LICENCE CONDITIONS FOR

ASSISTED REPRODUCTION SERVICE, RADIOLOGICAL SERVICE, OUTPATIENT MEDICAL SERVICE, OUTPATIENT DENTAL SERVICE, NUCLEAR MEDICAL SERVICE, AMBULATORY SURGICAL CENTRE SERVICE, COMMUNITY HOSPITAL SERVICE AND CONTINGENCY CARE SERVICE LICENSEES

PROVIDING OR INTENDING TO PROVIDE (1) SEDATION; OR (2) GENERAL ANAESTHESIA

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1 These licence conditions ("**LCs**") apply to:

(1) all persons who have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide one or more of the following licensable healthcare services:

(a) a contingency care service ("**CCS**");
(b) a community hospital service ("**CHS**");
(c) an ambulatory surgical centre service ("**ASCS**");
(d) a nuclear medicine service ("**NMS**");
(e) an outpatient dental service ("**ODS**")
(f) an outpatient medical service ("**OMS**")
(g) a radiological service ("**RS**"); or
(h) an assisted reproduction service ("**ARS**")

(2) that provide or intend to provide, as part of that service or those services:

(a) the administration of any anaesthetic to any patient to cause Sedation (as defined in paragraph 2.1(12)); or
(b) the administration of any anaesthetic to any patient to cause General Anaesthesia (as defined in paragraph 2.1(5)),

unless, that person is (A) concurrently licensed under the HCSA to provide an acute hospital service, and (B) the services described in paragraph 1.1(2) are provided or intended to be provided in the approved permanent premises for the provision of that acute hospital service.

(such persons referred to as "**Licensees**")

1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(1) suspension or revocation of the Licensee's ARS, CCS, CHS, ASCS, NMS, ODS, OMS and/or RS licence;

(2) shortening the term of the Licensee's ARS, CCS, CHS, ASCS, NMS, ODS, OMS and/or RS licence;

(3) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(4) a direction requiring the Licensee to pay a financial penalty.

1.3 The Licensee is exempted from the requirements in these LCs in relation to the administration of any anaesthetic to cause sedation for the sole purpose of providing palliative care.

1.4 For avoidance of doubt:

(1) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;

(2) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient; and

(3) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definitions

2.1 The following definitions shall apply to these LCs:

(1) "**Adult**" means a person who is above 12 years of age.

(2) "**Anaesthesiologist**" means a medical practitioner who is registered under the Medical Registration Act 1997 by the Singapore Medical Council as a specialist in anaesthesiology.

(3) "**Child**" means a person above 28 days but who is 12 years of age and below.

(4) "**Deep Sedation**" means a drug-induced depression of a patient's consciousness –

(a) during which, the patient cannot be easily aroused but will respond purposefully following repeated or painful stimulation;
(b) where the patient's ability to independently maintain ventilatory function may be impaired;
(c) where the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(d) where the patient's cardiovascular function is maintained.

(5) "**General Anaesthesia**" means a drug-induced loss of a patient's consciousness –

(a) during which the patient is not arousable even with painful stimulation;
(b) where the patient's ability to independently maintain ventilatory function is often impaired;
(c) where the patient often requires assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed respiratory function or drug-induced depression of neuromuscular function; and
(d) where the patient's cardiovascular function may be impaired.

(6) "**Minimal Sedation**" means a drug-induced state of a patient –

(a) during which the patient can respond normally to verbal commands; and
(b) where the patient's cognitive function and physical coordination may be impaired, but the patient's airway, ventilation and cardiovascular functions are unaffected.

(7) "**Moderate Sedation**" means a drug-induced depression of a patient's consciousness –

(a) during which the patient can respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation;
(b) where no intervention is required to maintain a patent airway and spontaneous ventilation of the patient is adequate; and
(c) where the patient's cardiovascular function is usually maintained without any pharmacologic intervention.

(8) "**Neonate**" means a person of or below 28 days of age.

(9) "**Non-Anaesthesiologist**" means a person who is not an Anaesthesiologist.

(10) "**Proceduralist**" means the medical practitioner or dentist performing the therapeutic or diagnostic procedure (as the case may be) on a patient.

(11) "**Registered Nurse**" means a nurse who is registered under the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act.

(12) "**Sedation**" means any of the following:

(a) Minimal Sedation;
(b) Moderate Sedation; or

(c) Deep Sedation.

(13) "**Sedationist**" means a medical practitioner, dentist, or Registered Nurse who administers any anaesthetic to any patient to cause Sedation or General Anaesthesia (as the case may be), and is responsible for monitoring the patient during the procedure.

