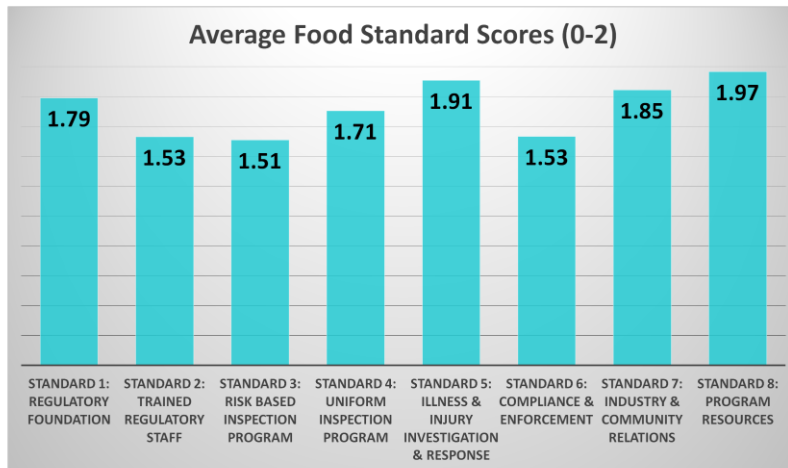
- **Statewide “scorecard” promotes consistency**
 - Improved morale in agencies that have a benchmark to meet
- **Basic policies and procedures in place, per the *Standards***
 - *Better understanding of the importance of documentation and internal reporting*

Having a statewide scorecard helps to promote consistency. Anecdotally, we’ve heard that morale has improved at some agencies, knowing that they have a benchmark to meet and something to measure themselves against.

All of the agencies that made it through the evaluation now have basic policies and procedures in place, and they are meeting the intent the Standards. Going through this process has really provided a lot of agencies with a better understanding of the importance of documentation

and internal quality controls.

Trends



From an MDH perspective, we're able to look at scores for the entire state and look at trends. Overall, the agencies scored really well in standards 5 and 8, but this shows we need to focus some energy in standards 2, 3 and 6. So we'll be taking this into account as we look at developing training and other resources in the months and years to come.

Benefits of “Value-Added”

- **These elements were indicators for overall higher scores / status**
 - Standardization
 - In/Out/NA/NO
 - Written policies

One interesting thing was that agencies who had the “value-added” items in place tended to score higher overall. Agencies that had things in place like having standardized staff, using the CFP inspection form, and having clearly-written policies and procedures for administering their program generally ended up with a higher status those that didn’t. We actually didn’t have any agencies that fell into the “Acceptable” category the first time around. They either fell into that B category of “Acceptable, needs improvement” or they overshot it and were

in the extra credit category of “Acceptable, exceeds minimum standards.”

Regulators' Breakfasts

- **Bi-monthly statewide “staff meetings”**
- **Videoconference**
- **Interpretations, updates, mini-trainings**
- **Promote consistency**
- **FoodSHIELD**

In an effort to be more intentional with sharing information with our delegated agencies on a regular basis, in 2012 we started the “regulators’ breakfast” meetings. These are bi-monthly videoconferences that all of our MDH district office staff and delegated agencies are invited to attend. We consider them as statewide staff meetings. We share code interpretations, news from the field, news from FDA, status updates on legislative issues, and just-in-time seasonal outbreak awareness when we’re ramping up to norovirus or crypto seasons.

We strongly encourage our agencies to participate and share things that are happening locally for them, in order to promote consistency from one part of the state to the next. We archive our agendas and meeting notes in a private workgroup on FoodShield, so any of our inspectors statewide can access them. We've even created our own version of the Food Code Reference System, where interpretations are stored, categorized and searchable according to keyword and food code citation.

Enrollment in the *Standards*

- **MDH & MDA enrolled in 2001**
- **Pre-2009: 6 delegated agencies**
- **2016: 17 delegated agencies**

I don't want to overlook what we see as a benefit to the national system. MDH and MDA have both been enrolled in the FDA Program standards since 2001. Pre-2009 – when we started the evaluation system there were only 6 delegated agencies that had enrolled. As of last week when I last checked, 17 of MN's 31 delegated agencies are enrolled. I know that there has been a push at the national level to get people enrolled, and modeling MN's system after the national program has been a good gateway for many of our locals to warm up to enrollment.

What's Next?

MDH

So that's where we've been, now I just want to take a few minutes to tell you where we're going...

