

# National Lung Health Education Program (NLHEP) Spirometer Review Process (SRP)

October 2004

Revised April 2007

## **Background:**

The National Lung Health Education Program (NLHEP) is committed to addressing the problems related to early identification of those most likely to have chronic obstructive pulmonary disease (COPD). These problems were highlighted in the Lung Health Study (JAMA 1994), the first study that demonstrated that early intervention in smokers (at risk for COPD) could impact the course of disease. *Respiratory Care* (May 2000) carried a copy of the article from *Chest* (2000; 117:1146-1161) by Ferguson et al that elaborated on that study – supporting the development of simple office-based spirometers for use in the primary care setting. To that end, NLHEP has developed The Spirometer Review Process (SRP) – a simple step-by-step procedure that will allow spirometry equipment manufacturers to submit their equipment to a group of pulmonary function experts for review (REV07: or the NLHEP will purchase DEVICES to review) to assure that the equipment meets the guidelines for office-based spirometers. It is important to note:

- This process is *not* a substitute for the mechanism already in place to assure that equipment meets the technical standards of the ATS.
- Committee members and reviewers [See List] do *not* represent any organization or group, to include the American Association for Respiratory Care, the American College of Chest Physicians, and the American Thoracic Society.
- Manufacturers of devices that “pass” this review process can use the wording “meets the NLHEP criteria for office-based spirometers” in their advertising and marketing. (REV07: The COMPANY must include the exact name and software version for the device that has passed the review.)

## **Nomenclature/Definitions used in this text:**

DEVICE - office-based spirometer

COMPANY - manufacturer or distributor of DEVICE

REVIEWER - a pulmonary function expert who will do the testing

SRP - Spirometer review process

## **Purpose of the SRP:**

The SRP REVIEWERS will use a Checklist to evaluate various models of DEVICES submitted by the COMPANY (REV07: or purchased by NLHEP) to determine if these DEVICES meet the criteria as developed and approved by the NLHEP, chaired by Dennis E. Doherty, MD. The goal of this process is to clarify the elements required to make a DEVICE appropriate for use in the primary care physician’s office and to provide a Checklist of these elements for use by COMPANIES and REVIEWERS to validate the DEVICE.

### **Definition of Office-Based Spirometer:**

An office-based spirometer (DEVICE) is one that is marketed and sold to office-based physician practices (primary care and non-pulmonary subspecialties) in the United States. Spirometers intended for use almost exclusively within the hospital (pulmonary function laboratory and occupational health) or in research should not be included in this review process.

Spirometers manufactured for more than one type of use may meet the guidelines as outlined in the aforementioned ***Chest*** article. *In order to meet the/NLHEP SRP criteria, the DEVICE must have a “PCP (primary care practice) mode” and come from the factory in this mode (the default mode).* The DEVICE may have other modes that allow for other options and variables, but it is not acceptable for a user to be required to go through a configuration mode and change the configuration to make the spirometer become a DEVICE. The Checklist refers only to operation of the DEVICE when the “PCP mode” is selected. (REV07: While the October 2004 definition remains the preferred one, the revision as it relates to this definition is as follows:

The DEVICE may come from the COMPANY in any mode, but the instructions must include a step-by-step process to reconfigure the DEVICE into the aforementioned “PCP mode.” Once the reconfiguration is made, the DEVICE must stay in that mode and not be required to be reconfigured each time the DEVICE is turned on and off.)

### **SRP Committee members:**

Administrator – Gretchen Lawrence (NLHEP program associate)

Co-Chairs – Paul Enright and Susan Blonshine

REVIEWERS: Catherine Foss, Carl Mottram, Gregg Ruppel, Steve Nelson, Jack Wanger, David Kaminsky, and Charles McArthur (REV07: The REVIEWER group may add or delete members based on need, change in REVIEWER status, etc.)

The Administrator and co-chairs will not perform any of the reviews.

### **Conflict of Interest:**

To avoid bias in reviewing and reporting, Each REVIEWER on this committee is required to disclose any and all relationships and compensation from all COMPANIES whose DEVICE[S] may go through the review process. Each REVIEWER has listed COMPANIES whose DEVICES he/she does not want to review based on possible conflict of interest. Any REVIEWER chosen by random drawing to review a DEVICE may also decline to review that specific DEVICE, even if the REVIEWER did not list that specific DEVICE company on his/her original conflict of interest statement. Each REVIEWER has submitted a “conflict of interest” statement to the SRP administrator to keep on file, and that statement is reviewed and revised on a yearly basis, or at the time a potential conflict of interest arises.