3 Specific Conditions in relation to General Anaesthesia

3.1 Unless permitted under paragraph 3.2, the Licensee **shall not** provide the administration of any anaesthetic to any patient to cause General Anaesthesia.

3.2 Notwithstanding paragraph 3.1, the Licensee may provide the administration of any anaesthetic to any patient to cause General Anaesthesia if:

(1) it is licensed to provide ARS, ASCS, NMS or RS;

(2) it is provided in the Licensee's approved permanent premises for the provision of ARS, ASCS, NMS or RS (as the case may be);

(3) the Proceduralist and the Sedationist are distinct individuals;

(4) the Sedationist:

(a) is an Anaesthesiologist;
(b) is involved only in (A) the administration of the anaesthetic and (B) the monitoring of that patient;
(c) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 3.2(4)(b), during the period when that patient is under General Anaesthesia.

4 Specific Conditions in relation to Sedation

A. Sedation of any patient caused by the administration of Propofol

4.1 Unless permitted under paragraphs 4.2 and 4.3, the Licensee **shall not** provide the administration of Propofol to any patient to cause Sedation.

4.2 Notwithstanding paragraph 4.1, the Licensee may provide the administration of Propofol to an Adult patient to cause Minimal Sedation if:

(1) it is provided in:

(a) the Licensee's approved permanent premises;
(b) the Licensee's approved temporary premises; or
(c) the Licensee's approved conveyances,

for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide;

(2) the Proceduralist and the Sedationist are distinct individuals; and

(3) the Sedationist:

(a) is an Anaesthesiologist;
(b) is involved only in (A) the administration of the Propofol and (B) the monitoring of that patient; and
(c) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 4.2(3)(b), during the period when that patient is under Minimal Sedation; and

(4) the conditions set out in paragraph 5 of these LCs are satisfied.

4.3 Notwithstanding paragraph 4.1, the Licensee may provide the administration of Propofol to an Adult patient to cause Moderate Sedation and Deep Sedation if:

(1) it is provided in the Licensee's approved permanent premises for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide;

(2) the Proceduralist and the Sedationist are distinct individuals; and

(3) the Sedationist:

(a) is an Anaesthesiologist;
(b) is involved only in (A) the administration of the Propofol and (B) the monitoring of that patient; and
(c) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 4.3(3)(b), during the period when that patient is under Moderate Sedation or Deep Sedation; and

(4) the conditions set out in paragraph 5 of these LCs are satisfied.

4.4 For avoidance of doubt, the Licensee shall not provide the administration of Propofol to any Child or Neonate patient to cause Sedation.

B. Sedation of Adult patients caused by the administration of any other anaesthetic that is not Propofol

4.5 Unless permitted under paragraphs 4.6, 4.8, 4.9 and 4.10, the Licensee shall not provide the administration of any other anaesthetic that is not Propofol ("**Non-Propofol Drug(s)**") to any patient to cause Sedation.

4.6 Notwithstanding paragraph 4.5, the Licensee may provide the administration of Non-Propofol Drugs to an Adult or Child patient to cause Minimal Sedation if:

(1) it is provided in:

(a) the Licensee's approved permanent premises;

(b) the Licensee's approved temporary premises; or
(c) the Licensee's approved conveyances,

for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide;

(2) in the event that the Non-Propofol Drug administered is nitrous oxide, the Sedationist is a medical practitioner or dentist;

(3) in the event that the patient is a Child that is of the age of 1 and above, the Non-Propofol Drug is administered via the oral or inhalation route;

(4) in the event that the patient is a Child that is below the age of 1, the Non-Propofol Drug administered is only Oral Chloral Hydrate;

(5) in the event that the patient is a Child and there is no Anaesthesiologist that is physically present when the Non-Propofol Drug is administered to the patient and during the period when the patient is under Minimal Sedation, either the Proceduralist or the Sedationist is (a) certified as having attended and completed in the Advanced Paediatric Life Support course ("**APLS**") or an equivalent course; and (b) maintains currency in the skills that are taught to them in that course; and

(6) the conditions set out in paragraph 5 of these LCs are satisfied.

4.7 For the purposes of paragraph 4.6, the Proceduralist and Sedationist that are involved in the Licensees' provision of the administration of Non-Propofol Drugs may be the same individual.

