

FACT SHEET



FS No. 031-0324

Application of the Environmental Protection Agency's Penalty Policy to Common Healthcare Facility Violations

Background: In 1976, Congress amended the Solid Waste Disposal Act with the Resource Conservation and Recovery Act (RCRA). Although RCRA has many objectives, its overriding purpose was to establish the framework for a national system that regulates solid and hazardous waste (HW).

Section 102 of the Federal Facilities Compliance Act of 1992 contains language that waives previously established sovereign immunity for the Federal Government with respect to waste management regulatory programs.

Significance to Defense Health Agency (DHA): The Environmental Protection Agency and authorized states have emphasized healthcare facility compliance on their inspections due to recent regulatory developments. Consequently, the DHA has experienced an increased number of Notice of Violations (NOVs) from regulators. The NOV contains information that regulators rely upon should it be necessary to institute an administrative or judicial enforcement action.

Regulators may also assess civil penalties in conjunction with these enforcement actions. The policy for determining the amounts of these penalties for violations may include the following factors:

- Potential for harm
- Extent of deviation from the requirement
- Good faith efforts to comply/lack of good faith (downward or upward adjustment)
- Degree of willfulness and/or negligence (upward or downward adjustment)
- History of non-compliance (upward adjustment)
- Ability to pay (downward adjustment)
- Economic benefit

Certain types of violations have frequently been identified by regulators in enforcement-related documents. Tables 1 and 2 provide estimated monetary penalties of the potential implications for non-compliance with those violations. Only the two most significant factors (potential for harm and extent of deviation from requirement) are used in this example as the other considerations are difficult to calculate and are often assessed arbitrarily. Additionally, the violations were not calculated on a per-day basis since most regulators reserve that factor for egregious problems.

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Table 1. Penalty Matrix Range

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		Extent of Deviation from Requirement						
		MAJOR	MODERATE	MINOR				
Potential For Harm	MAJOR	\$27,500 to \$22,000	\$21,999 to \$6,500	\$16,999 to \$12,100				
	MODERATE	\$12,099 to \$8,800	\$8,799 to \$5,500	\$5,499 to \$3,300				
	MINOR	\$3,299 to \$1,650	\$1,649 to \$550	\$549 to \$110				

Table 2. Findings and Estimated Penalties

Violation	Potential for Harm	Extent of Deviation from	Estimated Penalty
	Harm	Requirement	
Failure to properly mark/label containers of HW	Minor	Major	\$2,000
Records for shipments of potentially creditable HW pharmaceuticals not retained	Moderate	Major	\$10,000
Universal wastes not properly managed	Minor	Moderate	\$1,000
Failure to characterize effluents from laboratory	Moderate	Moderate	\$7,000
Improper disposal of HW pharmaceuticals	Major	Major	\$22,000
Lack of specific job description for Central Accumulation Area manager	Minor	Minor	\$200
Copies of contingency plan not maintained at satellite accumulation areas	Minor	Major	\$2,000
Total Penalty			\$44,200