

## **IKE Scenario 04-07: Experimentation with On-line Poultry Reprocessing In Accordance with 9 CFR 381.3(b)**

**Purpose:** This IKE is designed to help inspection program personnel understand verification activities and control actions when performing inspection of on-line reprocessing (OLR) systems in poultry slaughter establishments.

**Scenario:** You are an off-line inspector assigned to a poultry slaughter establishment with an experimental OLR system. Today's daily task list includes 04C04 and you decide to verify that the experimental on-line reprocessing system meets the regulatory requirements.

**Discussion:** You are aware that OLR systems do not comply with the requirements of 9 CFR 381.91(b)(1). You are also aware that, in specific cases, 9 CFR 381.3(b), authorizes the Administrator to waive regulatory requirements to permit experimentation, so that new procedures, equipment, and processing techniques can be tested to facilitate definite improvements. You are aware that FSIS permits OLR experimentation in accordance with 9 CFR 381.3(b) only after the official establishment submits an experimental protocol and obtains a "No Objection" letter from FSIS.

A "No Objection" letter sets out the conditions under which the official establishment can use the technology. The "No Objection" letter might set out one or more of the following conditions.

- Submission of experimental data at specified frequencies
- Written notification of additional equipment installations
- Written notification of equipment modifications
- Notification of related regulatory compliance requirements
- Requirements to conduct employee information and orientation sessions

Depending on the experimental protocol, the "No Objection" letter may identify additional conditions.

**Determination:** First, you request access to the official establishment's experimental protocol and FSIS "No Objection" letter for the experimental OLR system. You review the documents to familiarize yourself with the experimental protocol and identify the specific conditions set out in the "No Objection" letter. Next, you proceed to the slaughter department and verify the establishment's operation of the experimental OLR system against the experimental protocol and conditions set out in the "No Objection" letter. You observe that the official establishment implements the experimental protocol, but fails to meet one of the specific conditions set out in the "No Objection" letter.

You inform the official establishment of your findings. You take an appropriate regulatory control action in accordance with 9 CFR 500.1(a) and attach a US Reject Tag to the OLR system equipment. You document your findings/actions on a Noncompliance Record. You enter 9 CFR 381.91(b)(1) in Block 6 and 04C04 in Block 8. You mark the checkboxes for "PRODUCT" and "Economic" in Block 9C. In the narrative, you describe the specific conditions set out in the "No Objection" letter with which that the establishment failed to comply. Once the official establishment complies with the conditions set out in the "No Objection" letter, and after you verify compliance against the conditions set out in the "No Objection" letter, you remove the US Reject Tag.