

MALAYSIA: INVESTMENT IN THE SERVICES SECTOR

# SPECIALISED TECHNICAL SUPPORT SERVICES





## Introduction

This booklet is one of a series of 20 booklets prepared by MIDA for the purpose of providing investors with relevant information on establishing projects in the identified services sub-sectors in Malaysia. The complete list of booklets is as follows:

- Booklet 1:** General Policies, Facilities and Guidelines
- Booklet 2:** Regional Operations
- Booklet 3:** Research and Development (R&D) Services
- Booklet 4:** Logistics Services
- Booklet 5:** Specialised Technical Support Services
- Booklet 6:** Information and Communication Technology Services
- Booklet 7:** Environmental Management Services
- Booklet 8:** Distributive Trade Services
- Booklet 9:** Tourism and Travel Related Services
- Booklet 10:** Education and Industrial Training Services
- Booklet 11:** Legal Services
- Booklet 12:** Accounting, Auditing and Taxation Services
- Booklet 13:** Architectural Consultancy Services
- Booklet 14:** Surveying Consultancy Services
- Booklet 15:** Medical and Health Care Services
- Booklet 16:** Engineering and Energy Consultancy Services
- Booklet 17:** Management Consultancy Services
- Booklet 18:** Market Research Services
- Booklet 19:** Advertising Services
- Booklet 20:** Quick Reference

*The Ministry of International Trade & Industry (MITI) spearheads the development of industrial activities to further enhance Malaysia's economic growth. As an agency under MITI, the Malaysian Investment Development Authority (MIDA) is in charge of the promotion and coordination of industrial development in the country.*

*MIDA is the first point of contact for investors who intend to set up projects in manufacturing and services sector in Malaysia. With its headquarters in Malaysia's capital city of Kuala Lumpur, MIDA has established a global network of 20 overseas offices covering North America, Europe and the Asia Pacific to assist investors interested in establishing manufacturing projects and services activities in Malaysia. Within Malaysia, MIDA has 12 branch offices in the various states to facilitate investors in the implementation and operation of their projects.*

*If you wish to explore investment opportunities in Malaysia, please contact MIDA for more information as well as assistance in your decision-making (please see the last page of contact details of MIDA's headquarters and state and overseas offices).*

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# SPECIALISED TECHNICAL SUPPORT SERVICES

Investments are encouraged in the following areas:

- Machinery maintenance and related technical services;
- Occupational safety and health management services;
- Accreditation and certification services;
- Testing and calibration services;
- Irradiation and gas sterilisation services for the medical devices industry;
- Clinical trials, bioavailability/bioequivalence or efficacy trials for the pharmaceutical industry; and
- Central Utility Facilities (CUF).

## 1. MACHINERY MAINTENANCE SERVICES

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Machinery maintenance services include periodic maintenance, troubleshooting, preventive maintenance, calibration, measurement and tools inspection. 'Machinery' is categorised as certificated or non-certificated machinery and both must be certified by Department of Occupational Safety (DOSHS). The installation of any machinery in a factory must also be approved by DOSHS.

Certificated machinery is classified into the following:

- Boilers (e.g. waste heat recovery boilers, steam generators)
- Unfired pressure vessels (e.g. air receivers, petrochemical treatment vessels)
- Passenger lifts and hoisting machinery

The design of certificated machinery must be approved by DOSHS, and the machinery must be tested before it is installed. A company intending to provide maintenance services for certificated machineries must also register with DOSHS.

A company providing maintenance services for non-certificated machineries is not required to register with DOSHS.

## **1.1 Licensing and Registration**

Applicants intending to provide machinery maintenance services are required to incorporate a company under the Companies Act, 2016.

### **Registration as Boiler and Unfired Pressure Vessel Repairers**

A company intending to repair steam boilers or unfired pressure vessels is required to register with DOSH as boiler and unfired pressure vessel repairers. Repair involves the cutting, welding, patching or riveting of any part of the steam boiler or vessel that is subject to stress induced by fluid pressure.

The Factories and Machinery Act, 1967 and the Factories and Machinery (Steam Boiler and Unfired Pressure Vessel) Regulations, 1970 stipulate the requirements for the maintenance of steam boilers or unfired pressure vessels.

DOSH will consider the following criteria for applications:

- Qualifications and experience of the technical personnel involved in repairing boilers and unfired pressure vessels.
- Procedures of repair.
- Design calculations of the repair area.

Applications should be submitted to DOSH headquarters.

DOSH officers will inspect the premises and interview key personnel to ascertain their knowledge and experience in the repair of boilers and unfired pressure vessels. Upon approval, the DOSH headquarters will issue an approval letter to the applicant. The registration will be valid for a period of one (1) year.

## **1.2 Equity Policy**

There is no specific equity condition for companies undertaking machinery maintenance services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

## **1.3 Specific Immigration Procedures**

A company providing machinery maintenance services in Malaysia may employ expatriates. The company must submit its application for Employment Pass to the Immigration Department.

## **2. OCCUPATIONAL SAFETY AND HEALTH MANAGEMENT SERVICES**

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'Occupational Health' is the maintenance of the physical, mental and social well being of workers in all occupations and the prevention of health risks brought about by adverse working conditions.

'Occupational Safety' is the physical environment of the workplace and the well being of the worker, and the creation of a conducive working environment through the adoption of safe work practices, procedures and Occupational Safety and Health Management Systems.

Competent persons certified by DOSH including Assessors, Hygiene Technicians and Occupational Health Doctors must carry out the occupational safety and health management services.

'An Assessor' evaluates threats to health arising from the use of chemicals at work.

'A Hygiene Technician' inspects, examines and tests engineering control equipment (e.g. general ventilation equipment) installed in a place of work.

'An Occupational Health Doctor' is a medical practitioner registered with the Director General of DOSH to conduct the medical surveillance of employees.

## **2.1 Licensing and Registration**

Any person intending to provide occupational safety and health management services is required to incorporate a company under the Companies Act, 2016.

