

Michigan Department of Agriculture Guidance: Using a Risk Based Evaluation Schedule

Development of this Risk Based Evaluation Schedule was based on the determination that the same risk factor categories should apply to all food establishments in Michigan, whether inspected by MDA or LHDs. This process should create a greater consistency in **classifying facilities** across the state. The 2005 Food Code Model Schedule was used as a basis for development.

STEPS TO SET UP A RISK BASED EVALUATION SCHEDULE:

1. **Use the “MDA and LHD Optional Risk-Based Evaluation Schedule Memo” from November 13, 2008 to assign a category to each facility (X, Y, or Z).**
2. **Determine the evaluation schedule the agency will apply to each category. This schedule represents the minimum evaluation frequency allowed by law.**
3. **Adjust the evaluation schedule within each category, based on the active managerial control of the facility.**
4. **Assign the next evaluation due date using the new schedule.**
5. **Clearly document the evaluation frequency changes for each license**
6. **Vending**

STEP 1

7. **Use the “MDA and LHD Optional Risk-Based Evaluation Schedule Memo” from November 13, 2008 to assign a category to each facility (X, Y, or Z). (attached)**

Create a list of all licensed facilities, and the date of the last evaluation. You should be able to pull this up from your agency's computer program.

Assign a category to each facility (X, Y, or Z). When the categories have been assigned, look at the list and determine the number of facilities in each category.

STEP 2

Determine the evaluation schedule the agency will apply to each category. This schedule represents the minimum evaluation frequency allowed by law. Each agency should determine schedule that fits the needs of the agency, as long as the schedule meets the minimum frequency allowed by law.

The agency must determine the evaluation schedule that will be applied to each category. This schedule represents the minimum evaluation frequency allowed by law. An agency may choose to change evaluation frequencies at a later date based on staffing levels or other issues that may arise.

The minimum evaluation schedule allowed is:

X- Low Risk Establishments: every 18 months

Y- Medium Risk Establishments: every 12 months

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Z- High Risk Establishments: every 6 months

OPTIONS: A few of the options an agency might choose are listed below:

18/12/6

Some agencies may be in a staffing situation that will determine the use of a 6/12/18 month schedule. These categories have been set up so you will be spending more time in your high risk facilities; and less time evaluating low risk facilities where food safety issues are much less common.

12/12/6

Choosing a 12/12/6 month schedule would allow high risk facilities to be evaluated every 6 months; but the cook and serve; or the cook, serve, and holding with very little cooling and re-heating would be evaluated every 12 months allowing every facility to be evaluated annually at a minimum.

12/6/6

Your agency might want to choose a 12/6/6/ month schedule. Evaluating your "X facility" list will help you determine if this type of schedule would be helpful with staffing issues.

6/6/6

An agency may use the Risk-Based Evaluation Schedule to categorize facilities, and continue to maintain a 6 month evaluation schedule.

STEP 3

Adjust the evaluation schedule within each category, based on the active managerial control of the facility.

Only those facilities that are at the extremes (in control or out of control) should have their evaluation frequency adjusted. The majority of facilities will remain at the established evaluation frequency.

A review of the facility's history should be done using the last 3 evaluations, or the last 3 years of evaluations, whichever is less. Violations observed should be grouped into the **five foodborne illness risk factors** and **good retail practices**. This review should assist in determining if the facility has Active Managerial Control of the facility.

Evaluators should discuss the facility's history (active managerial control) with their supervisor, and recommend evaluation frequency changes. The decision to change frequency of evaluations should be a joint decision of the supervisor and evaluator.

EXAMPLE:

There are 2 McDonald restaurants in your agency. A McDonalds Restaurant would be classified as a "Y" facility. If your agency is using the 18/12/6 month schedule, each McDonalds should receive an evaluation every 12 months.

McDonalds #1 has a manager with EXCELLENT active managerial control. You look back at the last 3 evaluations, and not only do they have the risk factors under control, but they also manage the good retail practices well. A joint decision between the supervisor and the

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evaluator might be to adjust the facility from a 12 month frequency to an 18 month frequency. (From Y-12 to Y-18)

McDonald's #2 has a manager with POOR active managerial control. After review of the last 3 evaluations, it's clear that risk factors are not being controlled, and there are issues with their good retail practices. A joint decision between the supervisor and the evaluator might be to adjust the facility from a 12 month frequency to a 6 month frequency. (From Y-12 to Y-6)

EXAMPLE:

Your agency has determined that each school license will be evaluated twice annually. Schools are usually classified as "Y" facilities. These schools would then be classified as Y-6, placing them on a 6 month evaluation schedule.

