Annex 6

PMM Indicators survey: Data collection procedure for sentinels

Purpose: To ensure correct and consistent data collection by sentinels across locations, this procedure describes how to document the status of key post-market monitoring (PMM) indicators at regular monthly intervals to assess equipment performance after procurement and installation. The PMM indicators help to determine if refrigerator is working well enough or if follow-up by sentinels and/or EPI technicians is needed.

Use: For all refrigerators excluding obsolete refrigerators awaiting decommissioning.

Remote data collection: All questions can be answered by the sentinel via phone call to health facility. If sentinel is operating remotely the user in charge of the refrigerator at the facility should respond. Sentinel should verify answers as applicable if on site. Tools are not required.

Important notes

- The sequence of questions and order of Excel columns must be consistent with the order of questions as listed here.
- The same sample of refrigerators should continue to be monitored each month by inserting additional rows to the same Excel spreadsheet for each reporting period.
- All binary questions should only have a "0" for Yes, "1" for No, or should be left "blank" for questions that are skipped or do not apply (e.g., FT2 not installed, voltage stabilizer not installed, refrigerator not under warranty, etc.). Do not enter N/A, dashes, or any other data aside from these three response options.

Reporting Period

1. **Reporting period.** Enter the month and year of the reporting period using the format MONTH YEAR (i.e., MAY 2020).

Asset information

2. **Facility ID [string].** Enter facility name or ID.
3. **Make [string].** Enter the name of the manufacturer.
4. **Model [string].** Enter the model name.
5. **Refrigerator ID [string].** Enter serial number or asset ID.
6. **Is FT2 installed? [Y=0 / N=1].** Enter a "0" for refrigerators that have a FT2 installed and "1" for refrigerators that do not have FT2 installed. Refrigerators that do not have FT2 installed will require follow-up by a sentinel or EPI technician for FT2 installation. Continue to complete the rest of the questions except for the three temperature questions regarding the number of FT2 alarms for each reporting period until a FT2 is installed. A computer with a USB port is required to download FT2 data. If on site, determine if downloading the FT2 data is possible based on the resources available to the sentinel. If possible, download the data. If remote, determine if

downloading the FT2 data is possible based on the resources available to the user. If possible, have user download the data and send data to the sentinel.

Functional Status

The functional status for PMM is based solely on whether the equipment has maintained the acceptable temperature range based on the following questions.

7. **How many heat alarms with over 10 hour duration above 8°C show in the temperature log from the first day of the month to the last day of the month? [numeric].** View the downloaded FT2 data and count the number of heat alarms shown when the refrigerator was above 8°C for over 10 hours. If FT2 is not installed, skip this question and leave blank. Do not enter a dash, N/A, or any other data for this question. Only enter the number '0' if there were no alarms.

8. **How many freeze alarms with over 1 hour duration below -0.5°C show in the temperature log from the first day of the month to the last day of the month? [numeric].** View the downloaded FT2 data and count the number of freeze alarms shown when the refrigerator was below -0.5°C for over 1 hour. If FT2 is not installed, skip this question and leave blank. Do not enter a dash, N/A, or any other data for this question. Only enter the number '0' if there were no alarms.

9. **How many heat alarms with 48 hour or longer duration show in the temperature log from the first day of the month to the last day of the month? [numeric].** View the downloaded FT2 data and count the number of heat alarms shown when the refrigerator was above 8°C for 48 hours or longer. If FT2 is not installed, skip this question and leave blank. Do not enter a dash, N/A, or any other data for this question. Only enter the number '0' if there were no alarms.

10. **Is the refrigerator working properly? [Y=0 / N=1].** Enter a "0" for refrigerators that are working properly and "1" for refrigerators that do not meet the acceptable temperature range as defined by the three specific criteria below. For the purposes of PMM "working properly" is based <u>only</u> on whether the refrigerator is maintaining the acceptable temperature range during the reporting period and is calculated based on answers to previous questions. If the refrigerator does not have a FT2 installed or did not meet any of the temperature criteria listed below, the refrigerators should <u>not</u> be recorded as not working properly and <u>left blank</u>. Enter "1" for the refrigerator not working properly only if any of the following are true for the time period:
    a. Refrigerator had 5 or more heat alarms of over 10 hour duration
    b. Refrigerator had 1 or more freeze alarms of over 1 hour duration
    c. Refrigerator had 1 or more heat alarms of 48 hour duration or longer

