

modified the alternative according to the commenters' requests.

#### *J. Initial Compliance*

*Comment:* Several commenters indicated that the proposed requirements to complete initial compliance demonstrations and submit the NOCS report by the compliance date are unworkable and unreasonably and unfairly shorten the 3-year compliance period. Based on the commenters' experience, the entire 3-year period is needed to permit, plan, design, procure, install, and shakedown the equipment necessary for MACT compliance. In addition, the 150-day period after the compliance date that other rules allow before the NOCS report is due allows facilities to properly test their control systems, perform necessary shakedown operations, and set the parametric operating limits using actual data. The commenters requested that the final rule defer to the General Provisions regarding the timeline for initial compliance demonstrations and allow the NOCS report to be submitted no later than 150 days after the compliance date. Another commenter requested that area sources that become major sources be allowed up to 3 years to comply with the final rule because the level of effort would be the same as for any existing source when the rule is promulgated.

*Response:* We accept the argument that some facilities with numerous processes and controls may need the full 3 years from the promulgation date to the compliance date to bring all of the equipment on-line before completing the initial compliance demonstration. Therefore, we decided to change the due date for the NOCS report. In the final rule, the NOCS report for all sources, including area sources that become major sources, is due no later than 150 days after the compliance date. In addition, the final rule specifies that the compliance date for area sources that become major sources is 3 years after the area source becomes a major source.

*Comment:* Several commenters indicated that references to § 63.1257(d)(2)(ii) of the pharmaceutical MACT in the proposed rule inappropriately restrict the use of engineering assessments. The commenters indicated that the rule should not require sources to demonstrate that the calculation methods specified in the rule are not appropriate in order to be allowed to calculate uncontrolled HAP emissions using an engineering assessment. The commenters also objected to language in § 63.1257(d)(2)(ii) that restricts the use of modified equations to those that the source can demonstrate have been used

to meet other regulatory obligations. The commenters indicated that they should only be required to show that the selected method for determining uncontrolled HAP emissions is appropriate, and that it has no impact on the applicability assessment or compliance determination.

*Response:* We did not revise the restrictions on the use of the modified equations as requested because the suggested changes would not maintain our objective of having a replicable compliance protocol that is applied consistently across the source category. Therefore, the final rule, like the proposed rule, restricts the use of engineering assessments to situations where the equations are not appropriate.

*Comment:* Several commenters requested that the procedures for calculating uncontrolled HAP emissions be modified in the final rule so that it represents "post condenser" emissions if the condenser is recovering HAP for reflux, reuse, or use as a fuel. The commenters stated that, for many types of emission events, the proposed equations would require the use of the vessel temperature rather than the temperature of the receiver that receives condensed liquid. The commenters indicated that the procedures ignore the emission reduction realized by the condenser, inflates the uncontrolled emissions, and is inconsistent with the MACT floor database.

*Response:* We disagree with the suggested change. Our position is that uncontrolled emissions should be determined at the point the vent stream leaves the process and prior to entering any control device. A condenser that meets the definition of "process condenser" is considered integral to the process, and uncontrolled emissions are calculated at the outlet of the condenser. Process condensers must initiate vapor-to-liquid phase change in an emission stream from equipment that operates above the boiling or bubble point, including condensers located prior to a vacuum source. All other condensers serve primarily to reduce or remove air pollutants, with or without some product recovery benefits; therefore, uncontrolled emissions should be calculated prior to the condenser. This approach does not inflate uncontrolled emissions; it characterizes them properly. Furthermore, if a condenser is determined to be an air pollution control device, the removal efficiency is included as part of the overall control efficiency for the process; it does not ignore the emission reduction realized by the condenser. Finally, we consider the approach to be consistent with our database because we provided clear

instructions with the ICR regarding how to report emissions from condensers, and we trust that most respondents followed those instructions.

*Comment:* Two commenters objected to the proposed requirements for testing control devices that treat emissions from batch process vents under absolute or hypothetical worst-case conditions, as described in the Pharmaceutical Production MACT (§ 63.1257(b)(8)). One of the commenters was concerned that facilities would be forced to generate unwanted or off-specification material in order to satisfy the requirements for worst-case conditions. This commenter requested that the final rule either defer to the General Provisions at § 63.7(e)(1), which require testing under normal operating conditions, or replace paragraph § 63.2470(c) in its entirety with a reference to the performance test requirements of 40 CFR part 63, subpart SS. The second commenter stated that the worst-case testing provisions are technically infeasible and unjustified based on existing EPA regulations. That commenter noted that the Polymers and Resins IV NESHAP recognized this issue and require sources to test under worst-case actual production conditions as opposed to hypothetical worst-case conditions (*i.e.*, § 63.1325(c) of subpart JJJ).

One commenter also suggested that worst-case conditions may not always occur at the highest pollutant loading. According to the commenter, the control efficiency of thermal oxidizers generally increases as the loading increases, and the more challenging compliance demonstration would, therefore, occur under actual/normal operating conditions when the pollutant loading is changing several times over the course of a batch cycle. The commenter requested that the final rule allow facilities the option of using either the Polymers and Resins IV NESHAP testing protocols or the Pharmaceutical NESHAP testing protocols as a site-specific election in the pre-test protocols that facilities must submit prior to testing.

*Response:* We disagree with the commenters' suggestion that sources be allowed to conduct performance tests under "normal operating conditions." Specifically, we disagree with a commenter's contention that operators would be forced to generate unwanted or off-specification material in order to satisfy the requirements of worst-case conditions. The final rule, like the proposed rule, allows the source to test under "hypothetical worst-case conditions" as an alternative to testing under absolute worst-case conditions. Hypothetical worst-case conditions are