1. INTRODUCTION

1.1 a) This document describes the specific requirements to be complied by Clinical immunology sections before they can be accredited.

b) This document shall be studied in conjunction with ISO15189 Medical laboratories–Particular requirements for quality and competence, other MEDICAL Series Technical Notes published by PNAC-MLAS and Guidance Notes such as "ISO15190 Medical Laboratories Requirements of Safety".

2. GENERAL TECHNICAL NOTE: MEDICAL G-23/01

2.1 Please refer to **General Technical Note: Medical G-23/01** for the following:

- PERSONNEL
- COLLECTION AND HANDLING OF SPECIMENS
- PHYSICAL FACILITIES
- REAGENTS
- REFERENCE MATERIALS
- REQUISITIONS, TEST METHODS AND METHOD VALIDATION
- MAINTENANCE OF EQUIPMENT
- CALIBRATION OF EQUIPMENT
- QUALITY CONTROL AND PROFICIENCY TESTING
- LABORATORY SAFETY
- RETAINED SAMPLES
- WASTE DISPOSAL
- REPORTING OF RESULTS

3. DIAGNOSTIC IMMUNOLOGY

3.1 There shall be sufficient and appropriate space, equipment, facilities and supplies for the performance of the required volume of work with accuracy, precision, efficiency and safety.

3.2 There shall be an ongoing comprehensive quality assurance programme, which is designed to monitor and evaluate the overall quality of the total testing process.

3.3 Each laboratory shall have a safety programme designed to minimize risks to the health and safety of employees and patients. There shall be a written safety plan with procedures for biological, chemical and radiation safety and a system for monitoring training and compliance.

3.4 There shall be adequate and competent staff with the required education, training and experience to perform the procedures and tests. A comprehensive competency assessment programme should be in place with provisions made for all personnel to further their knowledge and skills.

3.5 Appropriate criteria must have been developed and should be available for test selection, specimen collection and processing. Procedures should be in place to ensure accurate and reliable test reporting systems.

3.6 There should be timely reporting of test results based on testing priorities and a system should be in place to document problems in communication of laboratory results.

3.7 There shall be appropriate internal quality control procedures for each testing process, selected on the basis of the analytical quality required. Positive and negative controls for qualitative tests shall be run at least once on each day of analysis, based on the manufacturer's instructions. For quantitative tests, control samples at more than one level shall be run at least once each day of analysis.

3.8 The quality control programme shall include method performance validation, preventative maintenance and instrument function checks in place. New kits and reagents must be checked against old reagents to ensure comparable reactivity.

3.9 The laboratory shall participate in recognised proficiency testing programme and show acceptable performance with proficiency testing specimens.

3.10 There shall be appropriate record storage and retrieval systems.

3.11 For laboratories involved in transplantation, the personnel must have the required knowledge and experience in the field of histocompatibility testing.