Subpart F—Reporting Defects and Recalling Engines/Equipment

§ 1068.501 How do I report emission-related defects?

This section addresses the certificate holder’s responsibility to investigate and report emission-related defects in design, materials, or workmanship. The provisions of this section do not limit your liability under this part or the Clean Air Act. For example, selling an engine/equipment that does not conform to your application for certification is a violation of §1068.101(a)(1) independent of the requirements of this section. The requirements of this section apply separately to each certificate holder if there is more than one certificate holder for the equipment.

(a) General provisions. As a certifying manufacturer, you must investigate in certain circumstances whether engines/equipment that have been introduced into U.S. commerce under your certificate have incorrect, improperly installed, or otherwise defective emission-related components or systems. This includes defects in design, materials, or workmanship. You must also send us reports as specified by this section.

1. This section addresses defects for any of the following emission-related components or systems containing the following components:

(i) Electronic control units, aftertreatment devices, fuel-metering components, EGR-system components, crankcase-ventilation valves, all components related to charge-air compression and cooling, and all sensors associated with any of these components.

(ii) For engines and equipment subject to evaporative emission standards, fuel tanks, fuel caps, and fuel lines and connectors.

(iii) Any other component whose primary purpose is to reduce emissions.

(iv) Any other component whose failure might increase emissions of any regulated pollutant without significantly degrading engine/equipment performance.

2. The requirements of this section relate to defects in any of the components or systems identified in paragraph (a)(1) of this section if the defects might affect any of the parameters or specifications in Appendix II of this part or might otherwise affect the emissions of any regulated pollutant.

3. For the purposes of this section, defects do not include damage to emission-related components or systems (or maladjustment of parameters) caused by owners improperly maintaining or abusing their engines/equipment.

4. The requirements of this section do not apply to emission control information labels. Note however, that §1068.101(a)(1) prohibits the sale of engines/equipment without proper labels, which also applies to misprinted labels.

5. You must track the information specified in paragraph (b)(1) of this section. You must assess this data at least every three months to evaluate whether you exceed the thresholds specified in paragraphs (e) and (f) of this section. Where thresholds are based on a percentage of engines/equipment in the family, use actual U.S.-directed production volumes for the whole model year when they become available. Use projected production figures until the actual production figures become available. You are not required to collect additional information other than that specified in paragraph (b)(1) of this section before reaching a threshold for an investigation specified in paragraph (e) of this section.

6. You may ask us to allow you to use alternate methods for tracking, investigating, reporting, and correcting emission-related defects. In your request, explain and demonstrate why you believe your alternate system will be at least as effective in the aggregate in tracking, identifying, investigating, evaluating, reporting, and correcting potential and actual emissions-related defects as the requirements in this section. In this case, provide all available data necessary to demonstrate why an alternate system is appropriate for your engines/equipment and how it will result in a system at least as effective as that required under this section.

7. If we determine that emission-related defects result in a substantial number of properly maintained and used engines/equipment not conforming to the regulations of this chapter during their useful life, we may order you to conduct a recall of your engines/equipment (see §1068.505).
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(8) Send all reports required by this section to the Designated Enforcement Officer.

(9) This section distinguishes between defects and possible defects. A possible defect exists anytime there is an indication that an emission-related component or system might have a defect, as described in paragraph (b)(1) of this section.

(b) Investigation of possible defects. Investigate possible defects as follows:

(1) If the number of engines/equipment that have a possible defect, as defined by this paragraph (b)(1), exceeds a threshold specified in paragraph (e) of this section, you must conduct an investigation to determine if an emission-related component or system is actually defective. You must classify an engine/equipment component or system as having a possible defect if any of the following sources of information shows there is a significant possibility that a defect exists:
   (i) A warranty claim is submitted for the component, whether this is under your emission-related warranty or any other warranty.
   (ii) Your quality-assurance procedures suggest that a defect may exist.
   (iii) You receive any other information for which good engineering judgment would indicate the component or system may be defective, such as information from dealers, field-service personnel, equipment manufacturers, hotline complaints, or engine diagnostic systems.