NOTES:

Seasonal establishments are usually categorized as "Y" establishments. A seasonal establishment must still be noted on the facility license application. As historically defined, evaluation frequency for a seasonal establishment is determined as compliant if one (1) evaluation was made during each operating season in the review period.

When setting up non-seasonal establishments on a 12 month schedule, it is understood that the evaluation frequency is 12 months, with a 30 day grace period.

Any establishment may be evaluated more frequently than the established evaluation schedule.

STEP 4

Assign the next evaluation due date using the new schedule.

Using the licensed facility list from Step #1 (which contains the last evaluation date) you should now assign the next evaluation due date. Use the category designation from Step #2; and the adjusted evaluation schedule from Step #3.

This new due date should be incorporated into an evaluation tracking system.

NOTE: If using Sword Solutions, after changing the "evaluation frequency" (ex: from 180 to 360) you will need to tab to the "next evaluation date" and click on **re-calculate** to change that date.

STEP 5

Clearly document the evaluation frequency changes for each license

Develop a POLICY that clearly defines the process the agency used to begin use of a risk based evaluation schedule. The MDA documents that you are using to begin the process should be included in this policy. This will clearly define the process for categorizing each new facility license.

It is important to clearly document in the facility file why a change of evaluation frequency was made, and what the new evaluation frequency is.

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Document:

- What the original evaluation frequency was (i.e.: Y-12)
- Why a change in frequency was made. (Excellent or poor active managerial control.)
- When the change was made (date)
- What is the new frequency schedule (i.e.: Y-6)

During the accreditation process, the evaluation schedule for each licensee should be clearly documented. The method of documentation should be determined by the agency.

NOTE: When setting up the initial RBE schedule you will not be required to document WHY the change of frequency was made. It is still very important that a procedure is set up to show WHEN the frequency was changed, and what the new schedule is. Several LHDs have used a colored sheet of paper placed in the file with the date of the change, and the new frequency (Y-6).

SOME EXAMPLES:

- Computer generated lists
- Files are color coded: X facilities are in red folders; Y facilities are in white folders; and Z facilities are in blue folders.
- Colored dots are placed on the file to designate either a category or a frequency schedule
- A color sheet is placed in each folder with its category and frequency:

Joe's Pizza
Y-12 Seasonal
6/29/09
What was the original evaluation frequency? (i.e.: Y-12) _____
Why a change in frequency? (ie: active managerial control) _____
When the change was made (date) _____

NOTE: During an accreditation review, the assigned frequency must be clear.

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STEP 6

Vending

Minimum evaluation requirements for vending machine locations: Every vending machine location is inspected at least once over a five year period. One-fifth of each operator's vending locations are inspected each year. For companies that have less than five locations, each location must be inspected within the 5 year period.

For accreditation program auditing purposes, each health agency must maintain a vending machine location policy document stating their evaluation frequency.



STATE OF MICHIGAN
DEPARTMENT OF AGRICULTURE
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

DON KOIVISTO
DIRECTOR

DATE: November 13, 2008

TO: All Local Health Departments (LHD's)
Attn: Medical Director / Health Officer / Director of Environmental Health
Michigan Department of Agriculture (MDA)
Attn: Food and Dairy Division Managers

FROM: Becky Peterson, Supervisor
Food Service Program
Food and Dairy Division *Rebecca Peterson*

SUBJECT: Michigan Department of Agriculture (MDA) and Local Health Department (LHD)
Optional Risk-Based Evaluation Schedule

This memo replaces the June 2, 2003 memo: "Reduced Inspection Frequency- Low Risk Establishments; Vending Machine Locations", eliminating low risk establishment inspection schedules, vending machine location inspection schedules, and Emergency Risk Based Inspection Schedules (ERBIS).

Background

Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served, all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments. Annex 5 in the 2005 FDA Food Code, as well as the FDA National Voluntary Retail Standards, encourage regulatory jurisdictions to develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.

MDA has utilized a risk based evaluation schedule since 2000. The option to administratively develop and implement a LHD risk based evaluation schedule was included in the 2008 food law update. To develop the schedule, a joint LHD/MDA "Risk Based Evaluation Schedule Committee" was formed. For development of this schedule, it was determined that the same risk factor categories should apply to all food establishments in Michigan, whether inspected by MDA or LHDs. This process would create a greater consistency in evaluations across the state. The 2005 Food Code model schedule was used as a basis for development.

