

GOOD LABORATORY PRACTICES

Good Laboratory Practice is defined in the OECD Principles as “*a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.*”

PRINCIPLES

- The purpose of the Principles of Good Laboratory Practice is to promote the development of quality test data and provide a tool to ensure a sound approach to the management of laboratory studies, including conduct, reporting and archiving.
- The Principles may be considered as a set of standards for ensuring the quality, reliability and integrity of studies, the reporting of verifiable conclusions and the traceability of data.
- The Principles require institutions to assign roles and responsibilities to staff in order to ensure good operational management of each study and to focus on those aspects of study execution (planning, monitoring, recording, reporting, archiving) that are of special importance for the reconstruction of the whole study.
- Since all these aspects are of equal importance for compliance with GLP Principles, it is not permissible to partially implement GLP requirements and still claim GLP compliance. No test facility may rightfully claim GLP compliance if it has not implemented and does not comply with, the full array of the GLP rules.

As far as pharmaceutical development is concerned, the GLP Principles, in their regulatory sense, apply only to studies which:

- are non-clinical, i.e. mostly studies on animals or in vitro, including the analytical aspects of such studies;
- are designed to obtain data on the properties and/or the safety of items with respect to human health and/or the environment;
- are intended to be submitted to a national registration authority with the purpose of registering or licensing the tested substance or any product derived from it.

Depending on national legal situations, the GLP requirements for non-clinical laboratory studies conducted to evaluate drug safety cover the following classes of studies:

- Single dose toxicity
- Repeated dose toxicity (sub-acute and chronic)
- Reproductive toxicity (fertility, embryo-foetal toxicity and teratogenicity, peri-/postnatal toxicity)
- Mutagenic potential
- Carcinogenic potential
- Toxicokinetics (pharmacokinetic studies which provide systemic exposure data for the above studies)
- Pharmacodynamic studies designed to test the potential for adverse effects (Safety pharmacology)
- Local tolerance studies, including phototoxicity, irritation and sensitisation studies, or testing for suspected addictive and/or withdrawal effects of drugs.

1. GLP Principles are independent of the site where studies are performed. They apply to studies planned and conducted in a manufacturer's laboratory, at a contract or subcontract facility, or in a university or public sector laboratory.
2. GLP is not directly concerned with the scientific design of studies. The scientific design may be based on test guidelines and its scientific value is judged by the (Drug) Regulatory Authority that provides marketing authorisation. However, adherence to GLP will remove many sources of error and uncertainty, adding to

the overall credibility of the study. Through the application of technically valid and approved Standard Operating Procedures many sources of systematic error and artefacts may be avoided.

3. The requirement to formulate a study plan with a defined scientific purpose for the study will prevent false starts and diminish the incidence of incomplete or inconclusive studies. Respecting the GLP Principles will thus indirectly optimise the scientific yield of studies.
4. When implementing GLP in a test facility, and particularly during training, it is important to clearly differentiate between the formal, regulatory use of the term Good Laboratory Practice and the general application of “good practices” in scientific investigations. Since the term “Good Laboratory Practice” is not a trademark protected term, any laboratory may consider that it is following good practices in its daily work. This does not comprise GLP compliance.
5. **It must be clearly understood that only adherence to, and compliance with, all the requirements of the OECD GLP Principles constitutes real compliance with GLP. Therefore, the use of similar terminology to describe quality practices outside the scope of GLP proper should be strongly discouraged.**

Quality Assurance

Quality Assurance (QA) – sometimes also known as the Quality Assurance Unit (QAU) - as defined by **GLP is a team of persons charged with assuring management** that GLP compliance has been attained in the test facility as a whole and in each individual study.

QA must be independent of the operational conduct of the studies, and functions as a “witness” to the whole preclinical research process.

PERSONNEL

The GLP standards require that an adequate number of trained personnel are available for the study. Typical analytical laboratories keep minimal records on the training of personnel, assuming that the quality control results in the individual tests speak for the capability of the analyst.