(2) If the number of shipped replacement parts for any individual component is high enough that good engineering judgment would indicate the component or system may be defective, such as information from dealers, field-service personnel, equipment manufacturers, hotline complaints, or engine diagnostic systems.

(3) Your investigation must be prompt, thorough, consider all relevant information, follow accepted scientific and engineering principles, and be designed to obtain all the information specified in paragraph (d) of this section.

(4) Your investigation needs to consider possible defects that occur only within the useful life period, or within five years after the end of the model year, whichever is longer.

(5) You must continue your investigation until you are able to show that there is no emission-related defect or you obtain all the information specified for a defect report in paragraph (d) of this section.

(6) If a component with a possible defect is used in additional families or model years, you must investigate whether the component may be defective when used in these additional families or model years, and include these results in any defect report you send under paragraph (c) of this section.

(7) If your initial investigation concludes that the number of engines/equipment with a defect is fewer than any of the thresholds specified in paragraph (f) of this section, but other information later becomes available that may show that the number of engines/equipment with a defect exceeds a threshold, then you must resume your investigation. If you resume an investigation, you must include the information from the earlier investigation to determine whether to send a defect report.

(c) Reporting defects. You must send us a defect report in either of the following cases:

(1) Your investigation shows that the number of engines/equipment with a defect exceeds a threshold specified in paragraph (f) of this section. Send the defect report within 21 days after the date you identify this number of defective engines/equipment. See paragraph (h) of this section for reporting requirements that apply if the number of engines/equipment with a defect does not exceed any of the thresholds in paragraph (f) of this section.

(2) You know there are emission-related defects for a component or system in a number of engines/equipment that exceeds a threshold specified in paragraph (f) of this section, regardless of how you obtain this information. Send the defect report within 21 days after you learn that the number of defects exceeds a threshold. Send us an updated defect report anytime you have significant additional information.
(d) Contents of a defect report. Include the following information in a defect report:

(1) Your corporate name and a person to contact regarding this defect.

(2) A description of the defect, including a summary of any engineering analyses and associated data, if available.

(3) A description of the engines/equipment that have the defect, including families, models, and range of production dates.

(4) An estimate of the number and percentage of each class or category of affected engines/equipment that have the defect, and an explanation of how you determined this number. Describe any statistical methods you used under paragraph (g)(6) of this section.

(5) An estimate of the defect's impact on emissions, with an explanation of how you calculated this estimate and a summary of any emission data demonstrating the impact of the defect, if available.

(6) A description of your plan for addressing the defect or an explanation of your reasons for not believing the defects must be addressed.

(e) Thresholds for conducting a defect investigation. You must begin a defect investigation based on the following number of engines/equipment that may have the defect:

(i) For engines/equipment with maximum engine power at or below 560 kW:

   (i) For families with annual production below 500 units: 50 or more engines/equipment.

   (ii) For families with annual production from 500 to 50,000 units: more than 10.0 percent of the total number of engines/equipment in the family.

   (iii) For families with annual production from 50,000 to 550,000 units: more than the total number of engines/equipment represented by the following equation:

   \[
   \text{Investigation threshold} = 5,000 + (\text{Production units} - 50,000) \times 0.04
   \]

   (iv) For families with annual production above 560 kW:

   (i) For families with annual production below 250 units: 25 or more engines/equipment.

   (ii) For families with annual production from 250 to 750 units: 15 or more engines/equipment.

   (iii) For families with annual production above 750 units: more than 2.0 percent of the total number of engines/equipment in the family.

(f) Thresholds for filing a defect report. You must send a defect report based on the following number of engines/equipment that have the defect:

(1) For engines/equipment with maximum engine power at or below 560 kW:

   (i) For families with annual production below 1,000 units: 20 or more engines/equipment.

   (ii) For families with annual production from 1,000 to 50,000 units: more than 2.0 percent of the total number of engines/equipment in the family.

