

IKE Scenario 1-08: FSIS Verification of 9 CFR 416.2(d) Regarding Frozen Condensate in Product Freezers (Part II)

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.

Purpose: This IKE is the second in a series to highlight the questions that inspection program personnel should ask when verifying compliance with 9 CFR 416.2(d), Ventilation. The instructions in [FSIS Directives 5000.1, Rev. 2, Amend.1](#), Verifying an Establishment's Food Safety System, provide the basis for this scenario.

Situation: You are a recently promoted Consumer Safety Inspector (CSI) assigned to a processing facility that produces a variety of fully cooked meat and poultry products. The establishment has elected to utilize separate freezers to store raw meat and poultry ingredients and finished products.

Today's PBIS schedule states that you are to perform Sanitation Performance Standard (SPS) procedure 06D01. You have randomly selected the regulatory requirements of 9 CFR 416.2(d), Ventilation, to verify throughout the facility. Because this is your first time in the facility, and because you know that it is important to learn the operation, you ask the plant manager if he would like to join you as you conduct your tour of the operation. He agrees and you proceed to walk through multiple areas of the facility. You explain to the plant manager that as part of your tour, you will be observing whether the ventilation is adequate to control odors, vapors, and condensation to the extent necessary to prevent the adulteration of product and the creation of insanitary conditions. You evaluate the establishment's control of odors, vapors and condensation in each of the product processing areas throughout the facility. You determine that the measures that the establishment has in place today in the processing areas are adequate to meet the regulatory requirement of 9 CFR 416.2(d). However, because you are aware that the control of ventilation is also necessary to prevent the creation of insanitary conditions that may affect products held in product storage areas, you also elect to observe the finished product storage freezer.

Upon entering the finished product freezer, you observe an accumulation of ice on the overhead doorframe of the freezer entrance. Further investigation reveals that there is an accumulation of ice on an overhead freezer unit and support structures as well as on closed boxes of product stored below the freezer unit. At this point, you determine that you will need to gather additional information by asking question such as, but not limited to:

- What conditions do you see in the freezer that could lead to the formation of ice over the door and on the overhead freezer unit?
- Is product affected (i.e. contaminated or adulterated) by the ice?
- Is there evidence that the establishment has initiated actions to address the observed conditions?

You observe the conditions over the entrance door and see that there is a damaged seal along the top of the door that is allowing warm air to continually enter the freezer. You then further investigate the boxes stored below the freezer unit and note that they, although covered with ice,

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are intact. You request that the plant manager open several boxes so you can observe the conditions of the package product inside. In doing so, you see that the ice has not contacted the fully packaged product inside the boxes. The plant manager then ensures that the boxes are free from ice and adequately resealed. You then survey the overhead freezer unit and observe a build-up of ice on the drip pan as well as on the support structures of the freezer unit.

Based on what you have seen, you determine that the fully packaged product is not adulterated. However, you must now determine whether the presence of the ice has created an insanitary condition, and whether or not the ice is an indication of inadequate ventilation or an indication of inadequate facilities maintenance. You continue to ask questions, such as the following, in order to determine whether an insanitary condition, and therefore a non-compliance, exists:

- Is this amount of ice expected to be present above the freezer door and on the freezer unit?
- Is this amount of ice expected to be contacting boxed product?
- Is there evidence that the establishment has not been pro-active in maintaining the facility (i.e. is there evidence that the ice has been there for a long time)?

Discussion: As you think about the conditions you have observed, you are aware that opening and closing the door throughout the production day can allow warm air from outside the freezer to contact the cold doorframe. In addition, you understand that improperly maintained door seals can allow additional warm air to enter the freezer when the door is closed, further allowing the creation of ice on the overhead doorframe. You suspect that the drip pan drain line is plugged and that during the defrost cycle, water flows out of the drip pan onto the support structure and the boxes below and then refreezes when the freezer unit re-starts. You consider whether the apparent lack of repair of the drip pan has led to the build-up ice on the freezer unit's support structure and on the boxes of stored product.

You discuss your observations with the plant manager and, although you have drawn some conclusions about what you have observed, you understand that management will have to determine the cause of these observed conditions. He informs you that the only full time maintenance person quit two months ago, and that it has been hard to get basic repairs done. He is aware that the drip pan is plugged, but he just hasn't been able to get it repaired. He thought the ice on the boxes was not an issue because the boxes were closed. He indicates that he was not aware that the door seals were damaged.

Resolution: Based on your observations throughout each of the product processing areas, you conclude that the establishment has controlled odors, vapors, and condensation in accordance with the regulatory requirement of 9 CFR 416.2(d) in those areas. However, based on your observations of the product storage freezer, you determine that the accumulation of ice on the door frame, drip pan, product boxes, and freezer unit support structures has created an insanitary condition. Even though you observed the non-compliance while performing the 06D01 procedures and while verifying the ventilation requirements of 9 CFR 416.2(d), the non-compliance is directly associated with the establishment's lack of maintenance of the facility and should be documented accordingly. You carefully describe the insanitary conditions and

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document the non-compliance on a Non-compliance Record (NR) as 06D01/Facility/Structural citing 9 CFR 416.2(b) as the appropriate regulation.

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.