

REGULATORY PROCESS OVERVIEW

Objective

After completion of this module, the participant will be familiar with the four components that are part of the regulatory process.

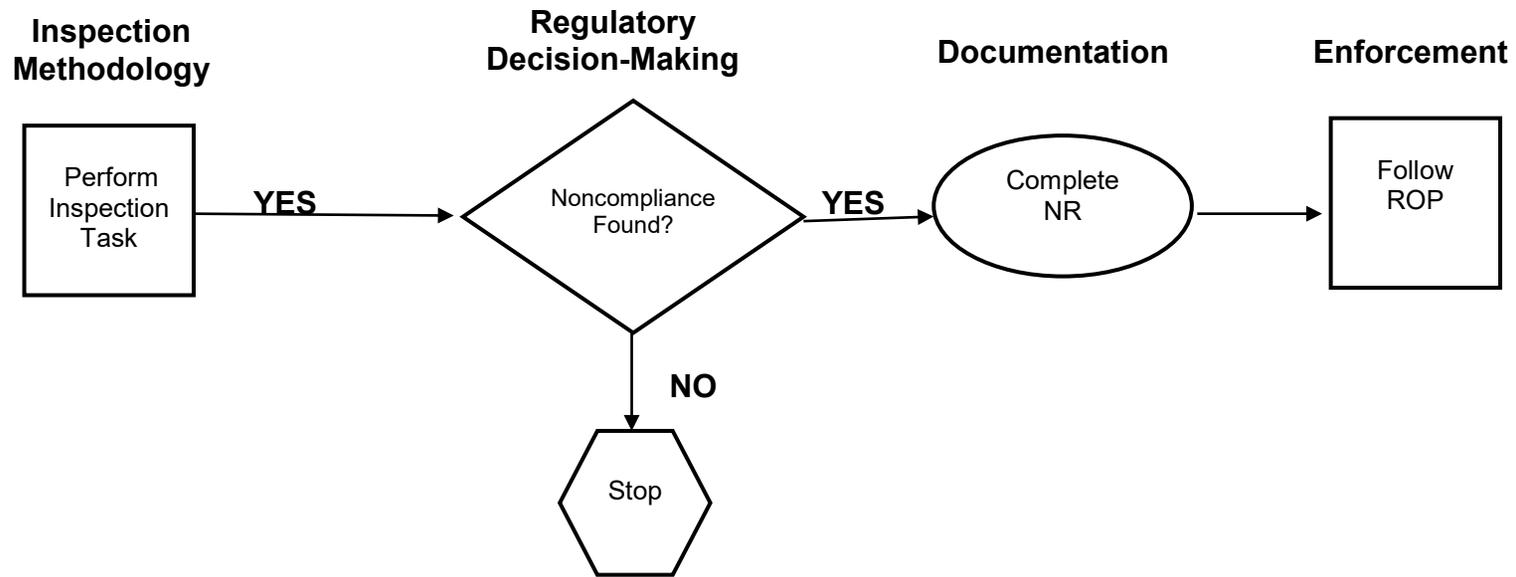
Overview of the Regulatory Process

An establishment's food safety system consists of the HACCP plans, a Sanitation SOP and other programs, like sanitary dressing procedures. These programs ensure that the product the establishment produces is wholesome and not adulterated. Inspection Program Personnel (IPP) allow products to be labeled with the marks of inspection when they are able to find that the products are not adulterated.

The diagram on the next page shows the **Regulatory Process**. This diagram is used to illustrate the HACCP-based inspection process used by FSIS inspectors. It includes the following four components:

- **Inspection Methodology**
 - Performing inspection tasks
 - Verifying specific regulatory requirements
- **Decision-making**
 - Gathering information, making observations, reviewing documentation, assessing the gathered information and arriving at a supportable compliance or noncompliance determination.
- **Documentation**
 - Entering the results of inspection tasks in PHIS
 - Documenting noncompliance on a Noncompliance Record
- **Enforcement**
 - Following the Rules of Practice (ROP)
 - Providing the establishment with due process

HACCP Regulatory Process



Regulatory Process Workshop

Read each of the following statements and identify which part of the Regulatory Process best applies.

- A – Inspection methodology
- B – Regulatory decision-making
- C – Documentation
- D – Enforcement

	1. An inspector is writing up a non-compliance observed during pre-operational sanitation inspection.
	2. A CSI is reviewing establishment records from HACCP monitoring.
	3. A PHV is looking at conditions of several carcasses and is making an evaluation of whether the establishment's sanitary dressing procedures are effective.
	4. An inspector is notifying the establishment management that a piece of equipment was rejected for use during pre-operational sanitation inspection due to product residue on food contact surfaces.
	5. A CSI found several piles of debris in the break room and is thinking about whether this finding is a non-compliance with sanitation regulations.
	6. An inspector is randomly selecting chicken carcasses from the line in order to perform a zero tolerance check.
	7. A PHV has determined that all regulatory requirements were met during a HACCP verification task.
	8. During operations, a CSI is observing employee hygiene and general sanitation conditions in the beef fabrication department.