### **General Requirements**

Any person intending to be registered as an Assessor or Hygiene Technician or an Occupational Health Doctor must fulfil the following requirements:

- A Malaysian citizen or, if a foreign resident, holds a valid Malaysian work permit
- At least 21 years of age at the time of application
- A healthy person and of good character
- Not guilty of any act of professional negligence as an engineer or a medical practitioner
- Not convicted of any offence under the Act or regulations made there under
- Not convicted of an offence under any law and sentenced to more than one (1) year's imprisonment or fined more than RM2,000

#### **(a) Registration as Assessors**

A person applying to be registered with DOSH as an Assessor must also fulfil the following requirements:

- (i) A certificate as an industrial hygienist recognised by the American Board of Industrial Hygiene or by any other accredited certification body recognised by DOSH.

Passed the examination for assessors conducted by National Institute of Occupational Safety and Health (NIOSH).

Or

- (ii) A degree or postgraduate diploma in occupational safety and health, occupational safety, occupational health or industrial/occupational hygiene recognised\* by the Government of Malaysia.

A minimum of one (1) year's practice in occupational safety and health.

Conducted a chemical health risk assessment or has successfully attended the course for assessors on chemical health risk assessment conducted by NIOSH or by any training provider recognised by DOSH.

Passed the examination for assessors conducted by NIOSH.

Or

A degree in medicine, engineering, physics, chemistry, biochemistry, ergonomics or natural and applied sciences, recognised\* by the Government of Malaysia.

A minimum of three (3) years' practice in occupational safety and health.

Conducted a chemical health risk assessment or has successfully attended the course for assessors on chemical health risk assessment conducted by NIOSH, or by any training provider recognised by DOSH.

Or

- (iii) A diploma in engineering, physics, chemistry, biochemistry, ergonomics or natural and applied sciences recognised\* by the Government of Malaysia.

A minimum of five (5) years' practice in occupational safety and health.

Conducted a chemical health risk assessment or has successfully attended the course for assessor on chemical health risk assessment conducted by NIOSH, or by any training provider recognised by DOSH.

Passed the examination for assessors conducted by NIOSH.

Or

- (iv) A diploma in medical, engineering, physics, chemistry, biochemistry, ergonomics or natural and applied sciences recognised\* by the Government of Malaysia.

A minimum five (5) years' practice in occupational safety and health.

Conducted a chemical health risk assessment or has successfully attended the course for assessor on chemical health risk assessment conducted by NIOSH, or by any training provider recognised by DOSH.

Passed the examination for assessors conducted by NIOSH.

Or

- (v) Degree of Science (Environmental & Occupational Health) from UPM - issued since January 2006.

A minimum of one (1) year's practice in occupational safety and health.

Passed the examination for assessors conducted by NIOSH.

\*Persons with qualifications that are not recognised by the Government of Malaysia may be registered on condition that they, in addition to the respective conditions under paragraphs (ii), (iii) or (iv), have passed the examination for assessors conducted by NIOSH.

Applications should be submitted to DOSH headquarters. An interview with the applicant will be conducted by DOSH. Successful applicants will be registered as Assessors for a maximum period of three (3) years.

To renew their registrations, applicants must fulfil the following requirements:

- Engaged in the work activities of an Assessor every year
- Undergone education in the field of occupational safety and health

#### **(b) Registration as Hygiene Technicians**

A person applying to be registered with DOSH as a Hygiene Technician must:

- (i) Possess a diploma in occupational or industrial hygiene that is recognised by the Government of Malaysia. Or
- (ii) Possess a valid DOSH certificate of competency in the monitoring of mineral dust exposures [i.e. approved as a Competent Person under the Factories and Machinery (Mineral Dust) Regulations, 1989].

Possess a valid DOSH certificate of competency in the inspection, examination and testing of local exhaust ventilation systems [i.e. approved as a Competent Person under the Factories and Machinery (Asbestos Process) Regulations, 1986, or the Factories and Machinery (Mineral Dust) Regulations, 1989 to conduct the inspection, examination and testing of local exhaust ventilation systems].

Or

- (iii) Possess a valid DOSH certificate of competency in the monitoring of mineral dust exposures, or a valid certificate for competency in the inspection, examination and testing of local exhaust ventilation systems.

Passed the examination for a Hygiene Technician conducted by NIOSH.

Or



- (iv) Possess the Sijil Pelajaran Malaysia (SPM) with at least a credit in Science subjects and Mathematics.

Completed at least one (1) year's practice in occupational safety and health.

Attended a course for Hygiene Technicians conducted by NIOSH, or any training provider recognised by DOSH.

Passed the examination for Hygiene Technicians conducted by NIOSH.

Although a competent person who does not possess the two (2) competencies will not be registered as a Hygiene Technician, he may be allowed by the Director General to carry out the duties of a Hygiene Technician for the respective competencies for a period of not more than one (1) year.

Applications should be submitted to DOSH headquarters. An interview with the applicant will be conducted by DOSH. Successful applicants will be registered as Hygiene Technicians for a maximum period of three (3) years.

For renewal of registrations, an applicant must fulfil the following requirements:

- Engaged in the work activities of a Hygiene Technician every year
- Undergone education in the field of occupational safety and health

### **(c) Registration as Occupational Health Doctors**

A person applying to be registered with DOSH as an Occupational Health Doctor must:

- Possess at least a postgraduate diploma in occupational health or occupational medicine that is recognised by the Government of Malaysia or by the Director General; Or
- Successfully completed an Occupational Health Doctor training course that is approved by the Director General, and has passed the Occupational Health Doctor's examination conducted by NIOSH.

Applications should be submitted to DOSH headquarters. An interview with the applicant will be conducted by DOSH. Successful applicants will be registered as Occupational Health Doctors for a maximum period of three (3) years.

Applicants intending to renew their registration must fulfil the following requirements:

- Engaged in the work activities of an Occupational Health Doctor every year
- Undergone education in the field of occupational safety and health

## **2.2 Equity Policy**

There is no specific equity condition for companies undertaking occupational safety and health management services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

## 2.3 Specific Immigration Procedures

A company intending to employ expatriates as Assessors and Hygiene Technicians should forward its application for Employment Passes to the Immigration department.

A company requiring the services of foreign Occupational Health Doctors must first obtain the approval of the Malaysian Medical Council (MMC) before applying for Employment Passes to the Immigration Department.