4.8 Notwithstanding paragraph 4.5, the Licensee may provide the administration of Non-Propofol Drugs to an Adult or Child patient to cause Moderate Sedation if:

(1) it is provided in the Licensee's approved permanent premises for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide;

(2) in the event that the Non-Propofol Drug administered is nitrous oxide, the Sedationist is a medical practitioner or dentist;

(3) the Proceduralist and the Sedationist are distinct individuals;

(4) in the event that neither the Proceduralist nor the Sedationist are Anaesthesiologists, either:

(a) an Anaesthesiologist; or
(b) a medical practitioner, dentist or Registered Nurse (who may be the Proceduralist or Sedationist) who is (1) certified as having attended and completed in the Advanced Cardiac Life Support ("**ACLS**") or its equivalent course; and (2) maintain currency in the skills that are taught to them in that course,

must be present in close proximity and available to attend to the patient immediately if required.

(5) the Sedationist:

(a) is involved only in (A) the administration of the Non-Propofol Drug and (B) the monitoring of that patient; and
(b) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 4.8(5)(a), during the period when that patient is under Moderate Sedation or Deep Sedation;

(6) in the event that the patient is a Child that is of the age of 1 and above, the Non-Propofol Drug must be administered only via the oral or inhalation route;

(7) in the event that the patient is a Child that is below the age of 1, the Non-Propofol Drug administered is only Oral Chloral Hydrate;

(8) in the event that the patient is a Child and there is no Anaesthesiologist that is physically present when the Non-Propofol Drug is administered to the patient and during the period when the patient is under Moderate Sedation, the Proceduralist or Sedationist must be (a) certified as having attended and completed in the APLS or an equivalent course; and (b) maintain currency in the skills that are taught to them in that course; and

(9) the conditions set out in paragraph 5 of these LCs are satisfied.

4.9 Notwithstanding paragraph 4.5, the Licensee may provide the administration of Non-Propofol Drugs to an Adult patient to cause Deep Sedation if:

(1) it is provided in the Licensee's approved permanent premises for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide;

(2) the Proceduralist and the Sedationist are distinct individuals;

(3) the Sedationist:

(a) is an Anaesthesiologist;
(b) is involved only in (A) the administration of the Non-Propofol Drug and (B) the monitoring of that patient; and
(c) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 4.9(3)(b), during the period when that patient is under Deep Sedation; and

(4) the conditions set out in paragraph 5 of these LCs are satisfied.

4.10 Notwithstanding paragraph 4.5, the Licensee may provide the administration of Non-Propofol Drugs to a Child patient to cause Deep Sedation if:

(1) it is licensed to provide NMS, RS, ASCS, ARS, CCS or CHS;

(2) it is provided in the Licensee's approved permanent premises for the provision of NMS, RS, ASCS, ARS, CCS or CHS (as the case may be);

(3) the Proceduralist and the Sedationist are distinct individuals;

(4) the Sedationist:

(a) is an Anaesthesiologist;
(b) is involved only in (A) the administration of the Non-Propofol Drug and (B) the monitoring of that patient; and
(c) does not assist the Proceduralist or perform any other task, other than the tasks described in paragraph 4.10(4)(b), during the period when that patient is under Sedation or Deep Sedation; and

(5) the conditions set out in paragraph 5 of these LCs are satisfied.

4.11 For avoidance of doubt, the Licensee shall not provide the administration of Non-Propofol Drugs to any Neonate patient to cause Sedation.

4.12 A summary of the requirements in paragraph 4 is provided in diagrammatic form in Annex A. For avoidance of doubt, if there is any inconsistency between any requirement of the in these LCs and the diagram in Annex A, the requirements in these LCs will prevail.

5 General Conditions in relation to General Anaesthesia and Sedation

A. Education and Training

5.1 The Licensee shall ensure that all dentists and medical practitioners that are involved in a procedure that requires the administration of any anaesthetic to a patient as a Proceduralist or Sedationist:

(1) have knowledge of and are familiar with the:

(a) use and pharmacology of that anaesthetic;
(b) that anaesthetic's indications and contraindications; and

(2) demonstrate competence in:

(a) the use of that anaesthetic; and
(b) the recognition and management of complications arising from the administration of that anaesthetic to that patient.

5.2 The Licensee shall ensure that all healthcare professionals that are involved in a procedure that requires the administration of any anaesthetic to a patient are trained in the handling of all equipment used for the administration of that anaesthesia.