### **The SRP web site:**

The NLHEP web site will host this sub-site. Included in the site will be the following:

- SRP REVIEWERS' names and credentials only
- Copy of the SRP document and checklist
- Link to AARC Buyers Guide (for listing of diagnostic spirometers' COMPANY listing)
- Hot link to manufacturer's site for all DEVICES that **pass** the review process
- Exact DEVICE name, model number and software version that **passed** the review process.  
(REV07: The COMPANY must provide both hardcopy and softcopy [PDF version] of the operators' manual for DEVICE that passed the SRP. The PDF will be posted on the site.)

### **Steps for Procedure/Validation Process:**

There is no charge to the COMPANY for participation in this process. However, the DEVICE(S) will not be returned to the COMPANY once the review has been completed. (See "Documentation")

(REV07: The NLHEP SRP committee will purchase DEVICE[S] marketed as being appropriate for use in the PCP setting. Purchase is accomplished in one of two ways: (1) purchased directly from the DEVICE manufacturer [preferred method of procurement] or 2) through a distributor. No attempt will be made to blind this process to the COMPANY whose DEVICE is being purchased for review. However, confidentiality of the process will be maintained as described in the original document.)

The following is a summary of the steps of the process:

- COMPANY sends a formal letter via email to the administrator requesting to enter the SRP. (REV07: NLHEP will contact the COMPANY to inform them of pending purchase of their DEVICE[S].)
- To choose the REVIEWERS, the Administrator will draw two names out of a hat (random method) and contact each to assure that he/she 1) has no conflict of interest with the COMPANY/DEVICE to be reviewed, and 2) can complete the review within 45 days. If one or both REVIEWERS cannot meet the criteria above, other name(s) will be drawn (using the same random drawing methodology), and the process of contacting/confirmation will be repeated.
- After each REVIEWER has confirmed that he/she can meet the criteria for reviewing the DEVICE, the COMPANY making the request (to enter the review process) will be contacted by the administrator and asked to send the following by registered mail to the administrator: (REV07: Once the REVIEWERS have been chosen, the purchased DEVICE[S] will be sent to them.)

- TWO (2) DEVICES (complete with operator's manual and patient/operator educational materials) and 20 flow sensors or mouthpieces. (REV07: The NLHEP may opt to purchase only one DEVICE to be shared between the two REVIEWERS.)
- A copy of the waveform generator testing results for the DEVICE being tested and a copy of the 501k pre-marketing approval letter from the FDA. (These documents should be sent to the Administrator under separate cover.) (REV07: Waveform generator testing results and FDA letter must be reviewed by the Administrator before the DEVICE[S] can be purchased. The Administrator will request these documents when she contacts the COMPANY to advise them the NLHEP would like to review their DEVICE.)
- The DEVICES must be packaged separately and clearly labeled with the COMPANY name and DEVICE name on each label. DEVICE labels should also indicate "DEVICE A" and "DEVICE B." The COMPANY will notify the administrator by email that the DEVICES have been sent, and the administrator will notify the COMPANY by email when the DEVICES have been received. If one or both of the packages do not arrive or the packaging is such that the administrator determines that the DEVICE(S) may not be in good working order, the package(s) will be returned to the COMPANY, with a request that the COMPANY send new DEVICE(S). (REV07: DEVICE[S] purchased by NLHEP will be sent to the Administrator, who will inspect, re-box, and re-label the DEVICE[S] before sending them to the REVIEWERS. In the event that only one DEVICE is purchased, REVIEWER #1 will send the devices to REVIEWER #2 after completing his/her review.)
- The Administrator will not open the packages. (See REV07 note above) The packages will simply be relabeled and sent by registered mail to the designated REVIEWERS. Upon receipt of a DEVICE, each REVIEWER will have 45 days to complete the review using the Checklist. The Administrator will check progress at 15 and 30 days to confirm that review is in progress (even though it is thought that the actual review process from start to finish should take no more than three [3] hours). If the REVIEWER reports that he/she cannot complete the review within the required 45 days, one (1) extension of 15 days will be granted. If that time has passed and the REVIEWER still has not completed the review, the REVIEWER will be asked to return the DEVICE to the administrator, and random drawing will choose another REVIEWER. The process as described previously will be followed. Until a REVIEWER has completed reviewing a DEVICE, that REVIEWER'S name will not be put into the drawing for any other DEVICE review, so as not to over-burden the individual REVIEWER(S).
- The COMPANY will not know the names of the REVIEWERS who are reviewing their DEVICE.

Equipment review will further be blinded by the following methods:

The REVIEWER will not contact the COMPANY at any time.