## 3. ACCREDITATION AND CERTIFICATION

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The Department of Standards Malaysia (STANDARDS MALAYSIA) is an agency under the Minister of Science, Technology and Innovation (MOSTI). It was established on the 28 August 1996 and is governed by the Standards of Malaysia Act, 1996. The Act governs matters relating to standardisation and accreditation activities in Malaysia. STANDARDS MALAYSIA is the National Standards Body (NSB) and National Accreditation Body (NAB). The Standards of Malaysia Act, 1996 (amendment 2012), has mandated STANDARDS MALAYSIA to provide accreditation services to organisations outside Malaysia.

The primary task of STANDARDS MALAYSIA with respect to accreditation is to be responsible for the assessment and accreditation of conformity assessment bodies (CABs). CAB, as defined by the MS ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, is a body that performs conformity assessment services and that can be the object of accreditation, such as laboratories, certification bodies and inspection bodies. The Accreditation Division of STANDARDS MALAYSIA carries out this specific task.

Currently there are three accreditation schemes available;

- (i) Skim Akreditasi Makmal Malaysia (SAMM)
- (ii) Scheme for the Accreditation of Certification Bodies (the ACB Scheme)
- (iii) Malaysia Inspection Bodies Accreditation Scheme (MIBAS)
- (iv) Good Laboratory Practice Compliance Programme (GLP CP)
- (v) Malaysia Proficiency Testing Provider Accreditation Scheme (MyPTP)

STANDARDS MALAYSIA is also one of the Compliance Monitoring Authority appointed by the Government of Malaysia on 13 February 2008 for test facilities conducting non-clinical health and environmental safety studies for pesticide, industrial chemical, feed additives and biotechnology (non-pharmaceutical) products.

### 3.1 Licensing and Registration

#### (a) Scheme for the Accreditation of Certification Bodies (ACB Scheme)

##### Approvals for Establishment

Conformity assessment bodies are required to incorporate a company under the Companies Act, 2016 or legally registered for organisation outside Malaysia.

The ACB Scheme provides an assurance of the competence, impartiality and integrity of certification bodies doing their day-to-day work for certification. This scheme offers accreditation to any certification body, governmental or privately owned, that has demonstrated compliance with published criteria and requirements of STANDARDS MALAYSIA. Currently, the ACB scheme offers accreditation to certification bodies operating certification of:

- Quality Management Systems (QMS)
- Environmental Management Systems (EMS)
- Product Certification
- Occupational Safety and Health (OSH) Management Systems
- Information Security Management Systems (ISMS)
- HACCP Systems (HACCP)
- Forest Management Certification (FMC)
- Food Safety Management Systems (FSMS)
- Certification of Persons (PERSONNEL)
- Work Environmental Management Systems (WEMS)
- Oil Palm Supply Chain Management Systems (OPSC)
- Medical Device Quality Management System (MDQMS)
- Energy Management System (EnMS)
- Good Manufacturing Practice for Food (GMP)

#### Requirements for Certification Bodies

Companies intending to be recognised as accredited certification bodies of all the programmes mentioned above are required to comply with the accreditation criteria as follows:

- (i) MS ISO/IEC 17021:2011, "Conformity Assessment-Requirements for bodies providing audit and certification of management systems";
- (ii) MS ISO/IEC Guide 65:1996, "General Requirements for Bodies Operating Product Certification System";
- (iii) MS ISO/IEC 27006:2007, "Information Technology - Security Techniques-Requirements for bodies providing audit and certification of information security management systems";
- (iv) MS ISO/IEC 17024:2003, "Conformity Assessment – General Requirements for Bodies Operating Certification of Persons";
- (v) ISO/TS 22003, "Food Safety Management Systems - Requirements for bodies providing audit and certification of food safety management systems".

#### International Recognition

STANDARDS MALAYSIA has gained international recognition through the acceptance into the Pacific Accreditation Cooperation (PAC), Multilateral Recognition Arrangement (MLA) and acceptance into International Accreditation Forum (IAF) MLA as described below. It has also established close linkages with its counterparts throughout the world through the IAF and PAC.

- (i) International Recognition for Quality Management Systems (QMS)
  - Pacific Accreditation Cooperation (PAC) Multilateral Recognition Arrangement (MLA) on 5 November 1998
  - International Accreditation Forum (IAF) MLA on 29 September 1999

- (ii) International Recognition for Environmental Management Systems (EMS)
  - Pacific Accreditation Cooperation (PAC) Multilateral Recognition Arrangement (MLA) on 31 December 2005
  - International Accreditation Forum (IAF) MLA on 9 February 2006
- (iii) International Recognition for product certification (PC)
  - Pacific Accreditation Cooperation (PAC) Multilateral Recognition Agreement (MLA) on 16 June 2009
  - International Accreditation Forum (IAF) MLA on 9 July 2009

## **(b) Malaysia Laboratory Accreditation Scheme (SAMM)**

### Requirements for Testing and Calibration Laboratories

A company intending to operate an internationally recognised testing and calibration laboratory is required to comply with the International Standard MS ISO/IEC 17025 or MS ISO 15189 (for medical testing laboratory) and SAMM policies/requirements.

SAMM accreditation system is open to any testing or calibration laboratory that wants to be recognized as competent, operating/compliance to MS ISO/IEC 17025 “General requirements for the competence of calibration and testing laboratories” or MS ISO 15189 “Medical Laboratories-Particular Requirements for Quality and Competence” criteria/requirements for both its technical capability and competence and quality management system.

### International Recognition

The primary objective of SAMM is to provide a credible accreditation service to testing and calibration laboratories including medical testing laboratories such that ultimately SAMM endorsed test reports and calibration certificates are accepted internationally. The accepted mechanism for recognition is by means of the Mutual Recognition Arrangements framework of the International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Laboratory Accreditation Co-operation (APLAC).

