How to Use the Inspection Checklist for the Pharmaceutical MACT 10/6/00

Inspection Checklist Instructions

Using the checklist requires a fair amount of pre-work prior to the inspection. In order to understand the processes that you will be inspecting at the facility that you are visiting, it is necessary to review several of the documents that the facility has sent the regulatory agencies. You will need to review:

Pre-Compliance Reports
Initial Notification
Notification of Compliance Status Reports
Title V permit
Periodic Reports
Excess Emission Reports

Much of the initial parts of the checklist can be filled out based entirely on information in these reports. From these reports you will also find many of the operating parameters that the facility will operate under in order to comply with their permits. Provided with the checklist are data sheets which will help you capture the information that you need from these documents for your inspection. To use these data sheets, identify which pieces of equipment you would like to look at during your inspection and photocopy a data sheet for each unit of the same type. Most of the data that you will need will come from the Notification of Compliance Status Report.

Read through the checklist thoroughly before conducting your inspection. The checklist must be tailored to the specific facility that you are inspecting. Depending upon the control equipment that the facility utilizes, certain parts of the checklist will not be required, and other parts may have to be reproduced multiple times in order to capture the required information for the inspection. The sections that may require either omission or reproduction would be those parts of the checklist that are used to review control equipment.

This checklist serves to point out the aspects of the facility where you should pay particular attention. It will help to remind you to cover all the substantive points of the MACT rule, however, you will have to assess whether the facility's control measures meet the standards for compliance.

Caveat for Inspecting R&D Facilities

While research and development (R&D) facilities are not subject to this rule, in facilities where both R&D and production exist, the potential to emit (PTE) of the R&D portion of the plant must also be considered in the facility's total PTE

Items Not Covered in the Checklist

Note that the checklist intentionally leaves out the portions of the rule concerning:

Floating Roof Tanks
Oil-Water Separators
Hydrogenation Vents

These provisions were excluded from the checklist due to the low occurrence of these pieces of equipment in actual pharmaceutical plants. It was felt that inclusion of these units would only serve to increase the bulk of the checklist without creating sufficient added value.

Should an inspector come across one of these units in the field, he or she should recognize that there are applicable regulations to these units, and the parts of the rule that pertain to these units should be researched back in the office.

Disclaimer

The United States Environmental Protection Agency (USEPA) designed this checklist as a compliance tool and/or a guidance document to be used by USEPA, State and Local agency inspectors, as well as the pharmaceutical industry, for the purposes of a facility compliance inspection or a self audit. This checklist is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA and State and Local officials may decide to follow this checklist or to act at variance with it, based on analysis of specific site circumstances. This checklist may be revised without public notice to reflect changes in EPA's policy. The most current version will be posted on the pharmaceutical MACT website. The address is: http://www.epa.gov/ttn/uatw/pharma/pharmpg.html

Please be aware that the USEPA made its best effort to make this an accurate inspection checklist, however, in the event that there are typing errors or deviations from the final pharmaceutical MACT rule, the final rule stands.