Each REVIEWER will not know who else is reviewing the DEVICE until the review of the DEVICE has been completed and the REVIEWER'S report has been returned to the administrator. (REV07: Each REVIEWER will know the name of the other REVIEWER of the device.)

Any requests for information on the status of the review to/from the COMPANY must come directly to the administrator. The names of the REVIEWERS for each DEVICE will be confidential, but the names of all REVIEWERS on the Committee will be listed on the web site.

If the COMPANY is required to resubmit their DEVICE to the FDA (based on FDA criteria for changes in software or hardware), that DEVICE *must* be resubmitted to the NLHEP as well (using the steps as described above) so that a new review of the modified DEVICE can be done. (REV07: The COMPANY whose DEVICE has passed the SRP is requested to advise the SRP committee if it must resubmit that DEVICE to the FDA as described above. If resubmitted to the FDA, the DEVICE must be re-reviewed by the SRP and [if the new DEVCICE passes the SRP] the appropriate hardware and software PDF must be provided by the COMPANY so that they can be posted on the NLHEP web site.)

### **Spirometry Accuracy:**

The REVIEWERS on the SRP committee will *not* be involved in testing that falls under the guidelines for accuracy or repeatability of spirometers, as these specifications are clearly established by the ATS. A DEVICE will be accepted for review only after it has been verified that the DEVICE has passed all ATS specifications for FEV1 and FVC (or FEV1 and FEV6 or FVC6) accuracy and reproducibility for a spirometer as documented by use of a BTPS waveform generator. A copy of the waveform generator testing report must be provided for the exact model and software version submitted for review to this committee in order for the DEVICE to enter the review process. (See “Steps for Procedure/Validation Process”)

### **Documentation:**

A “path of workflow” Checklist format developed by the SRP committee has been reviewed and approved by the NLHEP Executive Committee (EC), with input from the COMPANIES.

Items on the Checklist are derived directly from current ATS and NLHEP guidelines and divided into two categories – *required and optional*. All of the *required* items must be present in the DEVICE in order for it to be approved (“Pass”). Inclusion of the *optional* items is encouraged, but having these within a DEVICE is not necessary for approval.

The REVIEWER will go through the Checklist item-by-item, simply using a check mark by each *required* item to indicate that the DEVICE has “passed” that item. He/she will also use the check mark system to indicate which *optional* item(s) the DEVICE has. The REVIEWERS are encouraged to add complete and legible comments in the “Comments” sections on the Checklist, especially where the REVIEWER has indicated that there is an item that the DEVICE “fails.” (See “Documentation”) (REV07: The predicted values for Part 1: K and a list of references pertinent to this document have been added to the Checklist. The reference list will be posted on the NLHEP site so that COMPANIES may refer their customers to this site for information on spirometers and the SRP.)

Once testing results are received by the administrator, any disagreements between the REVIEWERS reports will be resolved by the co-chairs using the following steps in order as needed:

- 1) Convening a conference call with the original REVIEWERS to see if conflicts can be resolved;
- 2) Sending the DEVICE to another REVIEWER [using the random drawing method to choose that REVIEWER], followed by a conference call among all three (3) REVIEWERS to resolve areas of disagreement;
- 3) If a vote of all the REVIEWERS of the DEVICE is not unanimous, the co-chairs of this committee will make the final decision on “pass” or “fail.”

(REV07: If a vote of all the REVIEWERS of the DEVICE is not unanimous, the final decision on “pass” or “fail” will be determined by a simple majority vote of the three reviewers and the co-chairs.)

Once the final grade is agreed upon, a written report will be sent to the COMPANY who submitted the DEVICE for review. (REV07: A written report will be sent to the COMPANY whose DEVICE was purchased for review, along with the completed checklists from the two reviewers. The reviewers will be identified as “Reviewer A” and Reviewer B”.) The COMPANY will have 30 days to respond/contest by email to the administrator regarding the results of the review. The committee, upon review of the COMPANY’S written response, will convene a conference call to discuss if the reported results shall be modified and/or if the DEVICE should be re-reviewed. The administrator will notify the COMPANY of the committee’s decision by email. Only COMPANIES whose DEVICES “Pass” will be posted on the web site. Only the COMPANY will know if their device fails the review process. However, the COMPANY may post a rebuttal (200 words or less) on the web site if they choose to do so. At no time will the COMPANY know the names of the REVIEWERS or have access to the actual Checklist that the REVIEWER completed. That Checklist will be sent to the administrator and put into a confidential file. COMPANIES whose devices pass the Checklist may market their devices with the notation “**meets NLHEP criteria for office-based spirometers.**”

All DEVICES used in the SRP will become the property of the COMMITTEE and will not be returned to the COMPANY.

**To contact the SRP Administrator:**

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