

PPHRL-R&D /PP/L2-010		Procedure for Personnel (PP)	 Primary & Secondary Healthcare Department
Issue on	DD-MM-YYYY		
Revision	00		
Curator	PPHRL, P&SHD		
Approved By	IRB, P&SHD		

Purpose

The purpose of this procedure is to describe the process within PPHRL to formalize and document the personnel qualifications, job descriptions, authorization, training and his/her assessment.

Scope

The procedure covers the requirements regarding to personnel and implemented in all section of PPHRL under the guidelines of ISO 15189:2012 clause 5.1 “Personnel”.

Procedure

Personnel Qualification:

All sections of PPHRL has record of qualification of its personnel performing the managerial and technical service in the laboratory and offices. Personnel hired for the laboratory services having appropriate qualification and experience. To ensure that the personnel working in the labs have suitable qualification and experience required for the position following selection process is adopted by the laboratory.

- PPHRL advertised the vacant positions in the daily newspapers and its official website giving reasonable time to the applicants to apply against the position. Minimum time for applying is 15 days.
- HR section receive the applications.
- Laboratory Director designate a panel of experts from the laboratory to assess/scrutinized the application. Eligible candidates are called for interview
- Selection Board is competent forum for selection of suitable candidate.
- Offer letter sent to the selected candidate.
- by accepting the offer letter, the personnel join the laboratory
- Newly selected candidate have to follow the requirements of clause 3 of this procedure
- Laboratory maintains the record of each of its personnel (ref. clause), the record is available in ISO Cell under the custody of QM and one of its copy is available in the concerned lab/section for HoD/personnel.

Job descriptions & Lab Authorization

Personnel working in PPHRL as per their defined job descriptions which are approved by the laboratory Director. Job descriptions consist of following:

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- Brief contact information of the personnel
- Laboratory / section details
- Designation, role, responsibilities and reporting officer
- Technical information consist of test which he/she may perform directly or under the supervision of seniors
- Authority for reviewing the results, interpretations, opinions, etc.
- The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.
- Lab has maintained Lab Authorization for its technical staff giving the details of tests which he can perform under supervision / independently.

Introduction to the organizational environment

Each personnel who join the PPHRL is familiarize with laboratory environment. QM is responsible to:

Manage a visit for personnel for all sections offices for his/her introduction with other lab staff and to raise his/her awareness about the laboratory, its cope and level of services escorted by a staff nominated by QM. This activity is for very first day when an employee joins the PPHRL. Facility Orientation includes:

- Introduction to co-workers, personnel policies, working conditions, daily routine, issuance of manuals, quality assurance system and any miscellaneous matters.
- New-Hire Training include:
 - Orientation and Training to Laboratory Management System based on ISO 15189:2012.
 - Safety Training may include the topics of:
 - universal precautions (e.g. hand washing, chemical contact and hazard awareness),
 - exposure control,
 - personal protective equipment,
 - security briefing,
 - safety briefing,

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- fire extinguisher training
- emergency evacuation, and
- safety practices in the laboratory
- Chemical Hygiene
 - Hazardous Waste Management that includes annual training on handling, storage, and disposal of hazardous materials
 - Material Safety Data Sheets
 - Laboratory Management System (LMS) and related procedures.
 - On-the-job training, national training courses and manufacturer's training.
 - Training on policies, regulations, procedures, methods, and instruments.

An assessment is conducted by QM, HoD of the section and recommendations is sent to the laboratory Director and after approval the staff, perform his/her duties.

He/She has to participate in the training programs (ref. clause ----).

Training and Competence Assessment:

Laboratory has designed comprehensive training program (external training & internal training) to enhance the capabilities and skill of its technical and managerial staff. Quality Manager is responsible to organize the training programs and manage the record. The procedure for staff training is as below:

- External training by external training body will be planed when are required, Quality Manager is authority to decide about these trainings when offered / required.
- New hires must be trained on relative Standard Testing Methods, Quality System Procedures and other relative levels of documentation i.e. Policies, Forms, etc. (Ref. Clause)
- The level of training is determined by the employee's educational qualifications, experience, complexity of the standard test method being used and knowledge of the test method performed. It should be ensured before the commencement of a training that personnel attending the training are of the same skill and academic level.
- Employees may request training related to their job.