New Evaluation Workgroup

- Chartered by EHCIB
- Delegated agencies, MDH and MDA
- Just getting started (2nd meeting September 7)
- Evaluate entire state to one (or more) standards at a time
- MDH evaluated in addition to delegated agencies

MDH

I mentioned before that there is a new workgroup that was chartered by the Environmental Health Continuous Improvement Board, with the goal of revising and revamping the evaluation process. The workgroup consists of members from delegated agencies, MDH, and MDA. The workgroup is just getting started, and will be having its second meeting next week.

The direction at this point is to create a system where the entire state including MDH is evaluated one (or possibly more) standards at a time,

compared to the previous version where one agency at a time would be evaluated to **all** standards.

FDA Standards

- **FDA Standards as the foundation – as written**
- **Adding MDH & MDA requirements**
- **Minimum standards = mandatory**
- **“Gold standards” = optional and celebrated!**
- **Developing measuring tools for each standard**

MDH

This time around, the intent is to once again use the FDA Standards as the foundation, but we'll use them as written. However, we'll be adding certain items from MN statute & rule and the delegation agreements in order to make sure that our bases are covered.

The workgroup will be diving in and piecing out which of the items from the standards are going to be “mandatory” and which will be what we've started to call “gold standards.” So while we'll be using the FDA standards as the foundation, we

won't necessarily require our agencies to meet all of the components of each of the standards. If they do – we'll celebrate that!

A very important piece of this process is going to be developing standard measuring tools to use within the state, for each of the items in the standards in order to make sure there is no confusion on the rubric for scoring. My eval team has recently had an opportunity to do a FDA verification audit for another agency, and found a lot of the scoring items to be rather open-ended. That's great on a national level, but we need to be consistent internally.

We had originally intended to move away from the partial credit scoring system, and change to a "meets" or "doesn't meet" system, but now that it looks like the FDA standards might be moving towards a partial credit system themselves, we'll take that into consideration.

Aligning evaluations

- **MDH & MDA alignment**
 - Redundancy for dual-delegated agencies
- **Benefit to agencies enrolled in the FDA Standards**
 - State evaluation as a verification audit

MDH

The reason for trying to stick as closely to the FDA Standards as possible is to reduce the evaluation burden for agencies that have delegation agreements with both MDH and MDA, as well as for those who are enrolled in the FDA Standards. Rather than have multiple systems, it makes sense to try to consolidate our efforts and minimize the workload to the agencies.

Our intent and our hope is that if an agency is enrolled in the FDA standards, that an evaluation by MDH (or MDA) could count as a verification audit

for the FDA, if all of the components are in place. In theory, this could increase enrollment in the standards, if an agency knew they could double-dip.

Getting Buy-In

- **Grass-roots effort**
- **Lots of opportunity for input**
- **“All in” approach**
- **Exchange of resources and ideas**
- **Marketing**
- **Fingers crossed!**

MDH

Our biggest challenge is going to be getting buy-in to the new process. There is a lot of bad blood circulating throughout the state, and we are actively trying to fix that.

The EHCIB has done a good job of reaching out to constituents across the state to get feedback and input into the process. The workgroup is composed of people who were nominated by the board members to represent metro, non-metro, city, county, MDH-delegated, and MDA-delegated agencies.

The idea is that if the entire state working on one standard at a time, it will create an “all-in” type of atmosphere, where everybody knows that everybody else will be working on the same set of policies and procedures at the same time, so if they’re getting stuck, they can reach out to their colleagues and peers and work on them together. A big piece of this will be the marketing of the process, and I’m personally hoping for a terminology change from the top-heavy and frankly kind of intimidating use of the word “evaluation” to something more along the lines of the FDA standards where we call it a “verification.” The burden of proof should be on the agencies to show us through their own self-assessments that they’re meeting the standards, and the state can just verify that – YES YOU ARE. So we’ve got our fingers crossed. Stay tuned.

Lessons Learned

MDH

So to wrap it up, I just want to summarize with a few nuggets of wisdom that we've learned along the way.

Standard measuring tools

- **Defined measurement tools**
 - Time
 - Turnover
 - Consistency

MDH

If you're going to use the Standards as a mandatory evaluation tool, you really need standard measuring tools. To minimize scrutiny about subjective scoring over time, between individuals, and from one agency to the next, there must be a way to clearly define how scores are tabulated. This is especially true if you are going to offer partial credit for something.

