

EUB Persistent Noncompliance Framework (in accordance with *Directive 019: EUB Compliance Assurance—Enforcement*)

Introduction

- Each EUB group will use the following framework to determine whether a licensee is persistently noncompliant.
- Each group will track surveillance activities by compliance category. Items to be captured will include the total number of inspections/audits/investigations conducted and their results.
- If after management review, a licensee defined as persistent is not subject to persistent consequences, the decision and rationale must be recorded and maintained on file by the EUB group.

Definitions

- **Persistent noncompliance**—an unacceptable rate, ratio, percentage or number of noncompliances by a licensee, either in the same or in different compliance categories.
- **Licensee noncompliance rate**— the total number of noncompliances divided by the total number of conducted EUB inspections/audits/investigations on that licensee within a compliance category.
- **Licensee status**—for the purposes of determining High Risk persistence, “low” means the number of noncompliances or a threshold at which the EUB may intervene, “monitor” means the level at which the EUB will intervene, and “persistent” is the level at which the EUB will intervene and take High Risk Enforcement Action 2.
- **Noncompliance threshold**—for the purpose of High Risk persistence Option 2, the percentage of noncompliances found during an inspection/audit/investigation above which a licensee will be determined to be at low, monitor, or persistent status.
- **Industry average rate**—the total number of industry noncompliances divided by the total number of conducted EUB inspections/audits/investigations on industry within a compliance category.

Low Risk

- Within each compliance category, surveillance activity results must provide the ability to compare individual licensee noncompliance rates with industry average rates to assist in the determination of Low Risk persistent noncompliance.
- At the conclusion of each calendar year, or at a predetermined period as determined by the EUB group, the EUB group will generate a report that identifies licensees whose noncompliance rate exceeds the industry average rate.
- The five to ten licensees with the greatest exceedance of the industry average rate are defined as persistently noncompliant for Low Risk and are subject to the requirements of *Directive 019*, Section 4.1: Low Risk Review. The number of licensees identified is determined by the EUB group.

High Risk

By December 1 of each year, EUB groups will publish on the EUB Web site the [Persistent Noncompliance Criteria by Compliance Category](#). This will include the licensee status criteria for Persistence, Monitor, and Low.

Option 1: Number of Noncompliances

- Review period will be a 90-day rolling window (ongoing) or a period predetermined by the EUB group.

- For the review period, each EUB group will generate a report outlining the number of High Risk noncompliances in each compliance category experienced by each licensee. The number of noncompliances during the review period will determine the EUB response in relation to the Number of Noncompliances column below.
- Upon being designated as persistent, a licensee must operate in compliance for 60 days or a predetermined period of time from the date of the EUB accepting the High Risk Enforcement Action 2 action plan (see *Directive 019*) to return to a satisfactory compliance rating. If a licensee fails to operate in compliance during this time frame, High Risk Action 2 (Persistence Noncompliance) will be repeated and a licensee may be subject to additional enforcement consequences, as outlined in *Directive 019*. However, if conditions warrant, the EUB may escalate a licensee to High Risk Action 3.

The example below is for representative purposes only; exact noncompliance numbers are to be determined for each compliance category by the respective EUB group.

		Determined by EUB Group		
Licensee Status	EUB Action	Number of Noncompliances	Review Period	Operate in Compliance
Persistent	High Risk Noncompliance Action 2 and must intervene and educate	≥3	90-day or predetermined rolling window	60 days or predetermined period
Monitor	Must intervene and educate	2		
Low	May intervene and educate	1		

Option 2: Noncompliance Threshold

- Review period is annual or a predetermined review point, as determined by the EUB group, of a licensee’s activities within a compliance category.
- Licensees whose inspection/audit/investigation results indicate noncompliance equal to or greater than the Noncompliance Threshold are defined as persistent and may be subject to enforcement consequences, as outlined in *Directive 019*.
- Licensees that fail to improve their performance (i.e., their noncompliance rate is equal to or greater than the Noncompliance Threshold) after a subsequent review period will be subject to repeat High Risk Action 2 and may be subject to additional enforcement consequences, as outlined in *Directive 019*. However, if conditions warrant, the EUB may escalate a licensee to High Risk Action 3.

The example below is for representative purposes only; exact thresholds are to be determined for each compliance category by the respective EUB group.

		Determined by EUB Group		
Licensee Status	EUB Action	Noncompliance Threshold	Review Period	Operate in Compliance
Persistent	High Risk Noncompliance Action 2 and must intervene and educate	≥10%	Annual or predetermined review point	60 days or predetermined period
Monitor	Must intervene and educate	8 to 9.99%		
Low	May intervene and educate	7 to 8.99%		