Schedule Organization and Use

The attached Risk Based Evaluation Schedule is OPTIONAL and consists of two distinct parts:

- **Risk categories (W,X,Y,Z).** Upon adoption in your jurisdiction, an establishment would be categorized by establishment type, and would remain in that category unless a change in the type of establishment was determined:
 - **W-** Exempt from licensure. This category is for establishments that are exempt from licensure but are inspected on a complaint basis. This type of establishment category has historically been used by MDA, but may be used by LHDs, based on need.
 - **X-** Low risk establishments
 - **Y-** Medium risk establishments
 - **Z-** High risk establishments
- **Evaluation schedule.** This schedule represents the minimum evaluation frequency allowed by law. **Each jurisdiction may choose to adjust to a more frequent schedule, but may not decrease the frequency as follows:**
 - **X-** Low Risk Establishments: every 18 months
 - **Y-** Medium Risk Establishments: every 12 months
 - **Z-** High Risk Establishments: every 6 months

Accreditation / Standards / ERBIS

This is an optional schedule. Minimum Program Requirements are met if the schedule is used. Documentation must be completed, as specified in the schedule to allow files to be easily audited during self-assessments and accreditation reviews.

The schedule also addresses the minimum program requirements for vending machine location evaluations. A jurisdiction may always choose a more frequent evaluation schedule. As long as your vending evaluation schedule is at or above the minimum listed, no change is needed.

If your jurisdiction has enrolled in the Voluntary National Retail Standards, Standard 3 requires regulatory jurisdictions to develop and use a process that will group food into at least three categories based on potential and inherent food safety risks, and that they assign evaluation frequency based on the risk categories. Adopting this schedule would meet these requirements. The schedule also complies with the FDA Manufactured Food Regulatory Program Standards that MDA recently enrolled in.

This schedule will also replace ERBIS. By adopting the schedule, your jurisdiction would be conducting evaluations on a risk based schedule that is similar to the ERBIS model. If you are currently on an ERBIS schedule, please give me a call, and we can discuss if you would prefer to transfer to the Risk Based Inspection Schedule, or finish your ERBIS schedule and proceed to the current 6 month evaluation schedule.

MDA is currently working to implement this schedule for those establishments it evaluates.

If there are any questions, please call me at 517-241-0140, or email to petersonr2@michigan.gov.

Distribution List:
MIFood Listserve
MDA Food and Dairy Section Staff

<p>W Not Licensed</p>	<p>This category is for MDA to document food establishments exempt from licensure, but inspected on a complaint basis. Temporary establishments with non-potentially hazardous food that is pre-packaged and sold in single service quantities.</p> <ul style="list-style-type: none"> • Produce stands with whole, uncut produce. Does not include wholesale produce operations. • Retail establishments with non-potentially hazardous food that is pre-packaged and incidental in amount. • Retail Honey and Maple Syrup outlets of the seller's own production, pre-packaged and processed in a licensed facility. <p>Examples: card shops, gift shops, video stores, gas stations with a few candy bars and chips.</p>	<p>No Routine Inspection</p>
<p>X Low Risk Establishment</p>	<ul style="list-style-type: none"> • Serve or sell only raw or pre-packaged, non-potentially hazardous foods (non time/temperature control for safety (TCS) foods). • Do not prepare potentially hazardous foods (TCS foods). • Heat only commercially processed potentially hazardous foods (TCS foods) for hot holding. • No cooling of potentially hazardous foods (TCS foods). • Preparation/processing and or packaging limited to non-potentially hazardous food only. • Warehousing/storage limited to non-potentially hazardous food and/or pre-packaged potentially hazardous foods. <p>Examples: Most convenience store operations, convenience stores serving precooked hot dogs or sausages, popcorn, nachos, pretzels or frozen pizza.; hot dog carts, and coffee shops; cocktail lounges; theaters; nut kiosks; honey and maple syrup processors; most bakery operations; candy, snack, pasta, spice or other nonpotentially hazardous manufacturer, bottled water manufacturer; food warehouses.</p>	<p>Normal Inspection Schedule: X-18</p> <p>Increased inspection schedule: X- 12</p> <p>Frequency may be increased with enforcement</p>
<p>Y Medium Risk Establishment</p>	<ul style="list-style-type: none"> • Limited menu. • Products are prepared, cooked and served immediately. • Conducts hot and cold holding of potentially hazardous foods (TCS foods) after preparation or cooking. • Preparation of potentially hazardous foods (TCS foods) requiring cooking, cooling, and reheating for hot holding is limited to only a few potentially hazardous foods (TCS foods). • Seasonal establishments (operate 9 months or less per year.) • Sale of raw unprocessed potentially hazardous food to the customer for further processing/preparation • Warehousing/storage of unpackaged potentially hazardous foods • Sorting/reclamation of food <p>Examples: fast food operations; cook and serve operations; retail food store operations; schools; buffets that change the entrees each meal period, do not save leftovers, and only prepare one or two items in advance of the day of service; grocery store with rotisserie chicken; packaged for sale sandwich manufacturer; soft serve machines.</p>	<p>Normal inspection Schedule: Y- 12</p> <p>Decreased schedule: Y-18</p> <p>Increased inspection schedule: Y- 6</p> <p>Frequency may be increased with enforcement</p>