5.3 The Licensee shall ensure that all dentists and medical practitioners who are Non-Anaesthesiologists satisfy the following requirements before administering any anaesthetic as a Sedationist to a patient:

(1) possess adequate training in the following areas relating to persons that fall within the age group of that patient (i.e., Adult or Child):

(a) safe administration of any anaesthetic to cause Sedation;
(b) monitoring of patient under Sedation;
(c) management of complications arising from Sedation;
(d) proper documentation of Sedation; and

(2) has undergone training for the areas described in paragraph 5.3(1) under or as part of:

(a) a training programme for a relevant speciality of medicine;
(b) a relevant fellowship or post-graduate course (e.g., the Health Manpower Development Plan ("**HMDP**")); or
(c) a specific training program for that area (e.g., Paediatric Sedation Advanced Life Support course with respect to the management of complications arising from Sedation of a Child).

5.4 The Licensee shall ensure that all Registered Nurses are supervised by either (1) an Anaesthesiologist or (2) a medical practitioner or dentist who satisfies the requirements set out in paragraph 5.3, when administering any anaesthetic as a Sedationist to a patient.

5.5 If nitrous oxide is administered to a patient to cause Minimal Sedation, the Licensee shall ensure that the following additional requirements are satisfied:

(1) if the patient being administered the nitrous oxide is a Child patient, the Proceduralist and the Sedationist that are involved in the procedure have received training in and maintain currency in airway management and resuscitation skills, including the use of a bag valve mask; and

(2) the Sedationist must have received training the following areas:

(a) physiology and pharmacology of nitrous oxide;
(b) effects of nitrous oxide
(c) the use of nitrous oxide for behavioural management;
(d) indications and contraindications for the use of nitrous oxide;
(e) technique of nitrous oxide/oxygen administration;
(f) monitoring and documenting the use of nitrous oxide;
(g) recognition and management of adverse effects relating to the use of nitrous oxide;
(h) facilities, personnel, equipment required for safe administration of nitrous oxide; and
(i) occupational safety requirements for the safe administration of nitrous oxide.

5.6 Sedationists that are dentists may be regarded has having received the training in the areas specified in paragraphs 5.5(2)(a) to (i) if:

(1) they have undergoing training under or as part of:

(a) a training programme for a relevant speciality of dentistry that has been accredited by the Singapore Dental Specialty Accreditation Board ("**DSAB**") which offers hands-on training and didactics on nitrous oxide sedation in its curriculum;
(b) a relevant fellowship or post-graduate course (e.g., HMDP); or
(c) a specific training program for that area (e.g., nitrous oxide sedation under Continuing Dental Education (CDE) or Continuing Medical Education (CME) programmes);

(2) they have previously administered nitrous oxide to at least 3 patients under supervision, which may be provided in the course of the training described in paragraph 5.6(1); and

(3) the Licensee has documentation in support of the training described in paragraph 5.6(1), including the core syllabus of the training and a record of the previous administrations of nitrous oxide described in paragraph 5.6(2).

5.7 If nitrous oxide is administered by a Sedationist that is a dentist to a patient to cause Moderate Sedation, the Licensee shall ensure that the dentist has undergoing training under or as part of:

(1) a training programme for a relevant speciality of dentistry that has been accredited by the DSAB which offers hands-on training and didactics on nitrous oxide as an anaesthetic for Moderate Sedation in its curriculum; or
(2) a relevant fellowship or post-graduate course (e.g., HMDP).

5.8 For the purposes of paragraphs 5.5 and 5.7:

(1) nitrous oxide is regarded as administered to a patient to cause Minimal Sedation if it is:

(a) delivered in a mixture of nitrous oxide gas and oxygen, with the concentration of nitrous oxide gas being ≤50% of such mixture; and
(b) no other anaesthetic, sedative, opioid or depressant drug is administered to the patient before or during the delivery of the mixture described in paragraph 5.8(1)(a);

(2) nitrous oxide is regarded as administered to a patient to cause Moderate Sedation if it is:

(a) delivered in a mixture of nitrous oxide gas and oxygen, with the concentration of nitrous oxide gas being >50% of such mixture; or

(b) delivered in combination with other sedatives, including but not limited to Oral Chloral Hydrate, Midazolam, or opioids.

B. Patient Selection for Sedation and General Anaesthesia

5.9 The Licensee shall ensure that patients with significant underlying conditions who are deemed to be at high risk of complications arising from Sedation are only administered anaesthetics by an Anaesthesiologist.

