



MINISTRY OF HEALTH
SINGAPORE

Understanding MOH Clinic Inspection Process – How to Prepare for Outpatient Medical Service Inspection

Presented by Hospitals, Ambulatory Care and Research Regulations, Health Regulation Group
Ministry of Health
27 Sep 2025

Presentation Agenda

1. Background of HCSA

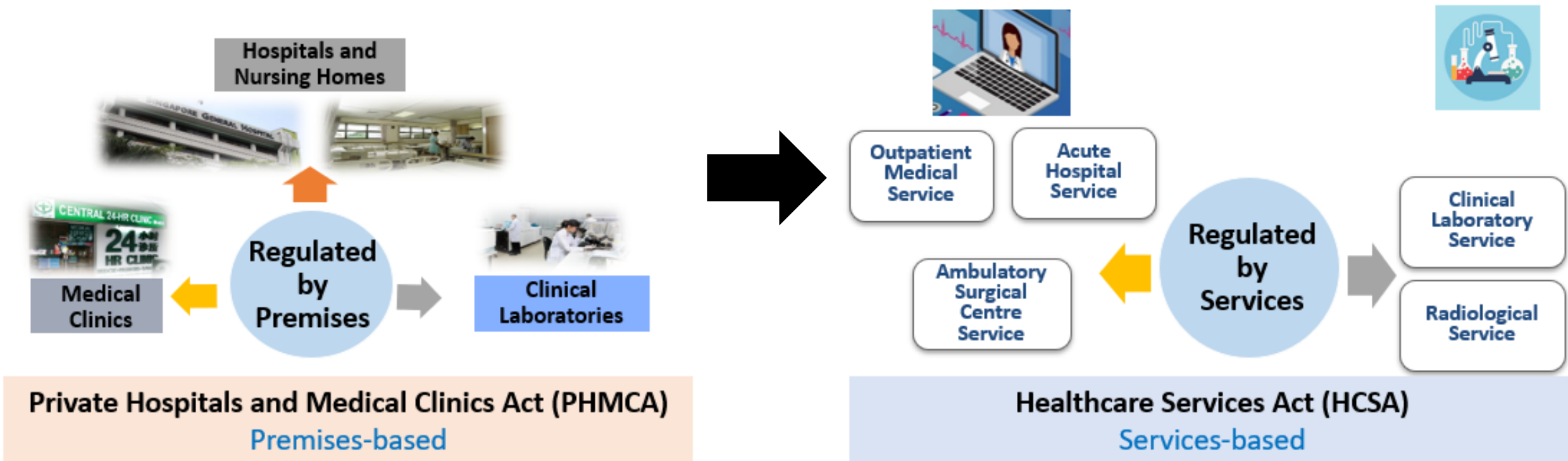
- What requirements must be complied under HCSA
- Mode of Service Delivery (MOSDs) and Specified Services (SS)
- Code of Practice

2. Understanding inspections

- Rationale
- What licensee(s) are to expect for inspections
- Further elaboration on identified requirements
- Basic Checklist

HCSA Licensing Regime

- **Background:**
 - HCSA took effect in Jan 2020 and replaces the PHMCA. It sets out a services-based approach to the licensing and regulation of health services.
- **Key Objectives:**
 - **Better safeguard patient safety and well-being;**
 - **Enable the development of new and innovative healthcare services.**



HCSA Licensing Regime

There are four Modes of Service Delivery (MOSDs) under the HCSA

Rationale: To better cater for emerging models of care and to futureproof HCSA, four different modes of service delivery were introduced for each Licensable Healthcare Service ("LHS").

4 Modes of Service Delivery



Permanent premises

e.g., brick-and-mortar premises such as GP or dental clinics



Temporary premises

no permanent premises
e.g., treating patients at home (home medical)



Remote

through virtual platforms or applications
e.g., virtual GP consultation



Conveyances

where the LHS is delivered from a vehicle
e.g., medical bus

1. Licensees need to **seek MOH's approval** for the applicable MOSD for each LHS.
2. Not all MOSDs are allowable for every LHS, and the allowable MOSDs for each LHS differs.
 - **Example:** For Outpatient Medical Services, approval is required for permanent premises, temporary premises, remote and conveyance.
3. It is an offence to provide a LHS via MOSDs without prior approval from MOH.