Under GLP standards additional records must be kept and be available for audit. This includes at a minimum

1. The resume of the individual, documenting education, prior job history, publications, presentations, patents, attendance at technical courses, and memberships in technical organizations. The resume must be updated during the course of employment to document additional training and changes in responsibilities. This document should be a brief history of the employee throughout his or her professional career and current to the time of the GLP study.
2. Training records in the organization. The personnel record should include documentation of training, including safety training, training in GLP regulations, and test-specific training. The records must include when the training was completed, and the topics covered, along with the signatures of the trainer and trainee.
3. A thorough job description for each employee and an organization chart showing the relationship of an individual to the rest of the staff must be documented.
4. All personnel records must be archived and available for audit even if the audit takes place after that individual is no longer with the organization.

The managerial and organisational requirements of GLP account for about 15% of GLP regulations but, unfortunately, are still seen by regulators and QA as one of the principal sources of non-compliance. Without full management commitment and formal involvement of all personnel, GLP systems lack credibility and will not function as they should. Personnel are, therefore, a critical element when implementing GLP and maintaining compliance in a laboratory.

It is clear that the manager of a test facility has overall responsibility for the implementation of both **good science** and **good organisation**, including compliance with GLP.

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GOOD SCIENCE

- Careful definition of experimental design and parameters.
- Performance of experiments based on valid scientific procedures.
- Control and documentation of experimental and environmental variables.
- Careful, complete evaluation and reporting of results.
- Assuring that results become part of accepted scientific knowledge.

GOOD ORGANISATION:

- Provision of adequate physical facilities and qualified staff.
- Planning of studies and allocation of resources.
- Definition of staff responsibilities and training of staff.
- Good record keeping and organised archives.
- Implementation of a process for the verification of results.
- Compliance with GLP.

In the matrix of good science and good organisation, GLP concentrates largely on organisational and managerial aspects of studies, many of which are directly dependent upon the competence of personnel running the studies.

Study Director and the Multi-Site Situation

- Special mention must be made of the important role of the Study Director. This person is the single point of study control. He/she has the overall responsibility for the planning and conduct of the study, the interpretation of the results and the authorship of the final study report.
- This responsibility is expressed through the signature of the study plan or protocol, the supervision of the study in progress and the signature of the final report.
- The Study Director must include in the final report a GLP compliance statement indicating the extent to which his/her study complies with the Principles of GLP.
- The Study Director who will decide whether or not the problem encountered requires his/her input, perhaps in the form of a protocol amendment.
- At the end of a multi-site study, it is the Study Director who has the responsibility of writing the final report even if it includes contributions provided by the Principal Investigator [PI]. The Study Director includes a GLP statement covering the entire study, including the phases that were delegated to the PI.

FACILITIES: BUILDINGS

Test facilities should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbances that could interfere with the study. They should be designed to provide an adequate degree of separation of the diverse elements of the study. The purpose of these requirements is to ensure that the study is not compromised because of inadequate facilities. It is important to remember that fulfilling the requirements of the study does not necessarily mean providing "state of the art" constructions, but carefully considering whether the objectives of the study can be achieved using the facilities available.

Separation ensures that disturbances are minimised and that different activities do not interfere with one another or adversely affect the study. This can be achieved by:

- **Physical Separation**; e.g. walls, doors, filters or separate cabinets or isolators. In new buildings, or those recently renovated, separation will be part of the design.

• **Organisational Separation;** e.g. carrying out different activities in the same area but at different times, allowing for cleaning and preparation between operations, maintaining separation of staff, or by establishing defined work areas within a laboratory.

As an illustration of the principles involved we shall consider:

- **Pharmacy and Dose Mixing Areas:** concerned with test material control and mixing with vehicles (although the same considerations would apply to other areas such as analytical or histopathology laboratories).
- **Animal facilities.**

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PHARMACY AND DOSE MIXING AREAS

The Pharmacy and Dose Mixing area is a laboratory zone dealing with test item work flow: receipt, storage, dispensing, weighing, mixing, dispatch to the animal house and waste disposal.