STANDARDS MALAYSIA attained signatory status for Asia Pacific Laboratory Accreditation Co-operation (APLAC) MRA on

- 14 November 2002 (Testing),
- 13 November 2003 (Calibration), and
- 13 September 2006 (Medical testing)

STANDARDS MALAYSIA attained signatory status for International Laboratory Accreditation Co-operation (ILAC) MRA on

- 16 Jan 03 (Testing), and
- 19 Nov 03 (Calibration)

The scheme is accessible to all laboratories in Malaysia, performing first, second or third party testing, measurement and calibration. These may include laboratories from the private and public sectors, commercial testing services, in-house testing facilities, site testing operation or mobile testing facilities. Participation in the scheme is voluntary. However, users of test or calibration services throughout the world are increasingly demanding that testing or calibration data should be from those complying with MS ISO/IEC 17025 or MS ISO 15189 requirements.

Applications for SAMM accreditation of testing and calibration laboratories should be submitted to the Accreditation Division of STANDARDS MALAYSIA. The certificate of Accreditation issued to accredited laboratories valid for three (3) years.

Laboratories services may fall under the following fields of testing and calibration:-

**Fields of Testing:**

**1. CHEMICAL**

Chemical tests and analysis on products and materials.

**2. BIOLOGICAL**

Biological, microbiology and biomedical, testing and measurement, including examinations of food, drugs and pharmaceuticals.

**3. ELECTRICAL**

Testing of electrical and electronic components, instruments and equipment including commercial and industrial equipment and household appliances.

**4. THERMAL**

Including thermal characteristics of building materials, fire testing such as tests evaluating fire resistance, ignitability, flammability, etc., of products and materials.

**5. MECHANICAL**

Mechanical/physical and metallurgical testing of materials and products. Includes tests such as tensile, rupture, elongation, elasticity, hardness and fatigue on materials.

**6. NON-DESTRUCTIVE TESTING (NDT)**

Examination of materials, components, and assemblies to detect defects without damaging the material, component or assembly. Tests include radiography, ultrasonic, penetrant, magnetic particle and eddy current.

**7. RADIOACTIVITY TESTING**

Radioactivity test and analysis on materials and samples.

**8. HOUSEHOLD PESTICIDES**

Includes testing on the following scopes; mosquito mats and electric liquid vaporizer, space spray aerosol, residual spray aerosol, direct spray aerosol, mosquito coils, cockroach baits, mosquito skin repellent, household rat baits, smokeless paper mosquito coils, mosquito gels and other similar products.

**9. TOXICITY**

Testing for chemical products, manufactured products, cosmetic and skin care products, medical devices and also wastes and environmental samples.

**10. ELECTROMAGNETIC COMPATIBILITY (EMC)**

Testing for electromagnetic compatibility (EMC) including electromagnetic disturbance test and immunity test.

**11. VETERINARY**

Includes testing on the following scopes; bacteriology, mycology, serology, virology, parasitology, pathology, molecular biology, clinical pathology, immunology, prions, chemistry, feed analysis and animal nutrition.

**12. GENETICALLY MODIFIED ORGANISM (GMO)**

Analysis for detection and quantification of GMO covers both DNA and protein based methods.

**13. NUCLEIC ACID**

Requirements for accreditation of laboratories involved in nucleic acid testing in a broad variety of sample that provide services in particular fields related to molecular biology and/or genetic analysis.

**14. DNA PROFILING**

Comprises DNA Profiling for forensic DNA profiling and paternity testing using DNA method.

**15. FIRE ACCELERANTS**

Includes testing for fire accelerants in fire debris for forensic science testing laboratories.

**16. DOCUMENT EXAMINATION**

Requirements for accreditation of questioned document examination for forensic science testing laboratories.

**17. INFORMATION TECHNOLOGY SECURITY EVALUATION AND TESTING: COMMON CRITERIA**

Requirements on functional and assurance of ICT products and systems, which provide a common baseline for security evaluation.

**Fields of Calibration:**

**1. HEAT AND TEMPERATURE**

Including heat, temperature and humidity measuring equipment.

**2. ELECTRICAL**

Including the calibration of electrical and electronic instruments and equipment.

**3. MASS AND MASS-RELATED QUANTITIES**

Including measurement of mass, density, pressure, force, hardness, viscosity, flow, and volume and the examination of machines and instruments used in these measurements.

**4. OPTICAL AND PHOTOMETRIC**

Including measurements made with and on optical and photometric equipment and instruments: measurement of colour and surface smoothness (reflectance, gloss); measurements involving visible (light) and near-visible (infrared, ultra violet) wavelength of radiation.

**5. DIMENSIONAL**

Including various length and dimensional calibration works.

## **6. ACOUSTIC & VIBRATION**

Including measurements of environmental noise and mechanical vibration, calibration of acoustic and vibration measuring equipment, acoustic and vibration characteristics of materials and structures, audiometry, measurement of sound power, acoustic and vibration performance tests and dynamic balancing.

## **7. RADIOACTIVITY**

Including calibration of radiation measuring equipment.

### **Fields of Medical Testing:**

#### **1. ANATOMICAL PATHOLOGY (CYTOPATHOLOGY)**

- Gynaecological Cytopathology (GYN Cytopathology)
- Non-Gynaecological Cytopathology (Non-GYN Cytopathology)
- Fine Needle Aspiration Cytology (FNAC)

#### **2. ANATOMICAL PATHOLOGY (HISTOPATHOLOGY)**

- Diagnostic Histopathology
- Intraoperative Frozen Section

#### **3. CHEMICAL PATHOLOGY**

- General Chemistry [General Chemistry for Blood, Urine and Body Fluids; Blood Gases and Co-Oximetry; Therapeutic Drug Monitoring; Limited Clinical Toxicology (Paracetamol, Salicylate, Benzodiazepine, Paraquat)]
- Toxicology (Clinical Toxicology, Drug of Abuse Testing, Heavy Metals and Trace Elements)
- Special Chemistry (Hormone and Metabolic Testing, Tumor Markers, Biogenic Amines and Special Protein, Special Lipids and Other Tests)
- Biochemical Genetic Testing

#### **4. HAEMATOLOGY**

- General Haematology
- Coagulation
- Immunohaematology
- Molecular Haematology
- Flow Cytometry for Haematological Applications

