

Subpart R - Public Interest Exclusions

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; failing or refusing to conduct a validity testing program when required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of "fatal flaws" or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a "litigation package";

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (e.g., a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a "blanket" consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (e.g., failure to properly conduct the selection process for random testing).