5.10 Before the Licensee offers to administer any anaesthetic to any patient to cause any Sedation or General Anaesthesia, the Licensee shall ensure that:

(1) the purpose and need for Sedation or General Anaesthesia is discussed with the patient by the following persons:

(a) if the anaesthetic is being administered to cause Minimal Sedation or Moderate Sedation, by (A) the Proceduralist; (B) the Sedationist if he is a medical practitioner or dentist; or (C) an Anaesthesiologist;
(b) if the anaesthetic is being administered to cause Deep Sedation or General Anaesthesia, by an Anaesthesiologist;

(2) if the patient is below 21 years of age, the discussion described in paragraph 5.10(1) is conducted with a person who is legally responsible for the patient (e.g., the patient's parents) instead of the patient;

(3) prior to the discussion described in paragraph 5.10(1), the person conducting the discussion assesses if alternative forms of pain relief may be offered to the patient instead of Sedation or General Anaesthesia; and

(4) if Moderate Sedation is offered and the person proposed to administer the anaesthetic is a Non-Anaesthesiologist, the person conducting the discussion offers the option of having an Anaesthesiologist perform the administration of the anaesthetic instead of a Non-Anaesthesiologist.

C. Pre-Sedation and Pre-General Anaesthesia Assessment

5.11 Before the Licensee administers any anaesthetic to any patient to cause any Sedation or General Anaesthesia, the Licensee shall ensure that:

(1) the patient's suitability for Sedation or General Anaesthesia is evaluated:

(a) if the anaesthetic is being administered to cause Minimal Sedation or Moderate Sedation, by (A) the Proceduralist; (B) the Sedationist if he is a medical practitioner or dentist; or (C) an Anaesthesiologist;

(b) if the anaesthetic is being administered to cause Deep Sedation or General Anaesthesia, by the Proceduralist and the Sedationist;

(2) the evaluation described in paragraph 5.11(1) shall minimally involve:

(a) a review of the patient's previous medical records and relevant history from the patient or the patient's relatives;
(b) a focused physical examination of the patient; and
(c) a review of available laboratory and/or radiological test results of the patient as indicated.

(3) the evaluation described in paragraph 5.11(1) shall minimally take into consideration the following:

(a) presence of abnormalities in or among the patient's major organ systems (e.g. cardiac, respiratory, renal, neurologic, sleep apnoea, metabolic, endocrine, congenital);
(b) presence of conditions predisposing the patient to the risk of aspiration of his stomach content;
(c) presence a difficult airway in the patient;
(d) the patient's past adverse experience with Sedation, General Anaesthesia and any regional anaesthesia;
(e) the patient's use of concomitant medications, in particular, those that may interact with anaesthetics, sedatives or analgesics;
(f) the patient's history of smoking, alcohol, substance abuse or drug allergies;
(g) the patient's history of prematurity (i.e., younger than 60 weeks post-conceptional age) and apnoea of prematurity;
(h) the patient's frequent exposure to any anaesthetic which causes Sedation, General Anaesthesia or any regional anaesthesia; and
(i) presence of the patient's contraindications to (A) Sedation, General Anaesthesia or any regional anaesthesia; or (B) any anaesthetic that causes Sedation, General Anaesthesia or any regional anaesthesia.

D. <u>Pre-Sedation/General Anaesthesia Patient Preparation</u>

5.12 Before the Licensee administers any anaesthetic to any patient to cause any Sedation or General Anaesthesia, the Licensee shall ensure:

(1) that (A) the patient; or (B) if the patient is below 21 years of age, a person who is legally responsible for the patient, is:

(a) provided counselling regarding the patient's discharge; and
(b) advised by:
(i) if the anaesthetic is being administered to cause Minimal Sedation or Moderate Sedation, by (I) the Proceduralist; (II) the Sedationist if he is a medical practitioner or dentist; or (III) an Anaesthesiologist;
(ii) if the anaesthetic is being administered to cause Deep Sedation or General Anaesthesia, by an Anaesthesiologist,

on the risk that if there are complications (I) the patient may experience a reversal of the state of Sedation or General Anaesthesia; and (II) the procedure that requires the administration of the anaesthetic may be abandoned; and

(2) that the patient observes an adequate pre-operative fasting period, that is in accordance with current medical evidence, to lower the patient's risk of aspiration.

5.13 Before the Licensee administers any anaesthetic to any patient to cause Moderate Sedation, Deep Sedation or General Anaesthesia, the Licensee shall ensure that (A) the patient; or (B) if the patient is below 21 years of age, a person who is legally responsible for the patient:

(1) is advised by:

(a) if the anaesthetic is being administered to cause Moderate Sedation, by (I) the Proceduralist; (II) the Sedationist if he is a medical practitioner or dentist; or (III) an Anaesthesiologist;
(b) if the anaesthetic is being administered to cause Deep Sedation or General Anaesthesia, by an Anaesthesiologist,

with respect to the risks, benefits and alternatives to Moderate Sedation, Deep Sedation or General Anaesthesia (as the case may be), including the risk that the patient may experience a prolonged period of impaired cognition after completion of the procedure that requires the administration of the anaesthetic, which may potentially impact the patient's ability to eat, drive, drink, operate machinery or make decisions;

(2) provides consent for the administration of the anaesthetic to the person providing the advice described in paragraph 5.13(1); and

(3) the consent described in paragraph 5.13(2) is recorded in writing in the form of a consent form, which must contain information regarding the risks, benefits and alternatives to Moderate Sedation, Deep Sedation or General Anaesthesia (as the case may be).