#### **5. MEDICAL MICROBIOLOGY**

- Isolation and Identification of Bacteria
- Isolation and Identification of Fungi
- Isolation and Identification of Mycobacteria
- Antimicrobial Susceptibility Testing
- Direct Examination and Identification of Parasites
- Antigen Detection for the Diagnosis of Infections
- Nucleic Acid Amplification and/or Detection for the Diagnosis of Infections
- Serological Diagnosis of Infections
- Immunological Diagnostics

## **6. MEDICAL MICROBIOLOGY (VIROLOGY)**

- Viral Serology
- Viral Isolation
- Non-Culture Methods for Detection of Viral Pathogens (Antigen Detection; Nucleic Acid Detection)

## **7. ASSISTED REPRODUCTIVE TECHNOLOGY (ART)**

- Semen Analysis
- Sperm Preparation
- Sperm Cryopreservation
- In Vitro Fertilization (IVF)
- Gamete Intra Fallopian Transfer (GIFT)
- Intra Cytoplasmic Sperm Injection (ICSI)
- Assisted Hatching
- Oocyte/Embryo/Blastocyst Cryopreservation

## **8. CYTOGENETICS**

- Prenatal Cytogenetics
- Postnatal Cytogenetics
- Cancer Cytogenetics/Oncology
- Molecular Cytogenetics (FISH)

### **(c) Malaysia Inspection Bodies Accreditation Scheme (MIBAS)**

#### Requirements for Inspection Bodies

A company intending to operate an internationally recognised inspection body is required to comply with the International Standard MS ISO/IEC 17020 and MIBAS policies.

MIBAS is national inspection bodies accreditation scheme and is multi-disciplinary in its scope of accreditation activities. Inspection body accreditation is a formal accreditation of the competence of an inspection body and its inspectors.

Inspection is the examination of a product design, product service, process or plant and determination of conformity with specific requirements or on the basis of professional judgement. This broad definition indicates the variety of inspection activities that exist. Example field of inspections offered by MIBAS are NDT inspection, vehicle inspection, welding inspection and product inspection.

Accreditation scheme for inspection bodies is applicable to all organisations providing inspection activities. With accreditation, inspection bodies receive formal recognition of their expertise, competence, quality systems, procedures, equipment and facilities based on independent assessment.

Inspection Body Accreditation allows an inspection body to benchmark its work practices against world's best practice. Manufactures may also use it to offer clients assurance of their own in-house inspection practices.

Applications for MIBAS accreditation should be submitted to the Accreditation Division of STANDARDS MALAYSIA. Certificate of Accreditation is valid for three (3) years.



## **(d) Good Laboratory Practice (GLP) Compliance Programme**

### Requirements for Test Facilities

GLP CP is a voluntary programme open to test facilities conducting non-clinical health and environmental safety studies, for purpose of registering and/or licensing on test item contained in products of the following categories:

- (i) Industrial chemicals;
- (ii) Pesticides;
- (iii) Feed additives;
- (iv) Biotechnology (non-pharmaceutical); and
- (v) Others (such as waste management, plant protection).

The purpose of the non-clinical safety studies of test items is to obtain data on their properties and/or their safety with respect to human health and the environment. Non-clinical health and environment safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses and in the field.

GLP Compliance Programme is intended to ascertain whether test facilities have implemented requirements as described in documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring according to the Malaysian legal framework.

### **Fees and Assessment Charges**

A nominal fee is imposed for each application and assessment. Application fee is non-refundable. An application is considered lapsed if the applicant fails to obtain accreditation within two years from the date of acceptance of application. The accreditation fees / charges are however subject to review by STANDARDS MALAYSIA from time to time.

### **3.2 Equity Policy**

There is no specific equity condition for companies undertaking accreditation services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

### **3.3 Specific Immigration Procedures**

A quality and standard certification services company requiring the services of expatriates is required to submit its application for Employment Passes to the Immigration Department.

Upon approval, it should forward its application for Employment Passes to the Immigration Department for endorsement.

## **4. TESTING AND CALIBRATION SERVICES**

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Companies providing testing and calibration services complying with ISO/IEC Guide 17025 are able to demonstrate that they operate a quality system, which are technically competent and able to generate technically valid test data and results.

Laboratories services may fall under the following fields of testing and calibration:

**(a) Testing**

- Biological
  - Biological, microbiological and biochemical testing and measurement, including examination of foods, drugs and pharmaceuticals, and testing for medical and veterinary purposes
- Chemical
  - Chemical tests and analysis on products and materials
- Electrical
  - Testing of electrical and electronics components, instruments and equipment including commercial and industrial equipment and household appliances
- Fire
  - Tests evaluating fire resistance, ignitability, flammability etc. of products and materials
- Mechanical
  - Mechanical and physical testing of materials and products include metallurgical tests to determine the structures by techniques such as radiography, ultrasonics, penetrants, magnetic particles and eddy currents

**Non-Destructive Testing (NDT)**

Examination of materials, components, and assemblies to detect defects without damaging the material, component or assembly. Tests include radiography, ultrasonics, penetrants, magnetic particle and eddy currents.

**Radioactivity Testing**

Radioactivity test and analysis on materials and sample.

**Household Pesticide**

Includes testing on the following scopes; mosquito mats and electric liquid vaporizer, space spray aerosol, residual spray aerosol, direct spray aerosol, mosquito coils, cockroach baits, mosquito skin repellent, household rat baits, smokeless paper mosquito coils, mosquito gels and other similar products.

**Toxicity**

Testing for chemical products, manufactured products, cosmetic and skin care products, medical devices and also wastes and environmental samples.

**Electromagnetic Compatibility (EMC)**

Testing for electromagnetic compatibility (EMC) including electromagnetic disturbance test and immunity test.

**Veterinary**

Includes testing on the following scopes; bacteriology, mycology, serology, virology, parasitology, pathology, molecular biology, clinical pathology, immunology, prions, chemistry, feed analysis, animal nutrition.

### **Genetically Modified Organism (GMO)**

Analysis for detection and quantification of GMO covers both DNA and protein based methods.

### **Nucleic Acid**

Requirements for accreditation of laboratories involved in nucleic acid testing in a broad variety of sample that provide services in particular fields related to molecular biology and/or genetic analysis.

### **DNA Profiling For Forensic Science**

Comprises of DNA Profiling for forensic DNA profiling and paternity testing using DNA method.