11. **Why did the refrigerator fail? [string].** Failure in this case only means temperature excursions in excess of the criteria noted in question 10. Enter a few words to describe the different probable causes of temperature failure here. Ask the user if they are aware of the circumstances surrounding the alarm(s), such as a power outage or unusually cold ambient temperature. Ask the user if maintenance or repairs have been performed on the refrigerator or requested for any reason within the month. If so, ask the user about any suspected causes of failure that were discovered and the actions taken to address the failure or complete any repairs. If the answer is YES to the previous question, skip this question and leave blank. Do not enter a zero, dash, N/A, or any other data for this question.

Build quality

12. **Have there been any issues related to build quality from the first day of the month to the last day of the month? [Y=0 / N=1].** Ask the user if they have experienced any issues related to build quality or have had any trouble using the refrigerator within the month. If there are issues or parts that continue to have or cause problems that may have already been recorded previously or have been continually having issues starting in previous months, continue to enter each of these each month until or unless they are repaired or addressed.

13. **Observation? [list].** Select the answer that most closely matches the user's description of the issue. If on site, visually verify the user's description of the problem by examining the refrigerator. For example, if the user describes corrosion of vaccine shelves, look inside the refrigerator to confirm this issue. If none of the options match the user's observation, select "Other" and enter a short description of the issue.
    a. Broken
    b. Burnt
    c. Corrosion
    d. Deteriorating
    e. Leaking
    f. Missing
    g. Noisy
    h. Other

14. **Location [list].** Determine the location of the problem based on the user's observation. Ask the user to clarify the specific location of concern if necessary. For example, a problem with door/lid hinge misalignment would be considered as "Appliance (exterior)," while a problem with the gasket would be considered "Appliance (interior)." Solar mechanical problems include, for example, poor support structure assembly, mounting, or obvious physical damage to the panels themselves. Solar electrical problems may include damage to cables, connections, or grounding.
    a. Appliance (exterior)
    b. Appliance (interior)
    c. Accessory (EMS)
    d. Solar (mechanical)
    e. Solar (electrical)
    f. Not determined

15. **Component [string].** Determine which component of the refrigerator or solar system is associated with the problem described by the user. Ask user for clarification if needed.

16. **Picture [image].** If on site, take picture(s) of the problem. If remote, have user take picture(s) of the problem and share with sentinel.

Note: If there is more than one issue, record all of them including the separate observations, locations, components and pictures. Record up to 3 of the biggest build quality issues. If there are more than 3 separate build quality issues, additional issues will be noted during subsequent follow-up evaluation and/or troubleshooting failure analysis.

Voltage stabilizer/regulator

17. **Is the voltage stabilizer working? [Y=0 / N=1 / Blank= leave empty and skip for refrigerators for which a voltage stabilizer is not present, or cases where this question is not applicable (e.g., SDD)].**

    i. If the unit is not an AC refrigerator and this question does not apply, skip this question and leave blank. Do not enter a dash, N/A, or any other data for this question.

    ii. If the refrigerator is an AC unit and connected directly to the power source, or if a voltage stabilizer is present but not in use, for both these circumstances the voltage stabilizer should be considered "not present" (leave the question blank).

    iii. If on site, find the voltage stabilizer (or other power quality device). It should be connected between the refrigerator and the power source (e.g. mains outlet). If remote, ask user to find the voltage stabilizer or otherwise confirm that the refrigerator is directly connected to the power source.

    i. Once it is confirmed that a power quality device is in use, verify that the power quality device in use is, in fact, a PQS prequalified voltage stabilizer, rather than a spike arrester, uninterruptible power supply, or other type of power quality device. A voltage stabilizer is an electrical device designed to reduce fluctuations in input voltage and frequency and ensure a stable electrical supply for refrigerators and freezers in situations where the supply voltage is subject to wide fluctuation. Voltage stabilizers must be connected to the power source to work. In contrast, an uninterruptible power supply contains a battery in order to operate during interruptions to the power supply, and may display an indication of remaining battery life. Spike arresters are typically smaller devices that plug directly into the AC mains outlet and contain a receptacle for the refrigerator power plug. If remote, ask user to describe the device. Confirm that the device in use is a voltage stabilizer. PMM data will not be collected about any power quality devices in use that are not PQS prequalified voltage stabilizers.

