

Pharmaceutical
Research Centre

STANDARD OPERATING PROCEDURE

0 LABORATORY & CLINICAL PERSONAL PROTECTIVE EQUIPMENT & STATUS

VERSION 3

REASON FOR REVISION: UPDATE OF HEALTH & SAFETY PROCEDURES

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1 INTRODUCTION

This Standard Operating Procedure describes the background, use and interpretation of laboratory & clinical Personal Protective Equipment. All personnel who require access to the laboratory areas or clinics must follow the instructions.

2 RESPONSIBILITIES

- 2.1 The company Health and Safety Supervisor is responsible for this procedure.
- 2.2 All members of staff are responsible for complying with the requirements of this procedure.

3 HAZARD CATEGORISATION

- 3.1 In order to minimise the risk to staff from working with hazardous chemicals in the laboratories & clinical areas, assessment is made of both the hazards associated with submitted test materials and the hazards and risks connected with the use of laboratory & clinical reagents and associated laboratory & clinical techniques. Test materials and procedures are categorised into three basic Categories A, B & C which relate to the required level of personal protection required within any particular laboratory & clinical area in which they are used or being carried out.
- 3.2 The categories are as follows:
 - Category A: Medical devices and other products (paper, fabrics, etc) which obviously present a very low hazard or which only pose a hazard via skin or eye contact.
 - Category B: All test materials and chemicals that do not fall into Categories A or C.
 - Category C: Materials which are either known to be associated with severe hazards which would not be prevented by the use of the personal protective equipment required for

Category B or whose physical characteristics (eg gases, particles size) demand the use of additional protective measures

- 3.3 The status boards are fixed to the entrances to laboratories & clinical areas and show pictograms that relate to the types of personal protective equipment to be worn by all personnel within that particular area. In addition the status boards have an additional space in which the specific requirements for Category C test materials/procedures may be written.
- 3.4 As many laboratory & clinical areas are multi-functional it is apparent that any area may have multiple test materials in use and differing test procedures, involving various reagents, being followed at any one time. In order to maximise the protection given to staff the use of the status boards has to reflect the personal protective equipment status of the most hazardous test material or procedure in use within the laboratory.
- 3.5 The status boards consist of slider panels that indicate whether Category A, B or C protection is required. Each category has pictograms associated with it to reflect the actual personal protective equipment that must be worn.

4 PERSONAL PROTECTIVE EQUIPMENT CATEGORIES

- 4.1 The Categories do not cover the wearing of laboratory coats that is mandatory in all laboratory areas. Such garments must be worn fully buttoned and with sleeves fully extended at all times.
- 4.2 **Category A**
This relates to the lowest hazard rating allocated to test materials, reagents and procedures or where general laboratory & clinical activities not involving chemicals. This will require the use of eye protection and either latex or nitrile gloves as a minimum. The normal latex or nitrile gloves have differing chemical resistances.
- 4.3 **Category B**
This Category covers most circumstances and hence is the norm for most laboratory & clinical work. The type of protection is the same

for all areas and requires the use of eye, hand and respiratory protection. It will apply in all circumstances where test materials, reagents or procedures cannot be assigned to Categories A or C.

4.4 Category C

This is the highest hazard Category and is open-ended with respect to the likely precautions to be adopted. Each case must be considered on its own merits. It is intended to cover test materials, reagents and procedures with severe hazards or specific personal protective equipment requirements. In addition its use may be triggered by the physical characteristics, e.g. gases or particle size of a material.

5 ASSIGNMENT OF CATEGORIES

Test materials are assigned a Category by the Health and Safety supervisor as soon as sufficient information is available. In the absence of information at the time of logging in materials to the Test Material Receipt system, the material will be placed in Category C. The process relies heavily on information supplied by the sponsor but may require additional decision making according to the physical characteristics of the material. The Category will be marked on the test material receipt form and all containers.

6 USE OF STATUS BOARDS

Staff must use the status boards to indicate the highest Category required from the categorisation of the test material. Where Category C is indicated on the board the person raising the laboratory & clinical status must indicate what additional protective precautions are required. This can be done by either ticking under the Category C pictograms or by writing, with a dry wipe marker pen, the precautions in the space provided on the bottom of the board. This must be done on entering the laboratory or clinical area to begin testing with a new test material or procedure. If the required Category is already indicated on the board then no further action is required but if this represents a higher rating than already in force i.e. $A \rightarrow B$, $B \rightarrow C$, $A \rightarrow C$ then this must be communicated to all other staff within the room immediately. All staff will be expected to wear the appropriate personal protective equipment assigned to the highest rated Category

within the area. Upon completing all work and removing the test material from the laboratory & clinical area, staff will need to communicate with each other to ascertain the highest Category of work still 'live' within the area. The status board may only be downgraded after such enquiries have been made.