### **Analysis Of Accelerant In Fire Debris For Forensic Science**

Includes testing for fire accelerants in fire debris for forensic science testing laboratories.

#### **(b) Calibration**

- Heat and temperature measurement
- Mechanical, mass and force measurement
- Electrical measurement
- Flow pressure, viscosity and density measurement
- Length and dimension measurement
- Optical And Photometric Measurements
- Acoustic & Vibration Measurement
- Radioactivity Measurement

#### **4.1 Licensing and Registration**

Testing and calibration laboratories are required to incorporate a company under the Companies Act, 2016.

#### **(a) Accreditation under the Laboratory Accreditation Scheme of Malaysia (SAMM) with the Department of Standards Malaysia**

Please refer to section 3.1 (b) for information on SAMM.

## **(b) Licence to Grade Cocoa**

A company intending to provide grading services for cocoa must obtain a Licence to Grade Cocoa from the Malaysian Cocoa Board (MCB). The requirements for the grading of cocoa are stipulated under the Malaysian Cocoa Act, 1988, Cocoa Regulations (Licensing and Grading), 1991 and Specifications for Grading of Malaysian Cocoa Bean (MS 293), 1995.

This licence is required for a registered company which intends to provide quality grading service for cocoa bean and products both for export and import as stipulated under the Malaysian Cocoa Board Regulation, 2011. A grading agent grades cocoa beans and issues grading certificates for export purposes.

To obtain a Licence to Grade Cocoa from MCB, grading agents must fulfil the following conditions:

- Provide the requisite facilities such as machinery and equipment for cocoa grading
- Employ at least two (2) graders of cocoa beans who hold at least the Malaysian Certificate of Education (the applicant should attend the cocoa grading course and sit for the exam, MCB will issue the licence to those who pass the exam), or Sijil Pelajaran Malaysia

Conditions to apply for this licence are as follows:

- A registered company
- Employ at least one (1) trained and qualified grader
- Equipped with adequate grading tools, equipments and facilities
- Tenure of licence for 1 year and is renewable
- Chargeable Fee of RM1,000 per year

Application of licence should be made through Online Services via [www.bless.gov.my](http://www.bless.gov.my) on Malaysian Cocoa Board website [www.koko.gov.my](http://www.koko.gov.my)

## **4.2 Equity Policy**

There is no specific equity condition for companies undertaking testing and calibration services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

## **4.3 Specific Immigration Procedures**

A company providing technical testing and quality control services that require the services of expatriates should forward its application for Employment Passes to the Immigration Department.

## 5. IRRADIATION AND GAS STERILISATION SERVICES

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'Irradiation' is the exposure of products to an ionising ray (beta ray, gamma ray and X-ray) to reduce/eliminate harmful bacteria, viruses and spores in products.

'Gas Sterilisation' involves the exposure of products to a sterilising gas such as ethylene oxide.

### 5.1 Licensing and Registration

An applicant intending to provide irradiation and gas sterilisation services is required to incorporate a company under the Companies Act, 2016.

#### (i) Licences for Radioactive Material and Irradiating Apparatus

A company intending to provide irradiation services for the medical devices industry is required to apply to Atomic Energy Licensing Board (AELB) for the following licences:

- Class A Licence - licence to manufacture, trade in, produce, process, and purchase, own, possess, use, transfer, handle, sell or store radioactive material
- Class C Licence - licence to manufacture, trade in, produce, process, purchase, own, possess, use, transfer, handle, sell or store irradiating apparatus

The management and operation of irradiation services are governed by the following Acts and Standards:

- Atomic Energy Licensing Act, 1984
- Atomic Energy Licensing Act, 1984: Radiation Protection (Licensing) Regulations, 1986
- Atomic Energy Licensing Act, 1984: Radiation Protection (Basic Safety Standards) Regulations, 1988
- Malaysian Standards (MS 838): Code of Practice for Radiation Protection (Medical X-Ray Diagnosis)

To obtain a Class A or Class C licence, an applicant must have competent persons to carry out the irradiating activities, and possess adequate equipment, facilities and procedures to protect the health and safety of employees.

#### (a) Class A Licence

To obtain a Class A Licence, the applicant must fulfil the following requirements:

##### **Radiation Protection Officer (RPO)**

The applicant must employ a Radiation Protection Officer (RPO) to deal with radiation gauging or X-ray gauging. If there is more than one candidate for the RPO, the applicant must select one of them to be the RPO and employ the rest as supervisors. The promotion of a supervisor to an RPO must be approved by AELB.

## **Radiation Protection Consultant Services**

If an RPO is unavailable, the applicant may hire a Radiation Protection Consultant from the authorised Consultant Agency approved by AELB, to take over the RPO duties. A Radiation Protection Consultant may be engaged for a maximum period of six (6) months, after which the company must employ its own RPO.

## **Operator (Radiation Gauges & X-ray Gauges)**

An applicant intending to employ workers to handle facilities or radiation gauges or X-ray gauges equipment must register them with AELB as radiation workers.

Applications for Class A Licences should be submitted to the Assessment and Licensing Division of AELB's headquarters. A Class A Licence is valid for a period of one (1) to three (3) years.

### **(b) Class C Licence**

To obtain a Class C Licence, the applicant must fulfil the following requirements:  
Person Responsible for the Licence

The licensee must possess a current Annual Practising Certificate (APC). The address of the practice as specified in his/her current APC should be the same as the address where the apparatus is to be used or stored.

#### **Person Operating the Apparatus**

- A qualified radiographer, full-time or part-time
- A worker trained in the programmes approved by the licensing authority (inclusive of training already carried out). The training syllabus and facilities will be vetted before approval is given.

#### **Irradiating Apparatus**

- The irradiating apparatus used must be of the approved type
- In an institution in which there is only one irradiating apparatus, the apparatus must not be more than 11 kW power (100 mA at 110 kV). The quality of radiographs will be increased and radiation hazards reduced with the use of a high power apparatus.

Applications for Class C Licences should be submitted to the Assessment and Licensing Division of AELB, which will forward the applications to the Ministry of Health (MOH) for processing and approval. The Class C Licence is valid for one (1) to three (3) years.

