

Pharmaceuticals Production NESHAP

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Use and Features of the Rule Assistant System

Disclaimer

The United States Environmental Protection Agency (USEPA) designed this Rule Assistant System as a compliance tool to be used by USEPA, State and Local agency staff, as well as the pharmaceutical industry. Its purpose is to help the user determine how best to demonstrate compliance with the Pharmaceutical NESHAP. It was created to be consistent with the requirements of the Pharmaceutical NESHAP. If there are inadvertent errors, the Pharmaceutical NESHAP is controlling. This Rule Assistant System is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States.

Use and Features of the Rule Assistant System

The Pharmaceuticals Production Rule Assistant System was designed and developed for environmental professionals involved in permit writing, or in determining how best to demonstrate compliance with the standard. As such, the program presents the critical features of a very complex rule in an organized and simple format.

In developing the system, the Pharmaceuticals Production NESHAP was broken into its essential component pieces to allow for easier understanding and interpretation. The rule was then charted to identify the critical decision points that define operating characteristics. Each decision point leads to alternate rule requirements and compliance approaches. Decision points may be:

- related to physical characteristics of the affected unit/process,
- related to characteristics and features of the operations, and/or
- driven by owner/operator requirements.

As the Rule Assistant is an interactive Internet-based system, it relies on user input to determine the decision points. To effectively use the system, a user must be familiar with the processes and equipment at the facility that is to be regulated by the standard. Based on the decision points made by the user, an endpoint will be reached at which the user will be presented with:

- specific requirements that apply to a particular operating condition,
- the actual rule citations that apply, and
- alternative compliance options.

Based on this output, the user should have direct access to all of the necessary information to determine the best options for demonstrating compliance in each unique operating scenario. Alternatively, a permit writer can quickly and easily determine which restrictions, operating conditions or standards a facility must comply with.

The Rule Assistant System provides the user with a choice of output. The user can either obtain a table with the pertinent paragraph numbers for the rule citations, or the user can obtain the actual rule citation text. The Rule Assistant System also provides explanatory text about specific features or conditions to help the user understand the rule requirements. In addition, the System includes explanatory language to help users understand the interactions among the various parts of the Rule Assistant and to provide "plain language" interpretation of selected rule requirements.

Organization of the Rule Assistant System

The Rule Assistant is organized and developed in a logical linear fashion. This means that the user is presented with introductory material, followed by information to determine applicability, and decision points that select major sections of the rule before advancing to the more complicated details of the system. To access the system, a user must first progress through the first "pages" of the system before being presented with the individual standards.

Introductory Page

This is the starting point for the Rule Assistant System. It provides both explanatory text pertaining to the system and links to questions and answers. In addition to providing information about the system, it also provides introductory information pertaining to the rule.

Applicability Determination

This page of the system will help the user determine whether a facility will have to comply with the rule. It is arranged to provide text followed by a series of interactive questions. This page also provides hyperlinked text that allows the user to bypass this page provided the user is certain that the Pharmaceuticals NESHAP is applicable to the facility in question.

Determination of New vs. Existing for Facilities

The user determines whether the facility is new or existing by reading a series of statements that use boolean logic. The user is then presented with two radio buttons, one for "new" and one for "existing." Users must enter a choice for new or existing status each time they enter the system. Currently, the system does not have capabilities to remember any individual user from a previous session.

Selecting an Emission Category

After determining whether a facility is new or existing, the user is presented with a page that lists the various regulated emission sources. As is customary throughout the Rule Assistant, pertinent questions and their answers are provided to facilitate the understanding of the rule and the system.

At this point the user is faced with a series of decision points regarding the regulated emission sources. The user must choose from among 5 emission categories, which include: process vents, storage tanks, equipment leaks, control equipment, and wastewater provisions. Upon making a decision at this point, the user will be presented with questions and further decision points to determine compliance options for the selected emission categories.

Emission Category Pages

A brief summary of the emission category pages is provided here. When choosing to determine the compliance options for the emission categories, it is of importance to realize that emission categories can not be analyzed simultaneously. Only one emission category can be analyzed at a time. The system does allow the user to go directly to other emission categories, but will always return to the beginning of that new emission category each time it is accessed. As was discussed previously, the user will be presented with a table which has the following format and information:

Standards, Test Methods, and Initial Compliance	Monitoring	Recordkeeping	Reporting
<u>View</u>	<u>View</u>	<u>View</u>	<u>View</u>
rule citations	rule citations	rule citations	rule citations

Figure 1. Sample rule citation table. By clicking on the underlined "View" text, the actual rule citations will become available.

Navigating through the Rule Assistant System

It is anticipated that most users of this system will have a rudimentary understanding of how Internet-based applications work. This system uses many of the same features and conventions that are encountered in applications that are run over the Internet. This section will provide a brief overview of how to navigate through the Rule Assistant System.

Navigation through the system is accomplished by clicking on icons with the aid of the computer's mouse. The system makes use of radio buttons, hyperlinked text, and linked icons. Where a link is provided, the mouse cursor will display a hand with which the user can click to access linked text and diagrams. It is of importance to realize that the use of radio buttons only allows for one choice to be made.

The system does not have a "memory" which will take the user back to the exact location from which he/she was working. This means that when the "BACK" button is pushed, the system will take the user back to the last page viewed, and not the exact location on that page.