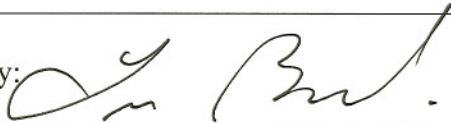


Title: NPPTL Respirator Certification Program Decision Review Process	Revision: 1.0
Approved by: 	Date: 30 January 2008

National Personal Protective Technology Laboratory (NPPTL)

(1) Purpose: To establish a formal, structured process that will enable stakeholders to request a review of decisions regarding NPPTL policy statements, test procedures, and test results pertaining to ongoing respirator certification activities. This Decision Review Process is intended to be used only after normal remediation efforts have taken place and a written decision has been rendered. Implementation of this process is intended to improve the quality of respirator certification activities by allowing the voice of the customer to be heard during an independent review of the decision. Implementation of the process will also serve to improve the Laboratory's relationship with its customers by providing a formal pathway to provide feedback on rendered decisions.

(2) Decision Review Process: There are two levels to the Decision Review Process. Level 1 Decision Review is with the Technology Evaluation Branch (TEB). Level 2 Decision Review is with the NPPTL Office of the Director. Level 1 Decision Review must be completed prior to use of Level 2 Decision Review.

(3) Decision Review Request (DRR): The DRR is a letter transmittal from the requestor. It can be submitted by e-mail or regular mail. The Level 1 DRR must be postmarked or e-mailed within 30 calendar days of the issuance of a written program policy statement or program decision. It must be addressed to the TEB Branch Chief. The transmittal is to be clearly identified as a "Decision Review Request, Level 1" and must identify the program policy statement or program decision and the date of the action that is the subject of the request. Only the manufacturer or representative submitting the application or written request for policy clarification may contend a written decision.

A Level 2 DRR must be e-mailed or postmarked within 15 calendar days of the issuance of a Level 1 DRR notification (See Section (4 d)). The transmittal is to be clearly identified as a "Decision Review Request, Level 2" and must identify the program policy statement or program decision and the date of the Level 1 DRR notification that is the subject of the request. It must be addressed to the NPPTL Director.

The DRR must state the rationale for contending that, for example: a decision regarding an NPPTL program policy statement, test procedure, or test result is flawed. The basis for reconsideration must be clearly and fully articulated in the DRR.

(4) Level 1 DRR, Decision Making Process:

(a) **Level 1 DRR, Responsible Officials:** The Branch Chief for the NPPTL Technology Evaluation Branch (TEB) is the responsible official for reviewing Level 1 Decision Review Requests (DRRs) and making the final decision on the request. The TEB Branch Chief may convene a Technical Review Panel to assist in the review.

(b) **Level 1 DRR, Technical Review Panel:** The TEB Branch Chief may, at his/her discretion, convene a Technical Review Panel to analyze the DRR and the original decision documents, and prepare a written recommendation to the TEB Branch Chief on whether to deny or uphold the request. The evidence to be considered in the Technical Review Panel's deliberation is strictly limited to that provided in the documents at hand. It is not within the scope of the Technical Review Panel's charge to conduct any additional investigation or inquiry in the matter.

(c) **Level 1 DRR, Technical Review Panel's Role:** The Technical Review Panel's role is advisory in nature. The TEB Branch Chief has full responsibility for the decision and may choose not to follow the Review Panel's recommendation.

(d) **Level 1 DRR, Notification:** The Level 1 DRR requestor will be notified of the results of the review via a letter signed by the TEB Branch Chief. The letter will state the basis for the determination issued.

(5) Level 2 DRR, Decision Making Process:

(a) **Level 2 DRR, Responsible Officials:** The Director of NPPTL is the responsible official for reviewing Level 2 Decision Review Requests (DRRs) and making the final decision on the request. The Director may convene an Advisory Review Panel to assist in the review and to develop a recommended determination.

(b) **Level 2 DRR, Advisory Review Panel:** If the Level 2 DRR contains substantial evidence, the Director may, at his/her discretion, convene the Advisory Review Panel, assign it responsibility for analyzing the DRR and the original decision documents, and preparing a written recommendation to the Director on whether to deny or uphold the request. The evidence to be considered in the Advisory Review Panel's deliberation is strictly limited to that provided in the documents at hand, i.e., the Level 1 DRR and the decision documents, which will be provided to the Advisory Review Panel by the TEB Branch Chief. It is not within the scope of the Advisory Review Panel's charge to conduct any additional investigation or inquiry in the matter.

(c) **Level 2 DRR, Advisory Review Panel's Role:** The Advisory Review Panel's role is advisory in nature. The Director has full responsibility for the decision.