E. <u>Intra-Procedural Monitoring of Patients</u>

5.14 The Licensee shall ensure that all patients that are under Moderate Sedation, Deep Sedation and General Anaesthesia are constantly monitored with respect to their vital signs, which shall include, but not limited to, the following:

Clinical Observation	(1) the patient's level of consciousness; and (2) the patient's respiratory rate and pattern of breathing.
Physiological Monitoring	(1) the patient's continuous pulse oximetry; (2) the patient's continuous heart rate; (3) the patient's blood pressure every 5 minutes; (4) if the patient's cardiac rhythm is expected to be

	affected, electrocardiography monitoring; (5) if the patient's ability to independently maintain ventilatory function is expected to be impaired, end tidal carbon dioxide monitoring by continuous capnometry.

5.15 For the purposes paragraph 5.14, the level of consciousness of a Child patient shall be monitored using a sedation scale and according to the Child's depth of sedation during and after the period that the Child is under Moderate Sedation and Deep Sedation.

5.16 The Licensee shall ensure that the audible alarms and the pulse oximeter tone of the physiologic monitors being used on a patient are activated and switched on during the period that such patient is under Sedation or General Anaesthesia.

F. Post-Procedural Management of Patients

5.17 After completion of the procedure that requires the administration of the anaesthetic to a patient to cause Sedation or General Anaesthesia, the Licensee shall ensure that:

(1) the patient is monitored for a period that is commensurate with the risk that is associated with that patient of complications arising from the administration of the anaesthetic;

(2) during the period described in paragraph 5.17(1), the patient is continually reviewed at 15-minute intervals (a) in respect of their vital signs as described in paragraph 5.14, and (b) for complications arising from the procedure or the administration of the anaesthetic;

(3) during the period described in paragraph 5.17(1), the management of the Patient for any complications arising from the administration of any anaesthetic is carried out by:

(a) if the anaesthetic was administered to cause Minimal Sedation or Moderate Sedation, by (I) the Proceduralist; (II) the Sedationist if he is a medical practitioner or dentist; or (II) an Anaesthesiologist;
(b) if the anaesthetic was administered to cause Deep Sedation or General Anaesthesia, by the (I) the Proceduralist; or (II) the Sedationist; and

(4) a standardised operating protocol is implemented to activate emergency services and facilitate the safe transfer of patients to an appropriate medical care facility during emergencies arising from the administration of the anaesthetic.

5.18 Before discharging a patient who was administered an anaesthetic to cause Sedation or General Anaesthesia, the Licensee shall ensure that:

(1) the patient's fitness for discharge is authorised by the relevant person that is described in paragraph 5.17(3); and

(2) (A) the patient; or (B) if the patient is below 21 years of age, a person who is legally responsible for the patient, is issued verbal and written post-procedural instructions, which shall minimally include instructions on the signs and symptoms of potential adverse outcomes arising from the administration of the anaesthetic.

G. Facilities, Equipment and Devices

5.19 The Licensee shall ensure that the following equipment are available whenever any anaesthetic is administered to a patient to cause Moderate Sedation, Deep Sedation or General Anaesthesia:

(1) physiologic monitors that are fully functional;
(2) oxygen therapy equipment that are fully functional and capable of providing an adequate supply of oxygen to the patient;
(3) operating tables and patient trolleys, if any, that are able to be tilted in the head-down position (i.e. Trendelenburg position);
(4) patient's couch and the necessary resuscitative equipment such as oxygen apparatus (i.e., oxygen source and oxygen delivery devices), suction, defibrillator, pulse oximetry and other monitoring facilities in the recovery area.

5.20 The Licensee shall ensure the availability of means to request for emergency assistance when necessary (e.g. phone, intercom).

5.21 The Licensee shall ensure that when any anaesthetic is administered to a patient as part of a procedure, a source of oxygen is readily available so that the patient can receive oxygen throughout the period of the procedure and the post-procedure monitoring period described in paragraph 5.17(1).