## 5.2 Equity Policy

There is no specific equity condition for companies undertaking irradiation and gas sterilisation services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

## 5.3 Specific Immigration Procedures

A company applying for incentives for gas sterilisation and irradiation services and requiring expatriate posts should submit its applications to MIDA.

A company not applying for incentives for gas sterilisation and irradiation services and which require expatriate posts should forward its applications for Employment Passes to the Immigration Department.

## 5.4 Tax Incentives

A company providing gas sterilisation and irradiation services can be considered for the following incentives:

### (i) Pioneer Status

Companies undertaking the above activities are eligible for Pioneer Status which provides a tax exemption on 70% of the statutory income for a period of five (5) years.

Or

### (ii) Investment Tax Allowance

As an alternative to Pioneer Status, a company may apply for Investment Tax Allowance (ITA). The ITA provides for an allowance of 60% on the qualifying capital expenditure incurred within five (5) years. The allowance can be offset against 70% of the statutory income for each year of assessment. Any unutilised allowances can be carried forward to subsequent years until fully utilised.

Applications should be submitted to MIDA.

### (iii) Exemption from Import Duty on Raw Materials/Components

Full exemption from import duty can be considered for imported raw materials/components used directly to provide irradiation and gas sterilisation services.

Applications should be submitted to MIDA

### (iv) Exemption from Import Duty on Machinery and Equipment

Full exemption from import duty can be considered for imported machinery and equipment not available locally and used directly to provide irradiation and gas sterilisation services.

Applications should be submitted to MIDA.

## **6. CLINICAL TRIALS, BIOAVAILABILITY/BIOEQUIVALENCE OR EFFICACY TRIALS FOR THE PHARMACEUTICAL INDUSTRY**

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### **Definition of clinical trial/study**

Clinical trial/study is any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

In Malaysia, all clinical trials/studies should be conducted in compliance with Malaysian Guidelines for Good Clinical Practice (GCP), Current Edition and the regulatory requirements. GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

### **6.1 Licensing and Registration**

#### **Approval to conduct clinical trials in Malaysia**

Anyone who intends to conduct clinical trial in Malaysia is required to obtain the following approval before the commencement of clinical trial:

- (i) Approval from Independent Ethics Committee (IEC)/Institutional Review Board (IRB)
- (ii) Regulatory approval

#### **(i) Approval from IEC/IRB**

Ethical approval must be obtained from Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia for clinical trials that are intended to be conducted on a Ministry of Health facilities/institution (Ref. Circular from Director General of Health Malaysia Bil.9/2007). Ethical approval from other recognised IEC/IRB in the country must be obtained if the clinical trials are to be conducted in non Ministry of Health facilities/institution. However, non Ministry of Health facilities/institutions may use the MREC if they do not have their own IEC/IRB.



## **(ii) Regulatory Approval**

An applicant is required to make an application for clinical trial import licence (CTIL) or Clinical Trial Exemption (CTX) when the clinical trial involves a product that meets criteria of a product as stipulated in section 2.2.3. Application for CTIL and CTX should be submitted to the National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia.

### **(a) CTIL**

A licence authorising the licensee to import any product for the purposes of clinical trials, notwithstanding that the product is not a registered product (Regulation 12(1) (c), Control of Drugs and Cosmetics Regulations, 1984).

### **(b) CTX**

A permit that authorises any person who wishes to manufacture any product solely for the purpose of producing samples for clinical trials (Regulation 15(6), Control of Drugs and Cosmetics Regulations, 1984).

## **Products that require CTIL/CTX**

Prior to importation/manufacturing product locally, the investigator or sponsor/ Clinical Research Organisation (CRO) with a permanent address in Malaysia is required to apply for CTIL/CTX from the Drug Control Authority (DCA). The following products will require a CTIL/CTX:

- (i) Products including placebo which are not registered with the DCA and are intended to be imported for clinical trial purpose;
- (ii) Products with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form and when used for unapproved indication/when used to gain further information about an approved use for clinical trial purpose;
- (iii) A traditional product with a marketing authorisation with indication for 'traditionally used' when used for unapproved indication/therapeutic claims for clinical trial purpose; and
- (iv) An unregistered product including placebo manufactured locally for the purpose of clinical trial.

For more information on Application for Clinical Trial Import Licence and Clinical Trial Exemption, please refer to Guidelines for the Application of Clinical Trial Import Licence and Clinical Trial Exemption, Edition 6.3, visit [www.npra.moh.gov.my](http://www.npra.moh.gov.my)

The Independent Review Boards/Institutional Ethics Committee (IRBs/IECs) of the respective universities, private sectors/hospitals and the Medical Research and Ethics Committee (MREC) of the Ministry of Health Malaysia for the public hospital, Clinical Trial Import Licence (CTIL) from the National Pharmaceutical Control Bureau or relevant clinical trial permits are required for the operation.

## 6.2 Equity Policy

There is no specific equity condition for companies undertaking clinical trials, bioavailability/bioequivalence or efficacy trials. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

## 6.3 Specific Immigration Procedures

A company applying for incentives for clinical trials, bioequivalence/ bioavailability and efficacy trials for the pharmaceutical industry may apply for expatriate posts.

Applications should be submitted to MIDA.

Upon approval, companies should forward their applications for Employment Passes to the Immigration Department for endorsement.

## 6.4 Tax Incentives

A company providing clinical trials, bioequivalence/bioavailability and efficacy trials can be considered for the following R&D incentives:

### (i) Contract R&D Company

Companies providing clinical trials, bioequivalence, bioavailability or efficacy trials and are contract R&D companies, i.e. companies that provide R&D services in Malaysia to a company other than its related company, are eligible for:

- **Pioneer Status** with income tax exemption of 100% of the statutory income for five (5) years. Unabsorbed capital allowances as well as accumulated losses incurred during the pioneer period can be carried forward and deducted from the post pioneer income of the company; or
- **Investment Tax Allowance (ITA)** of 100% on the qualifying capital expenditure incurred within 10 years. The allowance can be offset against 70% of statutory income for each year of assessment. Any unutilised capital allowances can be carried forward to subsequent years until fully utilised.

Applications should be submitted to MIDA.