HCSA Licensing Regime

Specified Services (SSes) are unique to each LHS and allowable only for specific MOSDs

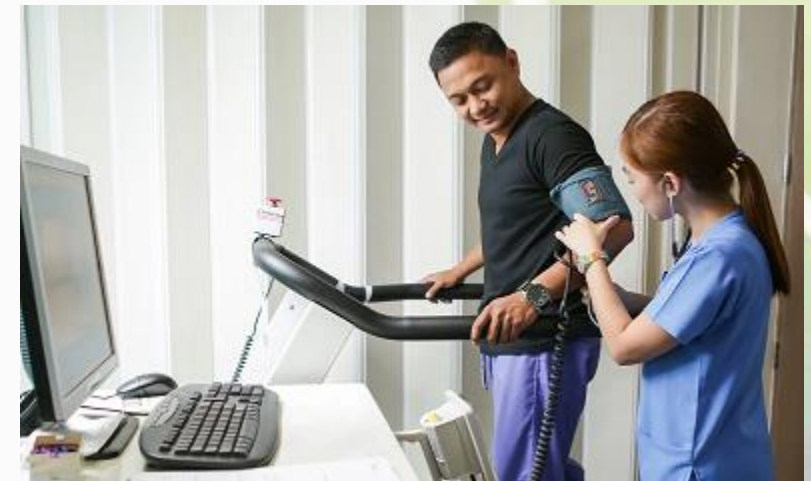
Rationale: To safeguard the provision of healthcare services licensees must seek approval from MOH before providing Specified Services (SSes).

- Licensees will need to obtain MOH's approval prior to providing SSes under their LHS. Doing so ensures that the licensee is first able to meet the base licence requirements before layering on further requirements to provide the SS.
- **It is an offence to provide a SS without MOH's approval.**

How does the SSes apply to a clinic?

Example: Medical Clinic that provides Treadmill services

Licensee will hold an **Outpatient Medical Clinic Licence**, with approval for Electrocardiography Stress Test (EST) as a **Specified Service**



HCSA Licensing Regime

Specified Services (SSes) are unique to each LHS and allowable only for specific MOSDs

Rationale: To safeguard the provision of healthcare services, licensees must seek approval from MOH before providing Specified Services (SSes).

Outpatient Medical Service (MOSDs)		Permanent Premises	Temporary Premises	Remote	Conveyance	Specific regulatory requirements available in:
Specified Services (SS)	Electrocardiography Stress Testing (EST)	✓			✓	Licence Conditions
	Blood Transfusion (Oncology, Haematology only)	✓				Licence Conditions
	Collaborative Prescribing	✓	✓	✓	✓	Regulations
	Endoscopy Services	✓	✓*		✓	Licence Conditions
	Liposuction Services	✓				Licence Conditions
	Radiation Oncology & Radiation Therapy	✓				Licence Conditions
	Proton Beam Therapy	✓				Licence Conditions

*Endoscopy services allowed under Outpatient Medical Service (Temporary Premises) will be limited to nasopharyngoscopy and cystoscopy which does not involve any sedation, biopsy, or removal of foreign body.

Understanding OMS Inspections – Roles & responsibilities

MOH has published a **Code of Practice** document for these key office holders under HCSA. It can be found on the HCSA website: go.gov.sg/hcsa-resources.

The same individual can be appointed for all these roles, subject to them meeting the specific requirements for each role.

Licensee

Can be either a corporation or an individual

- ✓ Responsible and accountable for overall compliance with the HCSA
- ✓ Appoints suitable individuals for other key roles

Key Appointment Holder (KAH)

This individual is appointed based on the ACRA registration of the business

- ✓ Responsible for strategic leadership and general management oversight
- ✓ For relevant KAH requirements according to business structure, refer to the **Code of Practice**
- ✓ Sole proprietor / partners of partnership / the entire Board of Directors

Clinical Governance Officer (CGO)

Must be an individual(s) who is a clinical and technical expert

- ✓ Assists the licensee in clinical governance and technical oversight of complex services
- ✓ Clinical qualification and experience requirements are detailed in the respective Service Regulations

Principal Officer (PO)