    ii. Next, verify that the voltage stabilizer turns on when connected to the power source and when the stabilizer is switched on (if it has an on/off switch and is not always on). Check this through a power indicator such as an LED light or display of input/output voltage. There may be a dial indicator with a needle that points to a non-zero value when working. The voltage stabilizer may have a delay of a few minutes before turning on if it was not already in use. If the voltage stabilizer does not turn on some time after being plugged in, it is not working. Also be sure that the power outlet is switched on, if applicable. If remote, direct user through this step to confirm that voltage stabilizer turns on. If helpful or needed, more information on LED indications, displays, delays and other specifics to each device should be available in user instructions or manuals that may be found on-site or might be locatable online by searching the manufacturer and make and model.

    iii. If the voltage stabilizer turns on when connected to the power source, examine the input and output voltage reading displayed. If remote, ask user to read the output voltage display. Is the output voltage of the stabilizer within an acceptable range for the input voltage to the refrigerator? The refrigerator manufacturer label should include input voltage requirements for the refrigerator (typically 220-240V in many countries).

![World Health Organization logo]

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    iv.   If the refrigerator is an AC unit and connected to a voltage stabilizer that is not operating properly, it is considered "not working" (enter "1").

    v.   Ask the user if they have had any concerns with performance or usability of the voltage stabilizer within the month. If the user expresses any concerns that indicate the voltage stabilizer is not working as intended, enter "1."

18. **If no, why not? [string].**

    i.   If the refrigerator is connected directly to the power source, ask the user why the voltage stabilizer was taken out of use. Did the user believe it was broken, and if so, why? Or was the voltage stabilizer removed for another reason (for example, to be used with a different refrigerator or other equipment onsite)?

    ii.   If the voltage stabilizer did not turn on when connected to the power source, please note that observation here.

    iii.   If the voltage stabilizer was turned on but the output voltage was unacceptable, please note that observation here.

    iv.   If the voltage stabilizer is not working and there appears to be damage to the refrigerator power cable, voltage stabilizer power cable, and/or power outlet, please note that observation here.

    v.   If the voltage stabilizer is not working and the user expressed any concerns with performance or usability, please note the concerns here.

19. **Has the voltage regulator been replaced from the first day of the month to the last day of the month? [Y=0/N=1].** Note: Always ask user this question even if the voltage stabilizer is functioning.

20. **If yes, why? [string].** Ask user.

Warranty

21. **Has a warranty claim been made during this period? [Y=0 / N=1 / blank=refrigerator is not under warranty].** Ask user. If the refrigerator is not under warranty and this question does not apply, skip this question and leave blank. Do not enter a dash, N/A, or any other data for this question. Enter "1" for "No" or a "0" for "Yes".

22. **When was the warranty claim made? [date].** Ask user.

23. **Was the warranty claim resolved within the reporting period? [Y=0 /N=1].** Ask user.

24. **How many days elapsed between when the claim was made and when the repair occurred? [numeric].** Ask user.

Comments

1. **Comments [string].** Enter the status of local action(s) that have been taken to correct problematic fridges requiring follow-up (i.e., 'open/resolved' or 'under investigation/requires follow-up', etc.). Then describe updates to fridge data or actions taken since last reporting period here or indicate any other concerns about the refrigerator that requires follow-up.

If this evaluation revealed any of the following indicators, a follow-up evaluation should be completed. If refrigerator is not working properly [Question 8], potentially a troubleshooting failure analysis (TFA) should also be completed. If not, then PMM is complete.

Indicators for triggering follow-up evaluation by sentinels:

- Refrigerator is not working properly [Question 10]
- Build quality issues (that were **not** noted in previous visits after which follow-up was done) have been observed [Question 12]
- Voltage stabilizer is not working [Question 17]
- Warranty claim was made during the reporting period [Question 21]
- User or sentinel has other concern about the refrigerator that requires follow-up [Comments]

If follow-up is required, answer the follow-up questions during the same phone call or site visit for PMM indicators.