<p style="text-align: center;">Z</p> <p>High Risk Establishment</p>	<ul style="list-style-type: none"> • A food establishment which, upon investigation, is implicated in a foodborne illness outbreak or chemical intoxication shall be evaluated at least every six months for not less than the next 12 months. • Extensive menu and handling of raw ingredients. • Complex preparation including cooking, cooling, and reheating for hot holding involves many potentially hazardous foods (TCS foods). • Establishments serving a highly susceptible population • Service of raw or partially cooked food for immediate consumption (requires a consumer advisory) • Establishments that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging. • Modified atmosphere packaging for extended shelf-life. • Canning of food under 21 CFR parts 113 or 114. • Complex manufacturing processes such as aseptic, acidification, dehydration, formulation control. • Establishment with mandatory HACCP systems. • Food salvage operations <p>Examples: A full service restaurant; some catering operations; establishments specializing in home-style cooking; hospitals; collecting surplus food from restaurants/facilities, distribute it to local programs on a regular basis; low acid and acidified processing; senior meal wholesale food preparation; smoked fish manufacturer; grocery store with significant cooling and/or reheating. Acidified Food eg. - Pickled vegetables, salsa, antipasto. Low Acid Food eg. - Peppers, some soups, asparagus, beans, some soups.</p>	<p>Normal inspection Schedule: Z- 6</p> <p>Decreased inspection schedule: Z- 12</p> <p>Increased inspection schedule: As specified through enforcement and/or agency specific schedule</p>
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ADJUSTING FREQUENCY OF EVALUATIONS:

- **These evaluation frequency schedules reflect minimum program requirements. A regulatory agency may set an inspection frequency, using the risk factor chart, at an increased evaluation frequency, but may NOT decrease the frequency to less than these requirements.**
- Within each risk factor category, **evaluation frequency can be adjusted based on the active managerial control of the facility.** This provides flexibility to increase an evaluation frequency when problems in a facility arise.
- Only those facilities that are at the extremes (in control or out of control) should have their evaluation frequency adjusted (the majority of facilities will remain at the normal evaluation frequency).
- A review of the facility's history should be done using the last 3 evaluations, or the last 3 years of evaluations, whichever is less. Violations observed should be grouped into the **five foodborne illness risk factors** and **good retail practices**. (The violations need not be the same one on each inspection, but will need to fit into the risk factors.)

FOODBORNE ILLNESS RISK FACTORS:

1. Food from approved sources
2. Adequate cooking
3. Proper holding temperatures
4. Employee health / Personal Hygiene
5. Contaminated food contact surfaces of equipment

GOOD RETAIL PRACTICES

- Evaluators should discuss the facility's history with their supervisor and recommend evaluation frequency changes. The decision to change frequency of evaluations should be a joint decision of the supervisor and evaluator.
- The decision to notify a facility of evaluation frequency changes is an agency specific policy decision.
- It is important to clearly document why a change of evaluation frequency was made, and what the new evaluation frequency is. Document:
 - what the original evaluation frequency was (i.e.: Y-12)
 - why a change in frequency was made
 - when the change was made (date)
 - what is the new frequency schedule (i.e.: Y-6)
- During the accreditation process, the evaluation schedule for each licensee should be clearly documented. The method of documentation shall be determined by the agency.

VENDING MACHINE LOCATION EVALUATION SCHEDULES:

Every vending machine location is inspected at least once over a five year period. One-fifth of each operator's vending locations are inspected each year. For companies that have less than five locations, each location must be inspected within the 5 year period.

For accreditation program auditing purposes, each health department must maintain a vending machine location policy document stating their evaluation frequency.