Plain Language Resources

- Protocol
- Best Practices
- Example policies

MDH

You need to have plain language resources. They need to be easily understandable by anybody who reads it, from evaluators to the governor's office. The existence of a resource center would have been incredibly helpful for some of the agencies who were struggling to write things like training plans and enforcement policies.

MDH started writing a best practices manual, and guidance is available for a couple of the standards, but that was one of the projects that unfortunately was put on the back burner when resources became

tight.

Sufficient resources

- **Agencies add positions**
 - Musical chairs
 - Filling positions, training new hires
- **Staff retention**

MDH

Which brings me to having sufficient resources. Please understand that mandatory evaluations come with mandatory consequences and they will likely have far-reaching impacts on your program.

Aside from the examples where MDH had to hire additional staff in order to absorb agencies that reverted to the state, I shared examples of success stories where agencies were just able to add staff. That's great – except for the last three years, there has been a giant game of musical chairs being

played throughout the state of Minnesota. When MDH took on St. Paul, we hired half a dozen new inspectors. Then some of our local agencies added positions, and they paid more! So inspectors would leave one agency to go to another one, which left more vacancies. In some cases inspectors who were working for local agencies have moved to MDH positions, leaving a gap in their previous agency, which means someone will come from somewhere else. The department of Agriculture just added dozens of new positions which have been filled from both MDH and locals, so now we're shuffling again. I can say that there have been more jobs posted in environmental health in the last 3 years than in my lifetime.

Plan and implement the entire process

- Appeals
- Continuous improvement
- Transparency
 - *The agreement must list criteria the delegating authority will use to determine if the designated agent's performance meets appropriate standards **and is sufficient to replace performance by the delegating authority.***

MDH

Our protocol had an “appeals process,” but it was fairly generic, and clearly was not satisfactory for some of our very vocal agencies.

Also, as I mentioned, we had issues implementing the continuous improvement portion of the evaluation cycle, since there was no mechanism for re-evaluation and getting an upgraded status.

Transparency became an issue, because the MDH was program was never evaluated. There was and continues to be a sense of mistrust and anxiety from the delegated agencies that MDH has something to

hide. The delegation statute clearly states that the performance measurement tool is there to determine if an agency's performance is sufficient to replace performance by the delegating authority. But without an assessment of the state's performance, how can the delegated agencies be measured against it? In a lot of cases, delegated agencies may actually be performing at a higher level than the state is.

Words have meaning

- **Delegation agreement status terms**
 - Nobody wants to be “conditionally acceptable”
 - “Acceptable” vs “Acceptable, Needs Improvement”
- **Confusing words**
 - Program, status, score, element, item, rating, conditional agreement
 - Essential vs. Required

MDH

Something that actually caused a lot of confusion was simple terminology.

The term “conditionally acceptable,” really struck a chord with people. Again, this was our “average” rating, but throwing the word “conditionally” in there really makes it sound intimidating.

Same thing with the terms “Acceptable” vs “Acceptable, Needs Improvement.” Which is it? Is it acceptable or does it need improvement? And that’s actually a higher rating than “conditionally acceptable” which means “average.” It was very

confusing.

So keep this in mind when developing terminology for things, especially if they're going to be stuck with it for awhile.

Just as a technical editing and accuracy footnote, the protocol itself contained a lot of confusing words that were used interchangeably. Program, status, score, rating, item, etc. There was confusion about what these terms actually meant when it came down to the scoring of things.

Who's Minding the Store?

- Analogous to AMC / PIC
- Delegated agency management background and expertise
- Internal QA programs
- Accountability

MDH

And finally, who's minding the store? This is a phrase that became the trademark of the evaluation team. We started to compare delegated agency oversight to active managerial control in a food establishment. The agencies that had intentional, dedicated, knowledgeable management overall had much better evaluations than those who didn't. Just like in a restaurant, if the person in charge doesn't really know what's going on in their establishment, they're probably not going to do very well on their inspections. We really saw that the agencies with

internal quality assurance programs, and who participated in workgroups and attended trainings sponsored by MDH overall had better evaluations. To put it simply, the agencies that showed up did better.

Thank you!

Kim Carlton
Environmental Health Supervisor
Partnership and Workforce Development Unit
kim.carlton@state.mn.us

 **Minnesota**
Department of Health
Food, Pools and Lodging Services

And with that, I will say thank you. Unless there are any questions?