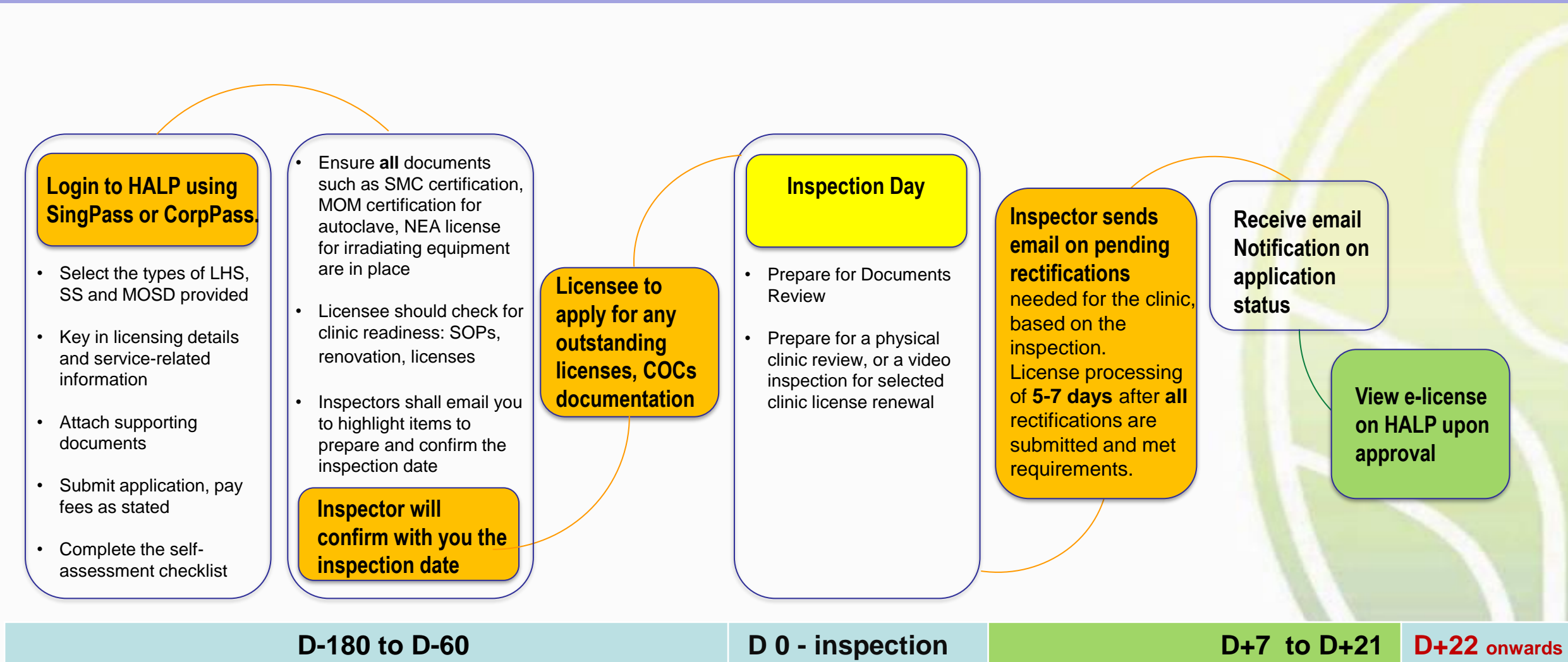
Must be an individual(s)

- ✓ Assists the licensee in ensuring overall operational compliance with the HCSA
- ✓ Oversees day-to-day management of the service, similar to the “Manager” role under the PHMCA

Understanding OMS Inspections – Rationale

1. Purpose of inspections:
 - To **safeguard patient safety** by ensuring licensees' compliance to the Healthcare Services Act and its subsidiary legislation
2. Inspections are de-linked from the licence renewal cycle; meaning that, they can occur several months before or after the expected license renewal date. This is part of our efforts to reduce regulatory burden and enhance efficiency of the licensing process.
3. There are several types of inspections which may be conducted:
 - Inspection for new clinic applications;
 - Inspection for request for change applications (change in address, addition of Specified Services)
 - Ad-hoc unannounced compliance audits or
 - Routine inspection of existing clinics.
4. Frequency of inspection:
 - Dependent on the present and past compliance history;
 - May range from less than a year to up to 5 years;
 - Ad-hoc inspections may be conducted to assess the continued compliance of the licensee to HCSA requirements.

