

12-Point Environmental Monitoring System Gap Analysis

Select one answer per row. Yes = you have records or a tested backup. No = a known gap. Unsure = you need to check. Fill in this PDF or print it.

REVIEW YOUR CURRENT PRACTICE		Yes	No	Unsure
01	Do dated records cover all required monitoring times, with missing readings explained? [1]	☐	☐	☐
02	Have you checked that each probe measures the storage area it should? [2]	☐	☐	☐
03	Are calibration checks up to date, with records of the reference used (such as NIST)? [2]	☐	☐	☐
04	Can you replace a probe while a checked backup keeps monitoring?	☐	☐	☐
05	Have you tested that alarm delays give staff enough time to act?	☐	☐	☐
06	Do staff know who must respond, including nights and weekends? [3]	☐	☐	☐
07	Have you tested a backup way to alert staff if the main method fails?	☐	☐	☐
08	Have you tested how monitoring will continue during a power cut?	☐	☐	☐
09	Have you tested what happens to readings and alerts if the network fails?	☐	☐	☐
10	Can you find past readings, alarms and actions for a chosen unit and date? [1]	☐	☐	☐
11	Can you show who can use the system and who changed electronic records? [4]	☐	☐	☐
12	Have you tested that the system works as intended, including after key changes? [2,4]	☐	☐	☐

ADD YOUR NO + UNSURE ANSWERS

Count both choices. Write the total in the box.

/ 12

3 or more? Take the next step:

[Assess Your Monitoring Risk →](#)

SOURCE REFERENCES - click a citation to open the regulation

[1] 21 CFR 606.160: records

[3] 606.100: written procedures

[2] 606.60: equipment / calibration

[4] 11.10: electronic record controls