H. Conditions relating to specific Non-Propofol Drugs

5.22 The Licensee shall ensure that when opioids are administered to a patient to cause Sedation or General Anaesthesia, antagonists like Naloxone are available.

5.23 The Licensee shall ensure that when benzodiazepines are administered to a patient to cause Sedation or General Anaesthesia, antagonists like Flumazenil are available.

5.24 The License shall ensure that when nitrous oxide is administered to a patient to cause Sedation or General Anaesthesia:

(1) an inhalational system is used that satisfies the following requirements:

(a) has the capacity to deliver 100% oxygen concentration at a flow rate appropriate for the patient;

(b) has a fail-safe system that is calibrated to ensure that the oxygen concentration delivered does not fall before 30%, which may be (A) a functioning device that prohibits the delivery of less than 30% oxygen concentration; or (B) an appropriately calibrated and functioning in-line oxygen analyser with audible alarm that alerts if the oxygen concentration is about to fall below 30%;

(2) an appropriate scavenging system is used to minimise air contamination in the room where the nitrous oxide is administered and the occupational risk to healthcare professionals involved in the said administration;

(3) a positive pressure oxygen delivery system is available for immediate use by the patient if necessary;

(4) an emergency cart or kit must be readily accessible and available for immediate use by the patient if necessary which consists of emergency equipment that is able to accommodate patients of all ages and sizes;

(5) the equipment described in paragraphs 5.24(1), (2) and (3) are designed for the dedicated purpose of administering nitrous oxide and maintained in accordance with the manufacturers' guidance, with regular servicing and safe storage that is supported by documentation;

(6) all equipment used in the administration of nitrous oxide undergo (a) a pre-procedural check before being used; and (b) routine checks for any cracks, wears, tears, leaks (e.g., pressure connections should be tested for leaks when the positive pressure oxygen delivery system is turned on and each time a tank is changed);

(7) the Licensee's (a) approved permanent premises; (b) approved temporary premises; or (c) approved conveyance, for the provision of the relevant licensable healthcare service or services described in paragraph 1.1(1) that the Licensee is authorised to provide, must be designed to take into account the ventilation and scavenging of waste gases in compliance with the standards required by the National Environmental Agency.

6 Documentation

6.1 The Licensee shall keep detailed records in respect of its compliance with the requirements set out in paragraphs 5.9 to 5.18.

6.2 For the purposes of paragraph 6.1, the records shall minimally include:

(1) the names of all persons involved in the procedure and the administration of any anaesthetic to cause Sedation or General Anaesthesia;

(2) the history, physical examination and investigations of the patient;

(3) the dosages and timings of any administered anaesthetic that cause sedation;

(4) vital signs monitored at 5-minute intervals intra-procedure and 15-minute intervals post-procedure (to keep electronic printouts, if available);

(5) any adverse event(s) and interventions performed on the patient, including the dosages and timings of resuscitation drugs (refer to Annex B for sample procedural sedation adverse event checklist);

(6) the recovery status of the patient; and

(7) the patient's fitness for discharge.

7 Quality Assurance

7.1 The Licensee shall implement a framework for receiving, evaluating, investigating and documenting all errors, adverse events and accidents arising from or in connection with the administration of any anaesthetic to cause Sedation or General Anaesthesia by the Licensee.

7.2 The Licensee shall ensure that details of each error, adverse event and accident are documented and form the basis of ongoing training, education and support of all personnel involved in the care of patients that have been administered any anaesthetic to cause Sedation or General Anaesthesia.

ANNEX A

<table>
<tr><th>State of Patient
Anaesthetics or Sedatives</th><th>Minimal Sedation</th><th>Moderate Sedation</th><th>Deep Sedation</th><th>General Anaesthesia</th><th>Type of Patient</th></tr>
<tr><td>Propofol</td><td colspan="4">Proceduralist and Sedationist <u>must be distinct individuals</u>
Proceduralist: Medical Practitioner / Dentist
Sedationist: Anaesthesiologist</td><td rowspan="3">Adult patients</td></tr>
<tr><td>Non-Propofol Drugs</td><td>Proceduralist and Sedationist <u>may be the same individuals</u>

Proceduralist: Medical Practitioner / Dentist

Sedationist
(A) Medical Practitioner / Dentist / Registered Nurse* or (B) Anaesthesiologst

*Additional conditions apply if (1) nitrous oxide is used, (2) the Sedationist is Registered Nurse, or (3) the patient is a child.</td><td>Proceduralist and Sedationist <u>must be distinct individuals</u>