Understanding OMS Inspections – Overview



Understanding OMS Inspections – Licensee's Role

1) License Application	2) Inspection Day	3) Post Inspection	4) License Issuance
			Timeline Guide
New Clinic			for Licensee's planning
<ol style="list-style-type: none"> HALP application must be submitted 2 to 6 months before the provision of the OMS Documents required to submit in HALP: <ul style="list-style-type: none"> Proof of Authorisation - if applicant is submitting on behalf of licensee ACRA Bizfile - for clinics whose licensee is a company Professional Qualifications/Certification of the CGO and doctor Gross Floor Area ("GFA") approval from URA for permanent premises, only for clinics located outside of HDB and Hospital premises 			D-180 to D-60
Existing clinic – Licence Renewal			
<ul style="list-style-type: none"> HALP application must be submitted 2 to 6 months before the OMS licence expiry Documents required to submit in HALP: <ul style="list-style-type: none"> Proof of Authorisation - if applicant is submitting on behalf of licensee ACRA Bizfile – to update the latest version of there is material changes in the company structure Professional Qualifications/Certification of the CGO and doctor – to update if there are any changes 			D-180 to D-60
<ol style="list-style-type: none"> Licensee to check that the following are valid: <ul style="list-style-type: none"> NEA License(s) for existing laser machine, ultrasound machine and/or x-ray machine MOM Certification for existing autoclave machine SMC certificates for all practicing doctors are valid 			
*If licensee is providing sedation, please refer to the Licence Conditions for Providing or Intending to Provide Sedation.			

Understanding OMS Inspections – Licensee's Role

1) License Application	2) Inspection Day	3) Post Inspection	4) License Issuance
			Timeline Guide
Personnel			for Licensee's planning
<ul style="list-style-type: none"> Personnel: the Inspection can be conducted in the presence of the CGO, or appointed clinic staff such as the clinic manager or an experienced clinic assistant Estimated duration: 1 hour up to half a day (Depends on the number of MOSDs, SSeS and other services) 			D-0 Inspection day
To have available during Inspection			
1. Documents review <ul style="list-style-type: none"> SMC certification Professional Certificate of Competency (COC) Training and competency assessment records 		<ul style="list-style-type: none"> NEA license(s) for ultrasound, laser MOM license for autoclave SOPs Price List 	D-0 Inspection day
2. Physical Inspection Equipment and devices should be maintained according to the manufacturer's specifications. This includes preventive maintenance (PM) records. <ul style="list-style-type: none"> autoclave, ultrasound, laser, x-ray, AED machine, if available We will also request to inspect the following <ul style="list-style-type: none"> Simple In-vitro devices (IVDs) Emergency Kit Medication Fridge Sharps and Biohazard disposal Personal Protection equipment and attire (PPE) Medications management Clinical Notes management 			

Understanding OMS Inspections – NEA Licences

Radiation Protection Act: Licensee will have to apply for the relevant NEA radiation licence(s) e.g. the N2 license if you intend to possess any ultrasound or laser equipment.

*If you are providing X-ray services, a separate Radiological Service HCSA licence is required.

How to Apply for Radiation Licences

Types of Application Forms	Platform
Apply for New, Renewal, Amendment and Cancellation Applications <ul style="list-style-type: none">• Ionising Radiation Licences (e.g. IR1, IR2, IR3 Licences)• Radiation Worker Registration (e.g. R1 Certificate)• Non-Ionising Radiation Licences (e.g. N1, N2, N3 Licences)	GoBusiness Portal
Apply for approval to accumulate or transport radioactive waste	Contact NEA via NEA's online feedback form or myENV app
Miscellaneous Forms <ul style="list-style-type: none">• Entertainment Laser Checklist for Organising of Laser Event• GIRO Application Form for Radiation Licences• Medical Certificate Form for R1 Applications (MC-1)• Medical Certificate Form for N3 Applications (MC-2)	NEA ePortal



Possession

(e.g. to keep, or possess, for use, or use)