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- Upon completion of training of attendees submit documentation such as Training Sign-In Sheets, Quality Form, for record purposes into training file.
- Participants should be evaluated in the end of the training. Evaluation can be conducted by performance of a practical demonstration or by filling a questionnaire and record will be organized through Quality Form “Trainee Evaluation Form” in training file / folder.
- NOTE :(for TRAINER) The evaluation exam must be related to the current training, participants must be made aware if the exam may include previous training sessions).

Training Technique

- The training process for technical procedures such as laboratory analysis consists of the following steps:
 - Trainee reads the laboratory procedures, work instructions, or other applicable documents
 - Trainee observes demonstration of the procedure by a trainer.
 - Trainee performs the procedure under observation by a trainer.
 - Trainee successfully completes the procedure.
 - Documentation of these tasks is submitted in training file / folder
- The training process for non-technical procedures includes, but is not limited to:
 - reading laboratory and organizational procedures,
 - instructions,
 - demonstrations,
 - lectures and discussions,
 - self study,
 - computer-based training,
 - viewing videotapes (if applicable), and
 - manufacturer’s training or demonstration.

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- Documentation of trainings is submitted for filing in the training file and corresponding entries are made in Quality Form “Lab Authorization Permits”

Training Verification

- An employee’s performance is assessed against a defined performance criteria as mentioned in Quality Form “Trainee Evaluation Form” The measures used to verify an employee’s performance are assessment tools. Assessment tools include the following:
 - Administration of a Written Evaluation:
 - Written evaluations can be used in areas where verification of a participant’s knowledge is desired. Knowledge of theory or principles, problem-solving ability, logical sequence used, and independent or group decision making may be ascertained.
 - Observation of Procedure, Process, or Outcome:
 - Observation by a trainer of an employee performing or demonstrating a procedure.
 - Verification of Response to Situational Problems or Calculations Related to the Procedure:
 - Example circumstances include resolution of a procedure-related situational problem or recommendation of procedure-related course of action that is consistent with policies and regulations.
 - Response to Oral Queries Related to a Step or Procedure:
 - Answers provided by the employee to questions asked by trainer.
 - Testing Blind QC Samples:
 - Employees are unaware when blind test samples are assigned. They appear identical to other samples, are in routinely used containers, and are from a similar source. The intent is to provide simulated samples to

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measure realistic analytic conditions. This tool assesses all phases of laboratory performance.

- Testing of Known Samples:
 - Participants participate in testing activities, such as Inter Lab Comparisons / PT and commercially prepared quality control samples. Samples for quality assurance or quality control purposes are identified immediately upon receipt in the laboratory. This tool assesses the analytical phase only.
- Testing Previously Analyzed Samples:
 - Duplicate or replicate testing provides accessible internal comparisons and contributes to the validation of the analytic phase. These sources may be previously tested samples, samples of known constituents, and already reported testing and Inter Lab Comparison / PT samples. This tool assesses the analytic phase only.

Retraining

- Employees will be retrained whenever significant changes occur in policies, values, goals, procedures, processes, and methods or instruments.
- Employees will be retrained when the level of performance is unsatisfactory as shown by any to the assessment tools
- Name of employees required retraining will be mentioned by the resource person in Quality Form “Training Completion / Summary” in his remarks

Personnel records

PPHRL has manage the personnel record; which is readily available to relevant personnel, which includes:

- educational and professional qualifications
- copy of certification or license, when applicable
- previous work experience
- job descriptions

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- introduction of new staff to the laboratory environment
- training in current job tasks
- competency assessments
- records of continuing education and achievements
- reviews of staff performance
- reports of accidents and exposure to occupational hazards
- immunization status, when relevant to assigned duties.

Related Documents

- Job Descriptions
- Lab Authorization
- Training Plan
- Training Sign-In-Sheet
- Trainee Evaluation Form
- Training Completion Form
- Personnel Record