Size

- The area should be big enough to accommodate the number of staff working in it, and allow them to carry on their work without risk of getting in one another's way or of mixing up different materials.
- Each operator should have a workstation sufficiently large to enable him/her to carry out the operation efficiently.
- To reduce the chance of mix-up of materials or of cross-contamination, there should also be a degree of physical separation between the workstations
- The pharmacy is a sensitive area, and access to such facilities should be restricted so as to limit the possible contamination of one study or compound by another.

Construction

- The zone must be built of materials that allow easy cleaning and that are not likely to allow test materials to accumulate and contaminate one another.
- There should be a ventilation system that provides air-flow away from the operator through filters which both protect personnel and prevent cross-contamination. Most modern dose mix areas are now designed in a "box" fashion, each box having an independent air system.

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Arrangement

There should be separate areas for:

- Storage of test items under different conditions.
- Storage of control items.
- Handling of volatile materials.
- Weighing.
- Mixing of different dose formulations, e.g. in the diet or as solutions or suspensions.
- Storage of prepared dose formulations.
- Cleaning equipment.
- Offices and refreshment rooms.
- Changing rooms.

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ANIMAL FACILITY

- The facility should be designed and operated in order to minimise the effects of environmental variables on the animal.
- Requirements will differ depending upon the nature and duration of the studies being performed. The risks of contamination can be reduced by a "barrier" system, where all supplies, staff and services cross the barrier in a controlled way, as well as by providing "clean" and "dirty" corridors for the movement of new and used supplies.

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- Consideration should also be given to measures which prevent the animal from coming into contact with disease, or with a test item other than the one under investigation

A well-designed animal house would maintain separation by providing areas for:

- Different species
 - Different studies
 - Quarantine
 - Changing rooms
 - Receipt of materials
 - Storage
 - bedding and diet test
 - doses
 - cages
 - Cleaning equipment
 - Necropsy
 - Laboratory procedures
 - Utilities
 - Waste disposal
- The building and its rooms should provide enough space for animals and studies to be separated and to allow the operators to work efficiently.
 - The environment and control system should maintain the temperature, humidity and airflow at the defined levels depending on the species concerned.
 - The surfaces of walls, doors, floors and ceilings should be constructed to allow for easy and complete cleaning, and there should be no gaps or ledges where dirt and dust can build up, or where water will collect, for instance on uneven floors.

Whatever the capabilities or needs of your laboratory, sensible working procedures will reduce potential danger to the study from outside influences and will maintain a degree of separation between activities. You can help achieve adequate separation by:

- Minimising the number of staff allowed to enter the building.
- Restricting entry into animal rooms.
- Organising work flow so that clean and dirty material are moved around the facility at different times of day (if the construction of the facility does not permit other solutions) and so that corridors are cleaned between these times.
- Requiring staff to put on different clothing in different zones within the facility.
- Ensuring that rooms are cleaned and sanitised regularly, particularly between studies.

EQUIPMENT

- For the proper conduct of the study, appropriate equipment of adequate capacity must be available.
- All equipment should be suitable for its intended use, and it should be properly calibrated and maintained to **ensure reliable and accurate performance**.
- Records of repairs and routine maintenance and of any non-routine work should be retained.
- Remember that the purpose of these GLP requirements is to ensure the reliability of data generated and to ensure that data are not invalidated or lost as a result of inaccurate, inadequate or faulty equipment.

1. Suitability

- Suitability can only be assessed by considering the tasks that the equipment is expected to perform: there is no need to have a balance capable of weighing to decimals of a milligram to obtain the weekly weight of a rat, but a balance of this precision may well be required in the analytical laboratory.

- Deciding on the suitability of equipment is a scientific responsibility and is usually defined in SOPs.