- Ionising Irradiating Apparatus and Radioactive Materials : **IR2¹**
- Non-Ionising Irradiating Apparatus (e.g. high power lasers, industrial ultrasound apparatus² $\geq 1,200$ W) : **N2³**



[NEA | Guidelines for Licence Application and Annual Payment](https://www.nea.gov.sg/our-services/radiation-safety/guidelines-for-licence-application-and-annual-payment)


<https://www.nea.gov.sg/our-services/radiation-safety/guidelines-for-licence-application-and-annual-payment>

Understanding OMS Inspections – MOM Certificate

Workplace Safety and Health (General Provisions) Regulations

You will have to register the following types of Pressure Vessels with MOM:

Pressure Vessels that need to be registered

In accordance with the [Workplace Safety and Health \(General Provisions\) Regulations](#) , you must register the following types of Pressure Vessels:

- Air receivers (AR)
- Steam receivers (SR)
- Refrigerating plant pressure receivers (PR)
- Steam boilers, including autoclaves (BR)
- Economisers (BE)
- Superheaters (BS)

[Register a Pressure Vessel](#)



Understanding OMS Inspections – Clinic Equipment

1. To ensure that all medical and surgical equipment are adequate, functional and effective,
 - medical practitioners should install, use, check, maintain and repair clinic equipment in accordance with the manufacturers' specification.
 2. Such equipment include Simple In-vitro Diagnostic Tests (IVD). Examples of common IVDs:
 - Glucometers
 - Urine dipstick test
 - Rapid test kits
 - Cobas point-of-care test
 - I-Stat point-of-care test
- ☒ Users to check for calibration instructions, where applicable
3. Ultrasound, laser, X-ray machines require NEA License
 - renewable yearly via the GoBusiness website.
 4. Autoclaves will require MOM certification
 - renewable yearly via the GoBusiness website.

4 Control Tests

When to Perform a Control Test

Performing a control test lets you know the meter and test strips are working properly. You should perform a control test when:

- you open a new test strip box.
- you think the test strips are damaged.
- you want to check the meter and test strips.
- the test strips were stored in extreme temperatures, humidity or both.
- you dropped the meter.
- your test result does not match how you feel.
- you want to check if you are performing the test correctly.

About the Control Solution

- Use only Accu-Chek Performa control solution.
- Close the control solution bottle tightly after use.
- Write the date you open the control

- The control solution can stain fabric. Remove stains by washing with soap and water.

Performing a Control Test

You need the meter, a test strip and control solution Level 1 or Level 2.

1



Check the use by date on the test strip container. Do not use test strips past the use by date.

2



Insert the test strip into the meter in the direction of the arrows.

Place the meter on a flat surface.

Understanding OMS Inspections – Emergency Kit

- The list of mandatory resuscitation drugs and equipment required for OMS* can be found in the [Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures](#) (“LC”). Extracted a screenshot from Annex A of the LC below for reference:

List of resuscitation drugs and equipment required for Clinics		
Licensable Healthcare Services	Resuscitative Drugs (minimum one vial each)	Resuscitative Equipment (minimum one set of each)
Outpatient Medical Service	<ol style="list-style-type: none">1. Injection adrenaline2. Injection antihistamine3. Injection steroid e.g., hydrocortisone4. Inhaled bronchodilator	<ol style="list-style-type: none">1. Bag-valve mask2. Airways of at least 2 sizes (if seeing paediatric patients, to cater 1 size each for adult & paediatric respectively)3. Means to set up IV infusion (eg.cannula, infusion set)4. IV infusion fluid5. Appropriate delivery devices for bronchodilator (e.g, spacer)



Ambu bag with expiry date

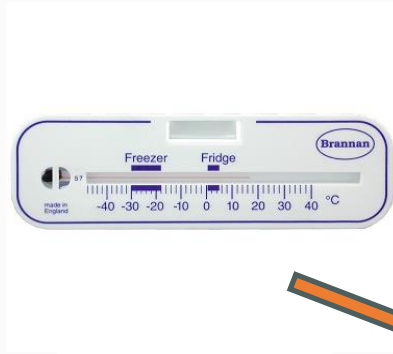
Licencee to consider the following:

- Bag-valve mask also known as Ambu Bag set, with expiry date.
- The delivery devices used for the inhaled bronchodilator should be suitable for the type of inhalation (i.e., nebuliser vs metered dose Inhaler)
- Aero chamber - to check and disposed of it 12 months after use
- AED – clinics that has a unit. to check battery pack and electrodes
- Checklist – to ensure currency and completeness of records



Understanding OMS Inspections – Cold Chain

1. There must be a thermometer placed on the central compartment of the refrigerator.
2. Temperature must be recorded twice daily, using a temperature tracking chart.
3. Vaccines must be kept in the central compartment of the refrigerator.
4. Established protocol to manage cold chain medication in the event of a power disruption.
5. **No storage of food nor drinks** in the refrigerator.



Cold Chain
Transport
Containers



Understanding OMS Inspections – COCs (Aesthetic Practices)

1. Medical practitioners intending to perform or are performing aesthetic services must abide by the **SMC's 2016 Guidelines on Aesthetic Practices for Doctors**.
2. Medical practitioners must also **obtain a Certificate of Competence ("COC") recognised by the Aesthetic Practice Oversight Committee (APOC)**, prior to performing the relevant aesthetic procedures in the clinic.



Understanding OMS Inspections – General Clinic Set-up

1. Signage for new clinics: to provide at least the mock-up of the signage
name on the clinic signage align with the clinic name that is registered in HALP
2. Display of clinic charges in a prominent location
3. Clinic management system
 - Patient's bill
 - Medical Certificates
 - Drug labels*to ensure your clinic name and contact details are captured in the above*
4. A system to ensure the traceability of specimen collection and despatch
5. Sufficient stockpile of PPEs for 7 days for all clinic personnel
to ensure sufficient disposable gowns, N95 masks and examination gloves

Understanding OMS Inspections – SOPs & Training Records

1. Documented Standard Operational Protocols (“SOPs”) are required to ensure:

- a. Consistency – Maintains quality standard in the clinic;
- b. Accountability – Easier to identify when processes are not followed accordingly;
- c. Risk management – Provides evidence that proper processes are followed;
- d. Knowledge preservation – Quality of work processes is not lost during staff attrition

2. List of SOPs that are required:

- (a) Preparation, dispensing and administration of medication;
- (b) Collection, packing and labelling of specimens;
- (c) Precautions to take to avoid contamination and degradation of specimens;
- (d) Proper and safe use of medical and surgical equipment, instruments, appliances, materials and facilities; and
- (e) Prevention, management, control and containment of the spread of any infection at those approved permanent premises, temporary premises or approved conveyances, as the case may be.
- (f) Assessment and follow-up measures of any patient who is in need of essential life-saving measures during the provision of the service (e.g., cardiovascular collapse etc)
- (g) [TEMP PREMISES] Protocol(s) involving OMS provided this service, if any, should specify at minimum the patient selection criteria and general conduct of OMS provided at the Temporary Premises (e.g., house calls etc)
- (h) [TELEMEDICINE] Protocol(s), if any, should specify at minimum the patient selection criteria, patient identification, conduct of the telemedicine service and subsequent medication prescription and delivery (if applicable)

Understanding OMS Inspections – SOPs & Training Records

1. Documented training and competency assessments are required to ensure:

- a) Consistency – Maintains quality standard in the clinic;
- b) Accountability – Ensures that all staff are competent in carrying out assigned task
- c) Knowledge preservation – Quality of work processes is not lost during staff attrition

2. Suggested Competency Checklists:

- (a) Staff onboarding
- (b) Dispensing of medication
- (c) Handling certain key devices in the clinic
- (d) Assisting in Medical Emergency

**Refer to R33(a) of the HCS(OMS)R: a licensee must maintain proper, complete and accurate records of the qualifications and competencies (including training and competency assessments) of each personnel, relevant to the provision of the outpatient medical service.*

