Structure of Observations

IMPORTANT: Before documenting preventive controls observations, please ensure: 1) the facility is subject to subparts C and G (e.g. is not a qualified facility, Seafood HACCP/Juice HACCP processor, etc.); 2) you have conducted your own hazard analysis

_			qualified facility, seafood HACCP/Juice HACCP processor, etc.J; 2) you have conducted your own hazard analysis
1)	Does the facility have a written Food Safety Plan? For each hazard requiring a PC, see Boxes 2-5:	No	Use cite 117.126(a)(1) <u>Supporting evidence</u> : • Product description • Lack of conducting a hazard analysis that identifies hazards requiring a preventive control (PC) (include why you think hazards require a PC) • Lack of any written PC procedures, including monitoring, corrective actions and corrections, and verification, and a recall plan • Lack of records documenting activities performed (or because no activities are performed) • Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern • If facility has adequate controls in place, but does not have a written FSP, it might be a discussion item* [no public health concern]. • No double-dipping! Do not also cite "no hazard analysis", "no adequate written PC programs", "no implemented controls", etc. as standalone cites.
2)	Did the facility identify the hazard as requiring a preventive control in its hazard analysis?	No	 Use cite 117.130(a)(1) <u>Supporting evidence</u>: Product description Lack of conducting a hazard analysis, or did not identify a hazard that requires a PC (include why you think hazard requires a PC) Lack of any/adequate written preventive control procedures, including monitoring, corrective actions and corrections, and verification Lack of records documenting activities performed (or because no activities are performed)
	Yes		 Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern If facility has adequate controls in place but misses identifying a hazard requiring a preventive control, this might be a discussion item* [no public health concern]. No double-dipping! Do not also cite "no adequate written PC programs", "no implemented controls", etc. as standalone cites.
3)	Does the facility have a written PC program for the hazard it identified as requiring a PC?	No	Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain <u>Supporting evidence</u> : Product description Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), but there is no written PC program for that hazard Lack of records documenting activities performed (or because no activities are performed) Supporting the hazard and there is a public health concern.
	Yes	-	 Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern If the facility has adequate controls in place, but does not have written PC procedures, this might be a discussion item* [no public health concern]. No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.
4)	Is the written PC adequate? [controls the hazard and meets regulatory requirements]	No	 Use cite 117.135(c) specific to the PC program [Process (c)(1), Allergen (c)(2), Sanitation (c)(3), Other (c)(6)] or 117.410(c) for Supply-chain <u>Supporting evidence</u>: Product description Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), there are written procedures, but the procedures are not adequate because: they do not meet regulatory requirements (e.g. monitoring, corrective actions and corrections, and verification); procedures
	Yes	I	 were not adequate (e.g. monitoring not done at adequate frequency to ensure hazard is being controlled), or the control procedures do not control the hazard (e.g. only using a detergent to sanitize food contact surfaces) Records showing that facility is implementing its inadequate procedures and/or lack of records documenting activities performed (or because no activities are performed) Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern If the facility is controlling the hazard despite having inadequate written PC procedures, this might be a discussion item* [no public health concern]. No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.
5)	Is the PC being implemented?	No	Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain <u>Supporting evidence</u> : • Product description • Hazard correctly identified as requiring a PC by the facility at specific step(c) (and why) written procedures are adequate, but precedures are not
Г	Yes	1	 Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), written procedures are adequate, but procedures are not being implemented Evidence the written procedures are not being implemented based on record review and observation/interview of employees E.g. Your procedures say [describe procedures]; however, [describe what you see employees do or records show what employees actually did])
	NOTES: * Repeat findings that were discussion items in initial inspections may become written observations in subsequent inspections ** If there is no evidence to support a written observation, the observation should not be written!		