   (iii) For families with annual production from 50,000 to 550,000 units: more than the total number of engines/equipment represented by the following equation:

   \[
   \text{Reporting threshold} = 1,000 + (\text{Production units} - 50,000) \times 0.01
   \]

   (iv) For families with annual production above 550,000 units: 6,000 or more engines/equipment.

(2) For engines/equipment with maximum engine power greater than 560 kW:

   (i) For families with annual production below 150 units: 10 or more engines/equipment.

   (ii) For families with annual production from 150 to 750 units: 15 or more engines/equipment.

   (iii) For families with annual production above 750 units: more than 2.0 percent of the total number of engines/equipment in the family.

(g) How to count defects. (1) Track defects separately for each model year and family as much as possible. If information is not identifiable by model year or family, use good engineering judgment to evaluate whether you exceed a threshold in paragraph (e) or (f) of this section. Consider only your U.S.-directed production volume.

(2) Within a family, track defects together for all components or systems that are the same in all material respects. If multiple companies separately supply a particular component or system, treat each company's component or system as unique.
§ 1068.505 How does the recall program work?

(a) If we make a determination that a substantial number of properly maintained and used engines/equipment do not conform to the regulations of this chapter during their useful life, you must report your progress and conclusions. In your reports, include the information specified in paragraph (d) of this section, or explain why the information is not relevant. Send us the following reports:

(1) While you are investigating, send us mid-year and end-of-year reports to describe the methods you are using and the status of the investigation. Send these status reports no later than June 30 and December 31 of each year.

(2) If you find that the number of components or systems with an emission-related defect exceeds a threshold specified in paragraph (f) of this section, send us a report describing your findings within 21 days after the date you reach this conclusion.

(3) If you find that the number of components or systems with an emission-related defect does not exceed any of the thresholds specified in paragraph (f) of this section, send us a final report supporting this conclusion. For example, you may exclude warranty claims that resulted from misdiagnosis and you may exclude defects caused by improper maintenance, improper use, or misfueling. Send this report within 21 days after the date you reach this conclusion.

(h) Investigation reports. Once you trigger an investigation threshold under paragraph (e) of this section, you must report your progress and conclusions. In your reports, include the information specified in paragraph (d) of this section, or explain why the information is not relevant. Send us the following reports:

(1) While you are investigating, send us mid-year and end-of-year reports to describe the methods you are using and the status of the investigation. Send these status reports no later than June 30 and December 31 of each year.

(2) If you find that the number of components or systems with an emission-related defect exceeds a threshold specified in paragraph (f) of this section, send us a report describing your findings within 21 days after the date you reach this conclusion.

(3) If you find that the number of components or systems with an emission-related defect does not exceed any of the thresholds specified in paragraph (f) of this section, send us a final report supporting this conclusion. For example, you may exclude warranty claims that resulted from misdiagnosis and you may exclude defects caused by improper maintenance, improper use, or misfueling. Send this report within 21 days after the date you reach this conclusion.

(4) If you correct defects before they reach the ultimate purchaser as a result of your quality-assurance procedures, count these against the investigation thresholds in paragraph (e) of this section unless you routinely check every engine or piece of equipment in the family. Do not count any corrected defects as actual defects under paragraph (f) of this section.

(5) Use aggregated data from all the different sources identified in paragraph (b)(1) of this section to determine whether you exceed a threshold in paragraphs (e) and (f) of this section.

(6) If information is readily available to conclude that the possible defects identified in paragraph (b)(1) of this section are actual defects, count these toward the reporting thresholds in paragraph (f) of this section.

(7) During an investigation, use appropriate statistical methods to project defect rates for engines/equipment that you are not otherwise able to evaluate. For example, if 76 percent of the components replaced under warranty are available for evaluation, it would be appropriate to extrapolate known information on failure rates to the components that are unavailable for evaluation. Take steps as necessary to prevent bias in sampled data. Make adjusted calculations to take into account any bias that may remain.

(i) Future production. If you identify a design or manufacturing defect that prevents engines/equipment from meeting the requirements of this part, you must correct the defect as soon as possible for future production of engines/equipment in every family affected by the defect. This applies without regard to whether you are required to conduct a defect investigation or submit a defect report under this section.