Understanding OMS Inspections – Remote Delivery OMS

1. 'Remote' MOSD means the provision of an Outpatient Medical Service (OMS) via **technological means** (including but not limited to telephone call, text message, internet-based video, email, and/or similar electronic-based communications) and where the **service provider and the patient are not in the same physical location**. It is not limited to the provision of OMS via a Teleconsultation platform.
2. Licensees providing OMS remotely must **establish, implement, and regularly review guidelines** to assist medical practitioners in **determining whether a particular medical condition may be managed remotely**, taking into consideration:
 - a) the patient's medical condition and history;
 - b) the patient's ability to use the teleconsultation modality effectively (e.g. functional capacity, technological literacy etc);
and
 - c) the medical practitioner's training and scope of practice.
3. When providing OMS remotely, licensees must ensure that **real-time, two-way interactive audio-visual communications** is used when **tele-consulting with new patients** accessing the licensee's OMS for the first time (i.e. no prior patient records and medical history with the licensee).
4. All medical practitioners providing OMS remotely should also **complete MOH's [telemedicine e-training](#)**.

Understanding OMS Inspections - Timeline

1) License Application	2) During Inspection	3) Post Inspection	4) License Issuance
			Timeline Guide
Post Inspection			for Licensee's Planning
<ol style="list-style-type: none"> Our Inspectors will send a list of follow up items to Licensees, so that the clinic can provide clarifications and/or furnish any pending documentation. Rectifications to the inspection findings should be sent to MOH within 1 to 2 weeks of the physical inspection. MOH requires 5 to 7 working days from the date that all rectifications meets licensing requirements. Application processing in view of approval will only commence once all rectifications are addressed. 			D+7 to D+21 Timeline shall exceed D+21 Licensee need to be cognisant and allocate additional time to settle the outstanding matters.
Delays to Inspection rectification			
<ol style="list-style-type: none"> If the Licensee did not apply for MOH's approval for a Specified Service (SS) Absence of specified Resuscitation drugs, PPE stocks or Biohazard disposal containers Absence of key licenses needing urgent procurement Clinic X-ray machine and room pending NEA clearance. Clinic still needed to furnish NEA license to MOH Remote MOSD – Licensee delayed in obtaining MOH Telemedicine E-training certification Remote MOSD – Licensee needed more time to provide website template with 4 key information for clinic: <ul style="list-style-type: none"> Business name, Clinic contact details, To notify patients that clinic is licensed to provide Remote OMS services To notify patients that Teleconsultation is not for medical emergencies 			Timeline shall exceed D+21 Licensee need to be cognisant and allocate additional time to settle the outstanding matters.

Understanding OMS Inspections - Timeline

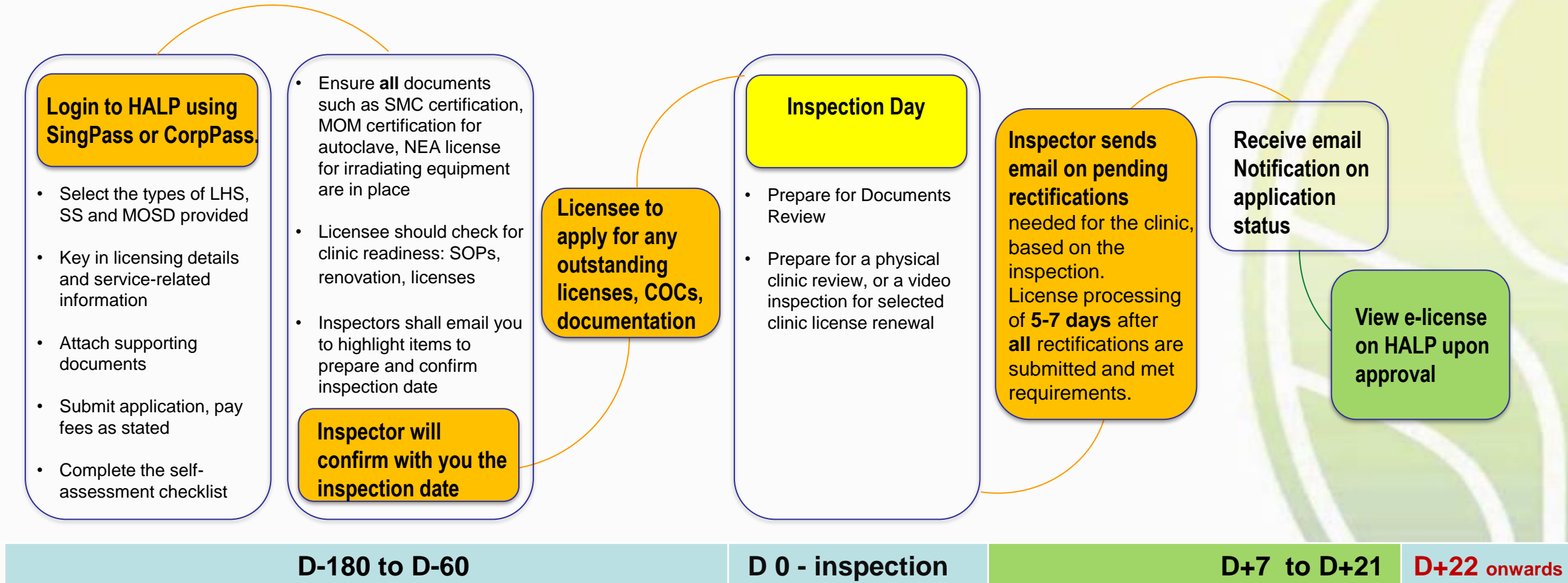
1) License Application	2) During Inspection	3) Post Inspection	4) License Issuance
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Post Inspection

