Verification vs. Validation in a Food Safety Program

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Principle 6 – Establish verification procedures

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

(NACMCF, 1997)

9 CFR 417.4(a)

Every establishment shall validate the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis and shall verify that the plan is being effectively implemented.

Validation

Determining that the plan is scientifically and technically sound, that all hazards have been identified, and that if the HACCP plan is properly implemented these hazards will be effectively controlled.

Initial Validation

9 CFR 417.4(a)(1) Initial validation: Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in context of other validation activities.

FSIS Compliance Guide

- Initial validation of any HACCP system must include scientific or technical support related to the establishment's process supporting the design of the HACCP system along with some practical in-plant validation data reflecting an establishment's actual early experience in executing the HACCP system.
- Validation must demonstrate not only that the HACCP system is theoretically sound (design), but also that the establishment can implement it and make it work (execution).

Validation – two elements

1) Design —

   The scientific or technical support for the HACCP system design (design) - that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards; and

Validation – two elements

2) Execution –

The in-plant validation data (execution) - that is the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective.

Scientific or Technical Support (Design)

Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for the HACCP system that:

- Closely matches the actual process; and
- Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the hazard analysis; and
- Identifies the critical operational parameters from the scientific support relevant to the establishment's process

In-plant validation

- Implements critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support;
- Identifies at least one product from each HACCP category to gather in-plant validation data;
- Collects in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
- Analyzes the data to determine whether the critical operational parameters are being implemented effectively.

Verification

- One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan.
- An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process.

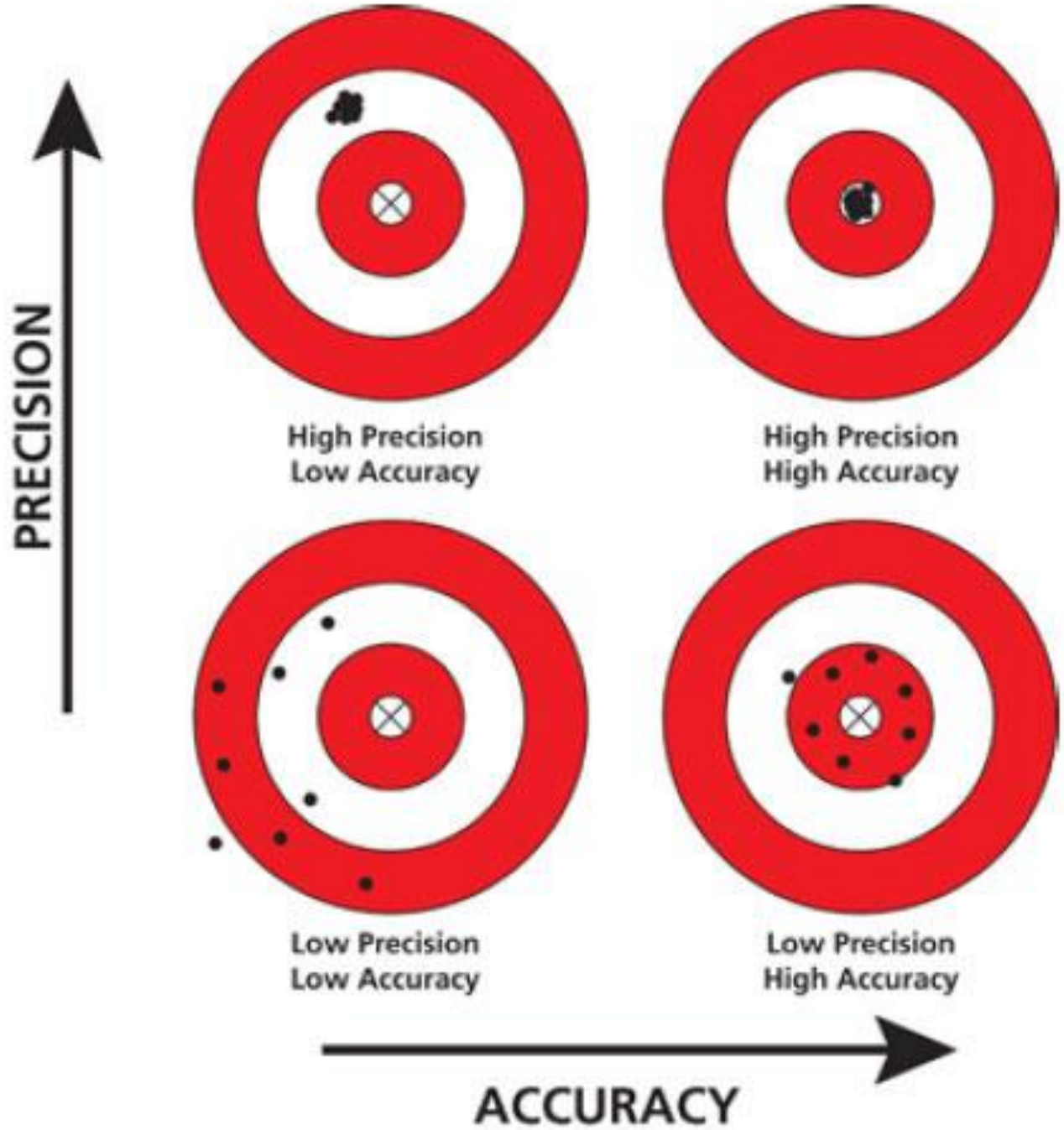
Ongoing verification activities

9 CFR 417.4(a)(2) Ongoing verification activities include but are not limited to:

(i) The calibration of process-monitoring instruments

(ii) Direct observations of monitoring and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.


PRECISION
High Precision
Low Accuracy
High Precision
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Low Precision
Low Accuracy
Low Precision
High Accuracy
ACCURACY

Questions?