2. Calibration

- All equipment, whether it is used to generate data (e.g. analytical equipment or balances), or to maintain standard conditions (e.g. refrigerators or air conditioning equipment), should work to fixed specifications. Proof that specifications are being met will generally be furnished by periodic checking.
- In the case of measuring equipment this is likely to involve the use of standards. For example, a balance will be calibrated by the use of known standard weights.
- In the case of analytical equipment a sample of known concentration will be used to ensure that the equipment is functioning as expected, as well as providing a basis for the calculation of the final result.
- Other equipment, such as air conditioning systems for animal facilities or constant temperature storage rooms, will be checked periodically by the use of calibrated instruments (probes, thermometers...).
- Verifications should be performed at a frequency that allows action to be taken in time to prevent any adverse effect on the study should it be discovered that the equipment is not operating within specifications.

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3. Maintenance

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The requirement that equipment be properly maintained is based on the assertion that this ensures the constant performance of equipment to specifications and that it reduces the likelihood of an unexpected breakdown and consequent loss of data.

- Maintenance may be carried out in two quite distinct ways:

- **Preventive maintenance;** when parts are changed regularly based upon the expected life of the part concerned. Planned maintenance of this type may be a useful precaution for large items of equipment or items that do not possess suitable backup or alternatives. Regular preventive maintenance therefore reduces the risk of breakdown.

- **Curative maintenance;** when repairs are made in the case of a fault being detected.

This approach particularly applies to equipment such as modern computer driven analysers or electronic balances that do not easily lend themselves to preventive maintenance. Back up for vital equipment should be available whenever possible as well as back up in the event of service failures, such as power cuts. A laboratory should have the ability to continue with essential services to prevent animals or data being lost, and studies irretrievably affected. For example, a laboratory carrying out animal studies may, as a minimum, need a stand-by generator capable of maintaining the animal room environment.

Early warning that equipment is malfunctioning is important; hence the checking interval should be assigned to assure this. Alarms are very valuable, particularly if problem occurs at a time when staff are not present in the laboratory.

4. Documentation

- Routine maintenance should be documented in such a way that users of equipment can be assured that it is reliable and not outside its service interval.
- A label attached to equipment or the provision of a clear service plan may ensure this.
- Records of equipment calibration, checking and maintenance demonstrate that the respective SOPs have been followed and that equipment used was adequate for the task and operating within its specifications.
- The records should also demonstrate that the required action was taken as a result of the checks that had been made, for example when parameters exceeded acceptable limits staff were aware of this and took appropriate remedial action.

TESTING FACILITIES**Standard operating procedures (SOP)**

Standard operating procedures shall be established for

- Animal room preparation
- Animal care
- Receipt, identification, storage, handling, mixing and method of sampling of the test and control articles.
- Test system observation
- Laboratory test
- Handling of animals found moribund or dead during study
- Necropsy of animals or post mortem examination of animals
- Collection and identification of specimens
- Histopathology
- Data handling, storage and retrieval
- Maintenance and calibration of equipment
- Transfer, proper placement and identification of animals

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Reagents and solutions

- all reagents and solutions in the laboratory areas shall be labelled to indicate identity, titre or concentration, storage requirements and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

Animal care

- There shall be standard operating procedures for the housing, feeding, handling and care of animals.
- All newly received animals from outside sources shall be isolated and their health status shall be evaluated.
- At the initiation of a non-clinical laboratory study, animals shall be free of any.
- If during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary.
- These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study
- The diagnosis, authorisation of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.
- Animals of different species shall be housed in separate rooms when necessary.
- Animal cages, racks and accessory equipment shall be cleaned and sanitised at appropriate intervals.
- Feed and water used for the animals shall be analysed periodically to ensure that contaminants known to be capable of interfering with study and reasonably expected to be present in such feed or water or not present in levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.
- If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

FACILITIES OF HANDLING TEST AND CONTROL ARTICLES

- As necessary to prevent combination or mix-ups, there shall be separate area for receipt and storage of the test and control articles, mixing of the test and control articles with a carrier, storage of the test and control article mixtures.
- Storage areas for the test and or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, activity, stability and bio availability of the articles and mixtures

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Laboratory operating areas

Separate laboratory space shall be provided, as needed, for performance of the routine and specialised procedures required by non-clinical laboratory studies.