Proceduralist:
Medical Practitioner /Dentist

Sedationist:
(A) Medical Practitioner / Dentist / Registered Nurse* or (B) Anaesthesiologst

*Additional conditions apply if (1) nitrous oxide is used, (2) the Sedationist is Registered Nurse, (3) the patient is a child; or (4) both the Proceduralist or the Sedationist are Non-Anaesthesiologst</td><td colspan="2">Proceduralist and Sedationist <u>must be distinct individuals</u>

Proceduralist: Medical Practitioner /Dentist

Sedationist: Anaesthesiologist</td></tr>
<tr><td rowspan="3">Permitted Licensable Healthcare Services and Modes of Service Delivery</td><td>ARS, CCS, CHS, ASCS, NMS, ODS, OMS and RS Licensees
Through <u>approved permanent premises</u>; <u>approved temporary premises</u>; or <u>approved conveyances</u>, only.</td><td colspan="2">ARS, CCS, CHS, ASCS, NMS, ODS, OMS and RS Licensees
Through <u>approved permanent premises</u> only.</td><td rowspan="2">NMS, RS, ARS and ASCS Licensees
Through their <u>approved permanent premises</u> only.</td><td rowspan="2">Child patients above 28 days</td></tr>
<tr><td colspan="2">Propofol: <u>Not Permitted</u>

Non-Propofol Drugs: Similar to the above</td><td>NMS, RS, ARS, ASCS, CCS and CHS Licensees Through <u>approved permanent premises</u> only.</td></tr>
<tr><td colspan="4"><u>Not Permitted</u></td><td>Neonates (below 28 days old)</td></tr>
</table>

ANNEX B: PROCEDURAL SEDATION ADVERSE EVENT CHECKLIST

Adverse Events during Procedural Sedation (if any)

	NO
	YES (to duplicate form if present) (Can √ more than 1)
	Oxygen desaturation [require airway intervention] Lowest SpO2 measured_____%
	Apnea [cessation of respiratory effort and requiring airway intervention]
	Partial airway obstruction [stridor, snoring or retraction AND required airway intervention(s)]
	Complete airway obstruction [Ventilatory effort with NO air exchange manifested by ALL of the following: a) Absence of upper airway (e.g. stridor or snoring) and breath sounds on auscultation b) Loss of CO2 waveform (when capnography is used) AND requiring airway intervention(s)]
	Laryngospasm [Complete airway obstruction WITH oxygen desaturation due to involuntary and sustained closure of the vocal cords preventing effective ventilation that REQUIRES positive pressure ventilation with or without neuromuscular blockade to overcome the symptom.]
	Clinically Apparent Pulmonary Aspiration [suspicion or confirmation of oropharyngeal or gastric contents in the trachea AND 1 or more of the following respiratory signs and symptoms in any of the 3 categories: (i) Physical signs: cough, crackles, decreased breath sounds, wheezing, tachypnoea or respiratory distress (ii) Oxygen requirement: desaturation requiring oxygen (iii) CXR: focal infiltrates, or consolidation]
	Vomiting No. of times_____[requiring additional treatment and delay in discharge]
	Bradycardia [e.g. For the child - HR < the minimum expected normal rate for the age range and/or with evidence of poor perfusion and require intervention.]
	Hypotension [e.g. For the child - systolic BP < 5th percentile for age AND required intervention]
	Myoclonus [involuntary brief contractions requiring an intervention /medication and interferes with procedure.]
	Generalised motor seizure
	Muscle rigidity [Involuntary muscle stiffening in extension that can be associated with shaking AND interferes with the procedure, requiring an intervention or administration of medications]
	Paradoxical response to sedation [unanticipated restless or agitation in response to sedation drugs during sedation AND results in administration of other sedative medication, delay in completion of procedure or discontinuation of procedure]
	Unpleasant Recovery Reactions [abnormal patient behaviour during recovery phase requiring treatment or delay in patient discharge]. Tick any of the following criteria: **Inconsolable crying** **Delirium** (state of severe confusion, altered mental) **Agitation** (restless, continuous activity) **Nightmares** **Hallucinations** (responds to sensory phenomena not physically present) **Dysphoria** (mood of restlessness, depression and anxiety)
	Permanent neurological injury
	Death
	Others, please state:
	Intervention (can tick more than 1): ☐ vigorous tactile stimulations

	☐ airway repositioning ☐ suctioning ☐ oxygen oral airway ☐ bagged and mask assisted ventilation ☐ intubation ☐ administration of medication, please state: ☐ Chest compression ☐ IV fluids ☐ physical restraints ☐ Delayed discharge