

## NIOSH PPT Program Evidence Package Aug 30, 2007

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## Respirator Certification Workflows

A manufacturer must register with the PPT Program and receive an applicant (or manufacturer) code under which all applications are submitted before submitting an application for approval . The process is part of the certification activities that help validate the level of quality assurance of the manufacturing facility to be at the level required to manufacture certified respirators. If a manufacturer does not have a manufacturer code, then a code is requested by filling out the application following workflow CWF\_1.0 Self Identification Workflow. CWF\_1.0 describes how the PPT program will process the application once the application is received, if the request is valid. If the request is not valid, then the process will proceed through workflow CWF\_2.0 Information Change Workflow for the change management of the process.

A manufacturer code remains valid, once issued to the manufacturer, to be used to submit any of the eight possible application types. The type of application received will determine how the information is processed through the PPT Program. The flow of the application is described in the various flow charts listed below:

Workflow CWF\_3.0 New Approvals Workflow (used for a configuration not previously listed with the PPT Program)

Workflow CWF\_4.0 Modification Workflow (used for a limited modification to a configuration previously listed with the PPT Program)

Workflow CWF\_5.0 Correlation Workflow (used for obtaining PPT Program official test results on sample hardware)

Workflow CWF\_6.0 Prototype Workflow (used for obtaining PPT Program official test results on a non-production version of a respirator configuration where the production version is expected to be a candidate for certification.)

Workflow CWF\_7.0 Private Labels (used for an already-certified configuration where the applicant is listed by the PPT Program as the manufacturer, and now wants to identify another entity on the approval label of the certified respirator, although the applicant remains solely responsible for the quality and performance of the respirator.)

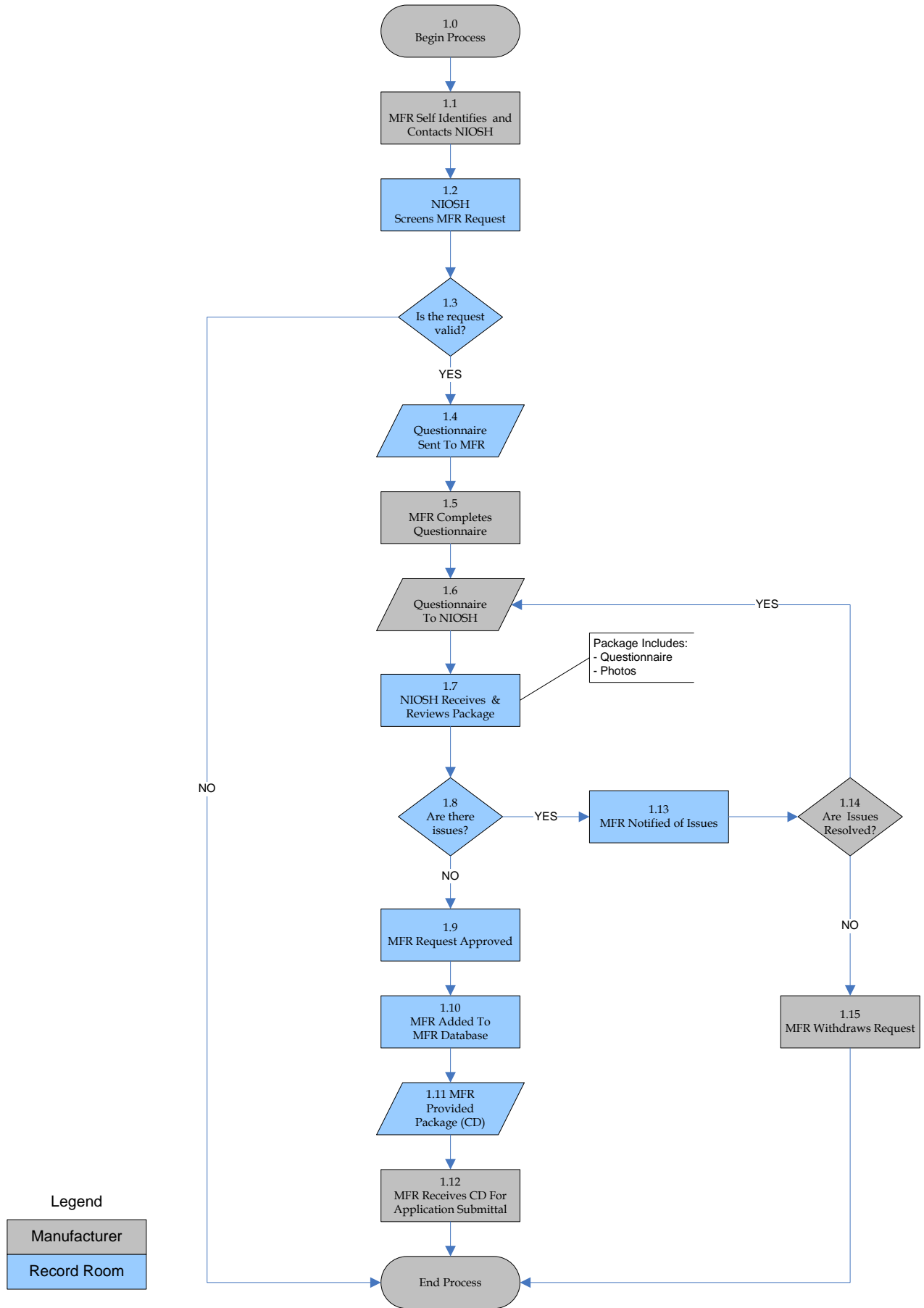
Workflow CWF\_8.0 Manuals Workflow (used for a requested review of the acceptability of the manufacturing site's quality system and it's documentation without application to or evaluation of any manufactured product.)