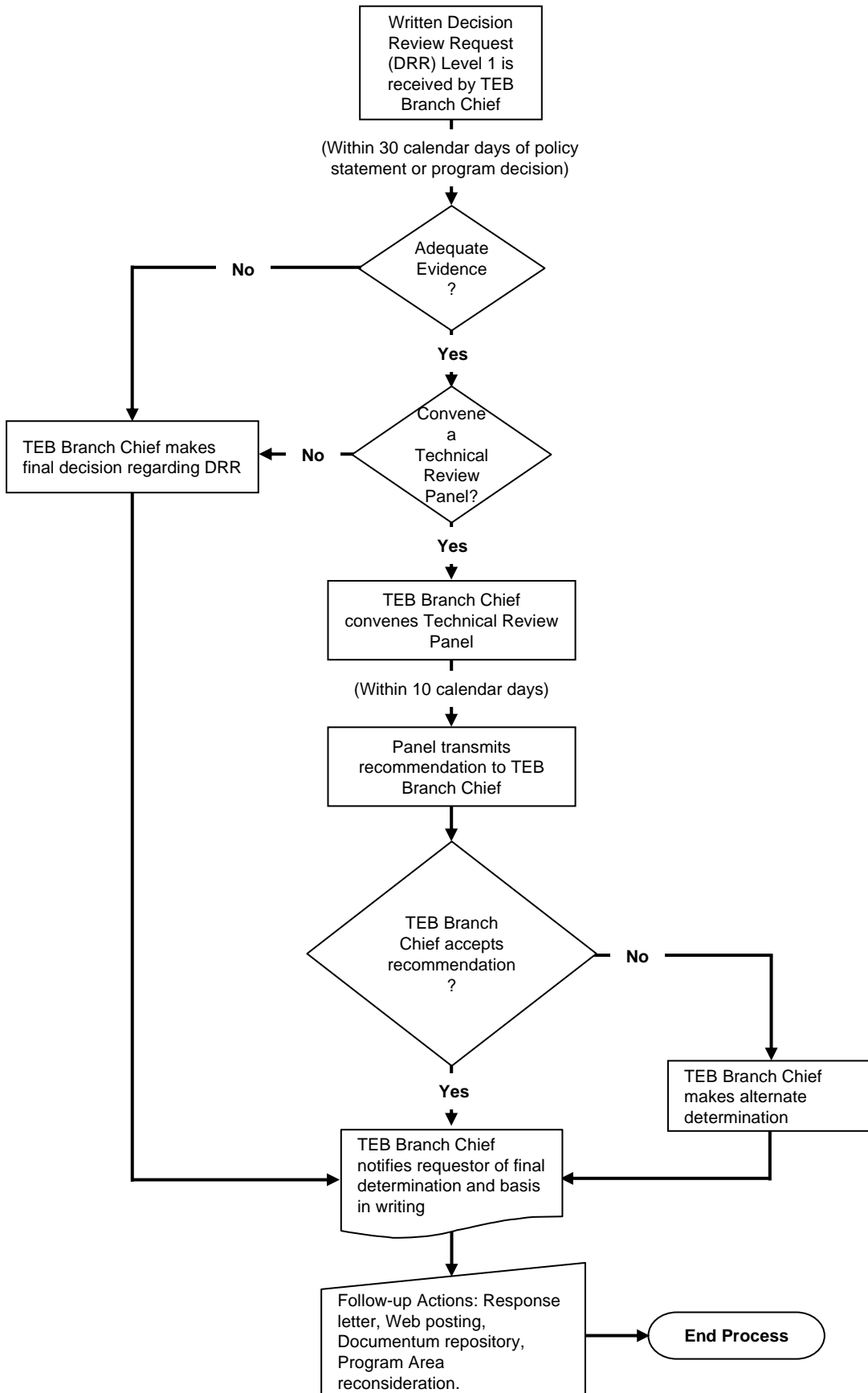
(d) Level 2 DRR, Notification: The DRR requestor will be notified of the results of the Level 2 DRR review via a letter signed by the NPPTL Director. The letter will state the basis for the determination issued.

(6) Follow-up Action:

The follow-up action for all DRRs shall be the listing of the request, response letter and resultant final program statement on the NPPTL webpage. All the documentation pertaining to the DRR shall be retained by NPPTL.

NPPTL Respirator Certification Program Decision Review Process

Decision Review Request (DRR) Level 1



NPPTL Respirator Certification Program Decision Review Process Decision Review Request (DRR) Level 2