Specimen and data storage facilities

Space shall be provided for archives, limited access by authorised personnel only, for the storage and retrieval of all data and specimens from completed studies

TEST AND CONTROL ARTICLES**Test and control article characterisation**

- the identity, strength, purity and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented.
- Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility.
- Each storage of container for a test or control article shall be labelled by name, chemical abstract number, or code number, batch number, expiration date, if any, and where appropriate storage conditions necessary to maintain the identity, strength, purity and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.

Test and control article handling

Procedures shall be established for a system for the handling of the test and control articles to ensure that

- There is proper storage
- Distribution is made in a manner designed to preclude the possibility of contamination, deterioration or damage.
- Proper identification is maintained throughout the distribution process.
- The receipt and documented. such documentation shall include the date and quantity of each batch distributed or returned.

PROTOCOL FOR CONDUCT OF NON-CLINICAL LABORATORY STUDY**Protocol**

Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study.

The protocol shall contain

- A descriptive title and statement of the purpose of the study.
- Identification of the test and control articles by name, chemical abstract number, or code number.
- The name of the sponsor and address of the testing facility
- The number, body weight range, sex, source of the supply, species, strain, sub strain and age of the system.
- The procedure for the identification of the system
- A description of the experimental design, including the methods for the control bias.
- Each dosage level to be administered and the method and frequency of administration
- The records to be maintained.

Conduct of non-clinical laboratory study

- The non-clinical laboratory study shall be conducted in accordance with the protocol.
- The system shall be monitored in conformity with the protocol
- Specimens shall be identified by test system, study, nature and date of collection.
- Records of gross findings for a specimen from post-mortem observations should be available to a pathologist when examining that specimen histo-pathologically.

- Any change in these entries shall be made so as not to obscure the original entry, shall indicate the reason for such change and shall be dated and signed or identified at the time of the change.

REPORTING OF NON-CLINICAL LABORATORY STUDY

A final report shall be prepared for each non-clinical laboratory study and shall include

- Name and address of the facility performing the study and the dates
- Statistical methods employed for analysing data.
- The test and control articles identified by name, code number, strength, purity, and composition or other characteristics
- Stability of the test and control articles under the condition of administration
- A description of the method used.
- A description of the test system used
- A description of the dosage, dosage regimen, route of administration and duration
- The name of the study director, other scientists, supervisory personnel involved in the study.
- A description of the transformations, calculations or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.
- The location where all specimens, raw data and the final report are to be stored.
- The statement prepared and signed by the quality assurance unit.
- The final report shall be signed and dated by the study director.
- Corrections or addition to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify the part of the report that is being added to or corrected and the reasons for the correction or addition and shall be signed and dated by the person responsible.

STORAGE AND RETRIEVAL OF RECORDS AND DATA

- All raw data, documentation, protocols, final reports and generated as a result of a non-clinical laboratory study shall be retained.
- There shall be archives for orderly storage and expedient retrieval of all new raw data, documentation, protocols, specimens and interim and final reports.
- An individual shall be identified as being responsible for the archives
- Only authorised personnel shall enter the archives
- Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

If work place doesn't comply with FDA GLP standards

DISQUALIFICATION OF A FACILITY

- Before a workplace can experience the consequence of non-compliance, an explanation of disqualification is needed
- The FDA states the purpose of disqualification as the exclusion of a testing facility from completing laboratory studies or starting any new studies due to not following the standards of compliance set by the GLP manual

POSSIBLE VIOLATION

- Falsifying information for permit, registration or any required records
- Falsifying information related to testing protocols, ingredients, observations, data equipment, etc.,
- Failure to prepare, retain or submit written records required by law.

