

01 and 02 HACCP Procedures

The 01 and 02 HACCP procedures are performed by inspection personnel to verify ongoing compliance with the regulatory requirements of 9 CFR Part 417 as the establishment executes its HACCP plan for the raw processing categories. The number of HACCP plans and the number of products produced within a processing category has no impact on the number of HACCP procedures that are scheduled for that process. The HACCP 01 and 02 procedures can be performed as scheduled or unscheduled procedures. Each of these procedures has two components:

- **Recordkeeping component**
- **Review and observation component**

In most instances, you will use one of these components. There may be occasions when you use both. For example, you may choose to perform recordkeeping at one CCP and review and observation at another CCP. Or, you may observe something during recordkeeping that may prompt you to perform a review and observation of that CCP.

How to Perform the Two Components

Recordkeeping

To perform the **recordkeeping** (Rk) component you will review HACCP records to determine if the establishment recorded its tests or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. When you perform the recordkeeping component you are only reviewing records. Typically this review would take place where the records are maintained and may not be at the physical location of the CCP.

***Example:** You are performing an 01 procedure and are verifying a monitoring procedure. You decide to perform the recordkeeping component. You examine the records associated with this monitoring procedure. You look at the frequency of the entries and the data recorded, and compare the recorded data to the critical limit at this step.*

Review and Observation

To perform the **review and observation** (R&O) component you may directly observe plant employees performing the procedures as stated in the HACCP plan (observation) or you may take measurements to see if the values you obtained match those recorded by the establishment (review).

***Example:** You are performing an 01 procedure and are verifying a monitoring requirement, which in this case is a product temperature check. You decide to perform both parts of the review and observation component. You directly observe the plant employee carry out the product temperature check. Then, you take a product temperature measurement, and compare the result that you obtained to the one just recorded by the plant employee.*

01 Procedure

The 01 procedure is for verifying one or more of the HACCP regulatory requirements as the establishment executes its HACCP plan for raw processes. The 01 procedure is designed to provide a “snapshot” of the HACCP system.

There are three requirements that are **randomly** verified during the 01 procedure: monitoring, verification, and recordkeeping. Corrective Actions and reassessment are not randomly verified as part of the 01 procedure since they are performed as a result of some event that triggers them. For example, you would verify the corrective action requirements are met anytime there is a deviation from a critical limit, a deviation not covered by a specific corrective action, or an unforeseen hazard. Similarly, you would verify the reassessment requirement if the establishment significantly changes its process, or encounters an unforeseen hazard.

You must have a method to randomly select one (or more) of the three requirements to be verified during the performance of the procedure. For example, you may choose to draw pieces numbered one through three from a container. You can use your FSIS, FAIM computer to select random numbers. See appendix 1 for instructions.

To perform the 01 procedure, you will do the following:

1. **Randomly** select one (or more) of the three HACCP requirements to verify.
2. Select one (or more) of the CCPs from the HACCP plan to verify .
3. Determine which component (review and observation or recordkeeping) to perform.
4. Perform the verification for **that requirement** for **that CCP**.

01 Example: *You're PS for today lists 03C01. The establishment to which you are assigned has one HACCP plan in this processing category, for marinated chicken. This HACCP plan has 3 CCPs. You have 3 cardboard chips labeled monitoring, verification, and recordkeeping, in a coffee can in your office. You decide to pick 2 regulatory requirements to verify.*

You shake up the can and choose 2 chips, which turn out to be monitoring and recordkeeping. You make a note of this. You decide to verify these requirements at CCP 1 of the HACCP plan. Next you think about which component to perform, and decide to perform the recordkeeping component.

You proceed to the HACCP lab to begin to perform the recordkeeping component to verify the monitoring and recordkeeping regulatory requirements at CCP 1 of the marinated chicken process.

Note: If you determine noncompliance while performing the 01 procedure, you must then perform the 02 procedure.

02 Procedure

The 02 procedure is for verifying **all regulatory requirements** at all of the critical control points in the HACCP plan for a **specific production**. The 02 procedure cannot be completed until the establishment performs the pre-shipment review for that specific production. Because 02 looks at a specific production, you are additionally determining whether the establishment prevented the distribution of adulterated product.

Note: You should follow-up on any 01 procedure that results in a noncompliance determination by performing an 02 procedure on that specific production.

Specific production is a term that is used to refer to whatever method the establishment uses to group product. FSIS does not determine the method used to define specific production; this is an establishment's responsibility. You will see a variety of different types of methods used. For example, a poultry slaughter plant might define all the birds from one house as specific production; another might define it by all carcasses produced in one hour on one line. Establishment's might define all product from one formulation batch, one shift's production, or the product in one chiller as a specific production. It is important for you to understand the method used by the establishment to which you are assigned. You can determine this by asking plant management.

There may be times when you are not able to finish reviewing the entire process on the day that the 02 procedure is begun. In this case you should mark the Procedure Schedule as "not performed" on the day that you start your review. When you have completed the review, you need to record on the Procedure Schedule that you completed the 02. If that particular 02 procedure is already scheduled on that day, then mark it according to your determination of compliance/noncompliance. If that particular 02 is not assigned on the day your review is completed, then document the 02 as unscheduled on the Procedure Schedule.

To perform the 02 procedure, you will do the following:

1. Verify that **all** of the HACCP requirements have been met for **all CCPs** in the HACCP plan for that **specific production**.
2. Verify that the **pre-shipment review** requirement for that specific production has been met.

02 Example: *You're PS for today lists 03B02. This establishment has one HACCP plan in this processing category, ground beef patties. You know from previous experience that this establishment defines specific production as each day's production, and that they generally perform pre-shipment review each morning on the previous day's production.*

They are not producing patties today, but they did produce them yesterday. You proceed to the HACCP office to begin your verification that all of the HACCP requirements were met for all of the CCPs in the HACCP plan for yesterday's production, including the pre-shipment review. You plan to use the recordkeeping component.

The following table summarizes the concepts we have just covered regarding the 01 and 02 HACCP procedures.

HACCP Procedures – Components Used and Requirements Verified

COMPONENTS USED BY THE CSI		HACCP REGULATORY REQUIREMENTS VERIFIED
01	<ul style="list-style-type: none"> • Recordkeeping and/or • Review & Observation 	One or more of the three regulatory requirements—randomly selected at one or more CCPs . Corrective Action and Reassessment can be verified using 01 but not randomly.
02	<ul style="list-style-type: none"> • Recordkeeping and/or • Review & Observation 	All of the regulatory requirements for all CCPs , including the pre-shipment review for a specific production