Workflow CWF\_9.0 CBRN Workflow (New) (used for a configuration not previously listed with the PPT Program as providing CBRN inhalation protection)

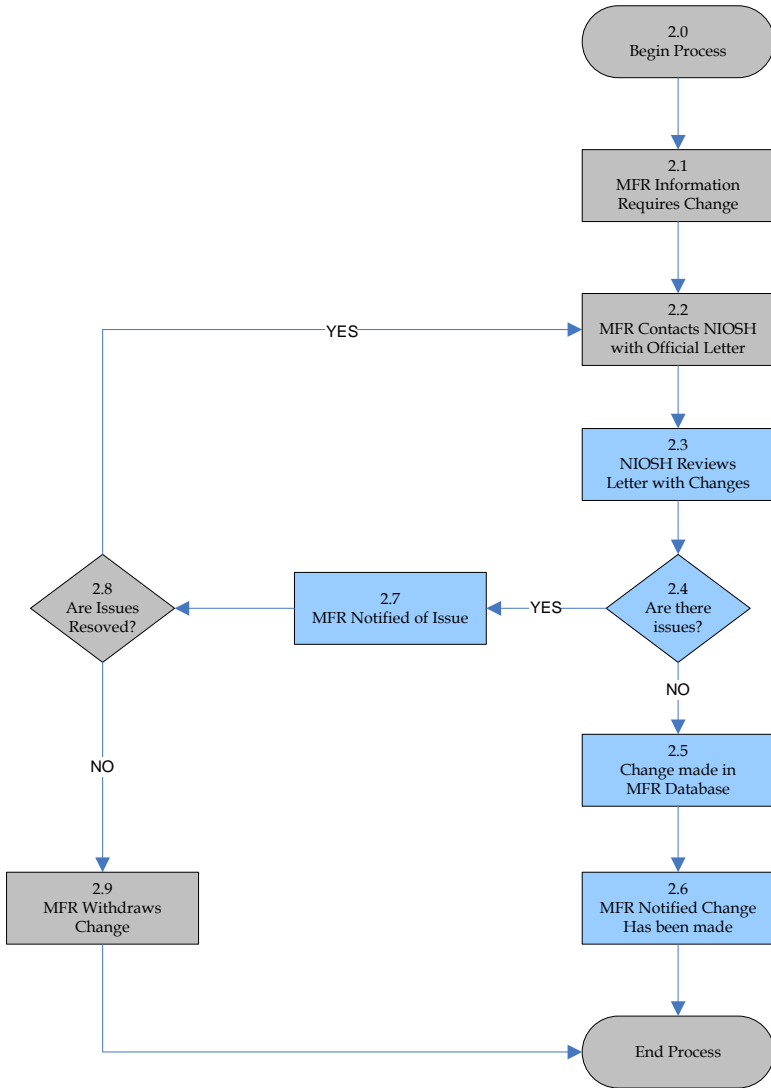
Workflow CWF\_10.0 CBRN Workflow (Modification) (used for a limited modification to a configuration previously listed with the PPT Program as providing CBRN inhalation protection)

These ten workflows all document PPT Program activities in the respirator certification activities then generate an output of either affirmative certification notification or negative (denial or rejection) certification notification.

### CWF\_1.0 Self Identification Workflow



### CWF\_2.0 Information Change Workflow



Legend

Manufacturer
Record Room