GROUNDINGS FOR DISQUALIFICATION

- The testing facility failed to comply with one or more regulations implemented by the GLP manual.
- The failure to comply led to adverse outcomes in the data: in other words, it affected validity of the study.
- Warnings or rejection of previous studies have not been adequate to improve the facility's compliance.

CONSEQUENCE OF NON-COMPLIANCE

The FDA states the following consequences of non-compliance:

- The commissioner will send a written proposals of disqualification will be scheduled.
- A regulatory hearing on the disqualification will be scheduled.
- If the commissioner finds that after the hearing, the facility has compiled, then a written statement with an explanation of termination of disqualification will be sent to the facility.
- Thus, if it can be shown that such disqualification did not affect the integrity and outcome of the study itself, or did not occur at all, then the study may be reinstated at the will of the commissioner.

UPON DISQUALIFICATION...

If the commissioner finds that facility was non-compliant on any of the grounds after the hearing, then a final order of non-compliance will be sent to the facility with explanations:

- If a testing facility has been disqualified, any studies done before of after the disqualification will need to be determined as essential to a decision (acceptable or not)
- If the study is determined unacceptable, then the facility itself may need to show that the study was not affected by the non-compliance that led to the disqualification
- Once finally disqualified, the facility may not receive or be considered for a research or marketing permit and the study is rejected.
- The FDA may turn it over to the federal, state or local law enforcement.
- The facility's sponsor may terminate or suspend the facility from doing any non-clinical study for a permit.
- The sponsor is required to notify the FDA in writing within 15 days that the facility is to be suspended or terminated.

REINSTATEMENT OF A DISQUALIFIED FACILITY

The disqualified facility will be required to put in writing to the commissioner reasons why it should be reinstated and any actions the facility will take or have taken to assure any disqualification problems will not happen again.

- The commissioner will inspect the facility and determine if it shall be reinstated.
- If it is reinstated, the commissioner is required to notify all persons that were notified of the disqualification including the facility itself.

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COMPLAINTS

A 'Complaint' simply designates, that something is wrong or not good enough. Generally, in the pharmaceutical industry, complaints are regarding the quality of drug product. A complaint shows customer dissatisfaction about a product and consequently, about a company.

Principle

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All complaints and other information concerning potentially defective products should be carefully reviewed according to written procedures and the corrective action should be taken.

NEED FOR COMPLAINT HANDLING SYSYTEM

- It gives the company an opportunity to improve the quality of the product.
- It is helpful to maintain cGMP.
- It maintains committed relationship between the customer and company.
- It is the regulatory obligations.

Objective

To immediately recall, investigate or to take remedial measures against the defective product.

Responsibility

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The quality manager along with manager of the complaint related department.

TYPES OF COMPLAINTS

Basically it's of three types

- 1. Quality Complaints:** originate at consumer level and concern with physical, chemical and biological properties or condition of labeling and/or packaging of the product.
- 2. Adverse reaction Complaints:** Due to allergic reactions of any other untoward reaction or fatal reaction or near fatal reaction.
- 3. Other medically related Complaints:** Include Complaints such as lack of efficacy or clinical response.
 - Time period for investigation after receipt of complaints:
 1. Product quality complaints- within 10 days
 2. Adverse reaction complaints- within 5 days
 3. Medical complaint- within 3 days
 - Complaint records shall be maintained at least one year after expiration date of medicines. Complaint records shall be reviewed and a monthly summary shall be prepared for the management.
 - Also the complaints are categorized as following
 - ✓ CRITICAL DEFECTS
 - ✓ MAJOR DEFECTS
 - ✓ MINOR DEFECTS

Critical Defects

- Those defects which can be life threatening and require the company to take immediate action by all reasonable means, whether in or out of business hours.