### (ii) R&D Company

A company providing clinical trials, bioequivalence, bioavailability or efficacy trials, and a R&D company, i.e. a company that provide R&D services in Malaysia to its related company or to any other company, is eligible for an ITA of 100% on the qualifying capital expenditure incurred within 10 years. The allowance can be offset against 70% of the statutory income for each year of assessment. Any unutilised allowances can be carried forward to subsequent years until fully utilised.

Should the R&D Company opt not to avail itself of the allowance, its related companies can enjoy double deduction for payments made to the R&D Company for services rendered.

Applications should be submitted to MIDA.

Eligibility criteria:

- Contract R&D and R&D companies that fulfil the following criteria can apply for the various incentives
- Research undertaken should be in accordance with the needs of the country and bring benefits to the economy
- At least 70% of the income of the company should be derived from R&D activities
- For manufacturing-based R&D, at least 50% of the workforce of the company must be appropriately qualified personnel performing research and technical functions
- For agriculture-based R&D, at least 5% of the workforce of the company must be appropriately qualified personnel performing research and technical functions

### **(iii) In-house Research**

A company that undertakes clinical trials, bioequivalence, bioavailability or efficacy testing, and in-house R&D to further its business may apply for an ITA of 50% on qualifying capital expenditure incurred within ten (10) years. The company can offset the allowance against 70% of its statutory income for each year of assessment. Any unutilised allowances can be carried forward to subsequent years until fully utilised.

Applications should be submitted to MIDA.

### **(iv) Incentives in Reinvestment of R&D Activities**

R&D companies/activities mentioned in categories (i) – (iii) are eligible for a second round of Pioneer Status for another five (5) years or an ITA for a further ten (10) years, where applicable.

### **(v) Additional Incentives for Research and Development**

#### **(a) Double Deduction for Research & Development**

- (i) A company can enjoy a double deduction on its revenue (non-capital) expenditure for research which is directly undertaken and approved by the Minister of Finance.
- (ii) Double deduction can also be claimed for cash contributions or donations to approved research institutes, and payments for the use of the services of approved research institutes, approved research companies, R&D companies or contract R&D companies.
- (iii) Approved R&D expenditure incurred during the tax relief period for companies granted Pioneer Status can be accumulated and deducted after the tax relief period.

- (iv) Expenditure on R&D activities undertaken overseas, including the training of Malaysian staff, will be considered for double deduction on a case-by-case basis.

Claims should be submitted to IRB.

## **7. INTEGRATED CENTRAL UTILITY FACILITIES**

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An Integrated Central Utility Facilities (ICUF) is defined as a facility capable of supplying utilities from a common complex at competitive prices and higher efficiency.

Core services provided by an ICUF include the supply, storage, handling and other services of energy, water and gas.

### **7.1 Licensing and Registration**

An investor intending to provide ICUF is required to incorporate a company under the Companies Act, 2016.

#### **(a) Type of Licence and Activities Governed Under Energy Commission**

The Electricity Supply Act, 1990, the Electricity Regulation, 1994, and the Energy Commission Act, 2001, govern activities that are related to the generation, transmission and distribution of electricity. There are two types of licences granted by the Energy Commission which are licence for public installation and licence for private installation as explained below:

“Public installation” means an installation operated by a licensee for the supply of electricity to any person other than the licensee:

Provided that the licensee may use electricity for his own purposes where the use is consistent with the terms of the licence.

“Private installation” means an installation operated by a licensee or owner solely for the supply of electricity to and use thereof on the licensee’s or owner’s own property or premises, or, in the case of a consumer, taking electricity from a public installation or supply authority, for use only on the licensee’s or owner’s property or premises.

The licences can be obtained from the Energy Commission. The requirement also applies to company involved in similar activities in the functioning of ICUF operations.

Application for public licence and private licence 5MW and above should be submitted to the Energy Commission headquarter in Putrajaya.

Whereas, for private licence less than 5MW should be submitted to the regional offices of Energy Commission respectively.

Further information regarding licensing and particular guidelines can be downloaded via [www.st.gov.my](http://www.st.gov.my)

**(b) Registration with EC as Competent Persons to Operate and Supervise the Installation of Electricity**

Activities related to the installation and operation of electricity are outlined in the Electricity Supply Act, 1990, the Electricity Regulation, 1994 and the Energy Commission Act, 2001. With regards to work and operation of an installation, no institution, no installation or electricity plant, includes those who are involved in similar activities for ICUF, shall be worked or operated except by or under the control of persons possessing a Certificate of Competency issued by the Energy Commission.

The competent person shall, unless exempted under the Act, be recommended by the following persons:

- (i) An Electrical Services Engineer;
- (ii) A Competent Electrical Engineer;
- (iii) A resident Competent Electrical Engineer.

Such Competent person must register himself with EC as a Competent Person to the installation in relation to his Certificate of Competency. The registrations as said above shall be valid for one (1) year and is renewable.

For further information regarding Competent Person please refer to EC's website at [www.st.gov.my](http://www.st.gov.my)

**(c) Approval for Waste Water Treatment Facilities and Effluent Discharge**

ICUF providers that operate facilities for treating waste water and effluents must apply for approval from the nearest DOE office, in accordance with the Environmental Quality Act, 1974.

**(d) Registration of Certificated Machinery with DOSH**

A company intending to install and operate unregistered certificated machinery such as boilers, unfired pressure vessels and hoists for ICUF operations is required to obtain prior written approval from DOSH. The machinery must first be registered with DOSH as certificated machinery.

Applications should be submitted to DOSH headquarters for design approval of unfired pressure vessels. Upon approval, applicants should seek permission to install and operate boilers, unfired pressure vessels and hoists from DOSH. The CF for boilers, unfired pressure vessels and hoists will be issued by DOSH.

**7.2 Equity Policy**

There is no specific equity condition for companies undertaking integrated central utility facilities services. However, the Government encourages joint-ventures between Malaysian and foreign investors to increase local participation in business.

### **7.3 Specific Immigration Procedures**

A company applying for incentives for ICUF services may apply for expatriate posts.

Applications should be submitted to MIDA.

Upon approval, companies should forward their applications for Employment Passes to the Immigration Department for endorsement



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