for Licensee's Planning

1. MOH will contact the Licensee in due course, when all rectifications for your/the clinic are completed.
 - MOH **requires 5 to 7 working days from the date that all rectifications meets licensing requirements**
 - License Application processing for Approval will only commence once all rectifications are addressed
 - There are set standardised benchmarks for clinics; and we urge licensees to focus on meeting all licensing requirements quickly as MOH needs to receive evidence of all rectifications done.
2. All roads shall still come to the Healthcare Regulations Department, MOH. Hence,
 - Please avoid sending chasers in the hope of expediting the approval;
 - Such chasers through various personnel shall slow down the process significantly

Understanding OMS Inspections – Overview



Basic Checklist

Basic Checklist* <small>*This is only a sample basic checklist of some of the pertinent requirements covered in this presentation and is not intended to be extensive. Clinic will still be subjected to all the relevant requirements under the HCSA.</small>	Yes	No
1. Services <ul style="list-style-type: none"> a) Am I providing any of the Specified Services under OMS? b) Am I providing any form of examination/assessment and medical advice over remote means (including phone call)? If so, do I have the Remote Delivery OMS licence and the telemedicine certificate c) If performing aesthetic procedures, do I have all the relevant COCs (approved by APOC) for performing the respective aesthetic procedures as listed in Table 2 of the SMC Aesthetic Guidelines 2016? 		
2. General clinic set-up <ul style="list-style-type: none"> a) Does my clinic name on my clinic signage align with the clinic name that is registered in HALP? b) Are my clinic charges displayed? c) Do I have 7 days of PPE supplies (in the form of disposable gowns, examination gloves and N95 masks) for all my clinic personnels? d) Is there a specimen despatch log for my clinic? 		
3. Equipment <ul style="list-style-type: none"> a) Do I have the necessary <ul style="list-style-type: none"> • NEA N2 licence(s) for the laser and ultrasound machines? • MOM safety certificate for the autoclave machine? b) Are my clinic equipment (including simple IVD) maintained in accordance with the manufacturer specification? c) Are there records of these maintenance and repairs? 		
4. Emergency Kit <ul style="list-style-type: none"> a) Do I have all the mandatory drugs and equipment as required in the relevant Licence Conditions? 		
5. Cold chain medication/vaccination <ul style="list-style-type: none"> a) Are there any food and drinks kept in the fridge? b) Is my thermometer kept in the central part of the fridge? c) Is the temperature of my fridge recorded minimally twice a day? d) Are the vaccines kept in the central part of the fridge? 		
6. SOPs and Competency Assessment <ul style="list-style-type: none"> a) Are there documented SOPs on the management of medications, specimen, equipment, emergencies and infection control practices? b) Are there documented SOPs for the conduct of medical services via the Remote Delivery and Temporary Premises MOSD (if applicable)? c) Are there documentation of my clinic personnels' competencies? 		

Should you have further enquiries, please write to MOH via HCSA Enquiries
Email: **HCSA_Enquiries@moh.gov.sg**

Thank you

