

4.2.3. Review of Work Instructions and Manufacturing Records.

Standard

Are work instructions and manufacturing procedures regularly reviewed to ensure they remain effective?

A regular review period for all procedures should be set. Example every 3 years or upon changes to processes.

Purpose

To ensure a system is established to regularly review work instructions and manufacturing procedures, to maintain their accuracy and effectiveness.

Reason

Work instructions and manufacturing procedures provide the critical information to manufacture a product to specification. Over time, these documents must be periodically reviewed to ensure continued effectiveness.

Any changes in equipment, raw material sources, or the product's risk profile may impact the relevance of instructions and introduce feed safety risks, necessitating updates to mitigate potential hazards.

What is Acceptable?

A review period of 3 years shall be set as a minimum for all work instructions and procedures. Annual Management Reviews are an excellent tool for determining the effectiveness of procedures and processes. Alternatively, internal audits may also be used for this purpose.

Where there has been a change in a process, personnel, or raw material – work instructions and manufacturing records shall be reviewed prior to the 3-year period. Additional factors that may warrant a review include, but not limited to:

1. Equipment upgrade.
2. Additional processing.
3. New source raw material.
4. Changes to feed safety risk profile.
5. CCP review.
6. Customer specification.

To conduct an effective review, the operator shall ensure regular internal audits are conducted (10.4.1).

Regular internal audits detect discrepancies and record any trends that require review or corrective action. A cross-check of batching records and manufacturing instructions can be conducted at random to identify any discrepancies. Operators may also implement a feedback mechanism, where staff working with production records may suggest areas of improvement and review.

The combination of factors discussed above, promote an effective review by focusing on identifying discrepancies, ensuring regulatory compliance and promoting continuous improvement.

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