IKE Scenario 02-08 Direct Observation of Corrective Actions

IKE scenarios are a tool that FSIS inspection program personnel can use to better understand Agency policy. In addition, the IKE scenario result may be just one approach to address a specific situation and is not intended to be a definitive answer, indicating there may be multiple approaches.

Purpose: This IKE provides guidance to inspection program personnel on how to verify that establishments are properly conducting both corrective actions and direct observation verification of corrective actions when there is a deviation from a critical limit.

Situation: You are a consumer safety inspector (CSI) assigned to a livestock slaughter operation. Today's schedule includes the 03J01 procedure. You are aware that the establishment identified a deviation from its critical limit at the zero tolerance CCP yesterday, so you decide to verify that the corrective actions taken by the establishment meet the requirements of the regulation 9 CFR 417.3(a). In addition, you decide to verify the verification requirements of 9 CFR 417.4(a)(2) at all critical control points (CCPs). You can verify these two regulatory requirements as part of today's scheduled 03J01 procedures using either the recordkeeping or review and observation component.

You decide to perform the recordkeeping component of the 03J01 procedure to verify that both the verification and the corrective action requirements were met. You request the corrective action records for the previous day from the HACCP coordinator. You review the corrective action record and see that the establishment documented that it implemented corrective actions. Your review of those corrective action indicates that the actions taken met the requirements of 9 CFR 417.3(a). However, you do not see any record entry that the actions the establishment took yesterday were verified through direct observation. Before making a decision about compliance you decide to seek additional information from FSIS Directive 5000.1.

Discussion: You review the directive and find the following information:

- since it cannot be predicted when a deviation from a critical limit or an unforeseen hazard will occur, it would be counterproductive to require that the establishment have specific procedures and frequencies in its HACCP plan for directly observing corrective actions

- it is necessary for an establishment to directly observe corrective actions frequently enough to verify that these actions are being performed in a manner that meets the applicable regulatory requirements

- the establishment is to document these direct observations in the same manner that it documents other verifications

Based on the discussion points above, what additional questions could you seek answers to that would help you determine if non-compliance with 9 CFR 417.4(a)(2)(ii) exists?

- Does the establishment have a history of deviations from its critical limits?
- When a deviation occurs does the establishment implement corrective actions as required by 9 CFR 417.3(a)?
- When was the last time any part of the corrective actions were verified through direct observation?

You review the establishment's records for corrective actions, focusing on the frequency that the establishment conducts the direct observation of corrective actions verification. You see that once per month the establishment directly observes the performance of all four parts of corrective actions listed in 9 CFR 417.3(a) being implemented. Those corrective action requirements are:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Results of this verification activity are documented as required by 9 CFR 417.3(c) and 417.5(a)(3).

You meet with the HACCP Coordinator and ask what support the establishment has for the frequency selected to directly observe corrective actions. The HACCP Coordinator tells you that they have historical documentation collected since the implementation of HACCP in its operation that supports its frequency of once per month. He tells you that initially the frequency was twice weekly but as a result of their periodic analysis of their records, over time, the frequency was increased to once per month. The establishment's HACCP team has determined that, based on the cumulative records, the current frequency shows that the requirements of corrective actions have consistently been implemented properly and successfully. You ask to review the documents and confirm that they sufficiently support the frequency at which the establishment conducts direct observation of the corrective actions.

Resolution: You determine that there is regulatory compliance with both 9 CFR 417.3(a) and 417.(4)(a)(2)(ii). You record the 03J01 procedure as performed.

IKE Scenario 02-08 Direct Observation of Corrective Actions

Access the IKE Scenario home page and review previously posted IKEs from:
http://www.fsis.usda.gov/FSIS_Employees/IKE_Scenarios/index.asp

This information should also be shared with plant management