

**Independent Hospitals with surgical services**

**Pre-Registration Self-Assessment Form (SAF)**

****

Independent Hospital – Surgical Services

Name of service: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- |
| **Name of hospital:** |       |
| **Address:** |       |
| **Name of organisation:** |       |
| **Name of applicant registered person/responsible individual:** |       |
| **Name of applicant registered manager:**  |       |

**Persons involved with completing the SAF:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name**  | **Job title** | **Department** | **Telephone number** | **Email**  |
|       |       |       |       |       |
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**Form completed by:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job title** | **Department** | **Date**  |
|       |       |       |       |

**Signed by the registered person/ responsible individual as a true record to the best of our knowledge:**

|  |  |
| --- | --- |
| **Name** | **Job title** |
|       |       |
| **Signature** | **Date**  |
|       |       |

1. **Introduction**

Independent Hospitals offering surgical services are required to register with The Regulation and Quality Improvement Authority (RQIA) as independent hospitals in accordance with [The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003](https://www.legislation.gov.uk/nisi/2003/431/made/data.pdf).

RQIA will undertake an initial pre-registration inspection of the independent hospital. Should registration be granted RQIA will monitor the service provided by the hospital and will undertake an inspection at least once in every 12-month period as set out in the legislation.

The purpose of the pre-registration inspection is to determine compliance with the following:

* [The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003](http://www.legislation.gov.uk/nisi/2003/431/pdfs/uksi_20030431_en.pdf)
* [The Independent Health Care Regulations (Northern Ireland) 2005](http://www.legislation.gov.uk/nisr/2005/174/pdfs/nisr_20050174_en.pdf)
* [The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005](https://www.legislation.gov.uk/nisr/2005/99/pdfs/nisr_20050099_en.pdf)
* [The Department of Health, (DOH) Minimum Care Standards for Healthcare Establishments July 2014](https://www.rqia.org.uk/RQIA/media/RQIA/Resources/Standards/Independent_Healthcare_Minimum_Standards.pdf)

In addition, the pre-registration inspection will determine if providers have knowledge of the relevant legislation and minimum standards.

* 1. **Pre-registration self-assessment**

The pre-registration self- assessment document sets out the regulations, standards and associated criteria, which must be in place to achieve registration.

Where asked in the self-assessment you are required to indicate a yes no or not applicable (N/A) response. **You are also asked to provide a brief narrative in the "text box"** evidencing how the service meets the criterion set out immediately above the box or to provide an explanation when a "no" response is given.

Following completion of the self-assessment, please return to the registration team in RQIA (registration@rqia.org.uk) along with the supporting documentation requested.

The responses in the self-assessment will be validated by RQIA during the pre-registration inspection and your responses may form part of the pre-registration inspection report.

For assistance in completing this self-assessment form, please see the covering email. Where you refer to the hospital’s written procedures in your responses on this form, please clearly indicate the specific procedure.

**1.** **Previous external audits, reviews or inspections**

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| **1.2** | **Has there been a previous audit, review or inspection of the hospital by an external body within the last two years?** If yes, please name the external body and provide the date of the last audit, review or inspection  |
| **External body** | **Date** |
|       |       |
| **1.3** | **Are there any actions outstanding?** If yes, please list briefly and indicate reason for non-completion and attach a copy of the report from the external body. |
|       |
| **RQIA comments:** |

**2. Hospital information – services**

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| --- | --- | --- |
| **2.1** | **Describe the services provided within the hospital?**  | **Provide detailed information** |
| **Surgical services – outline specific categories of surgical procedures** |       |
| **Day procedures-** **Inpatient surgical procedures-**  |       |
| **Endoscopy service – outline specific procedures** |       |
| **Class 3B or 4 laser and or intense pulse light (IPL) services – outline specific laser/IPL procedures** |       |
| **Minor injuries unit** |       |
| **Outpatient services- outline details**  |       |
| **Radiology services – outline details*** **Diagnostic**
* **Nuclear medicine**
 |       |
| **On-site pathology services – outline details**  |       |

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| --- | --- | --- |
|  | **On-site sterile services department-*** **Reprocessing of surgical instruments**
* **Endoscopy decontamination suite**
 |       |
| **Private doctor services – outline details**  |       |
| **Paediatric services – outline details to include if surgical services are provided, consultation only, radiology services** |       |
| **Any other services not covered above – outline details**  |       |
| **RQIA comments:** |

**3. Hospital information - facilities**

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| --- | --- | --- |
| **3.1** | **Please describe the number and details of facilities**  |  |
| **Inpatient rooms -** |       |
| **Day procedure facilities – describe** **admission pods, patient changing, recovery area, discharge area (if appropriate)** |       |
| **Theatres -** |       |
| **Endoscopy suite** |       |
| **Recovery areas (for theatre/endoscopy)**  |       |
| **Critical care unit** |       |
| **Consultation rooms** |       |
| **Treatment rooms (minor procedures)** |       |
| **Clinical rooms**  |       |
| **Pathology laboratories and supporting facilities** |       |
| **Clean utility**  |       |
| **Dirty utility**  |       |
| **Patient toilet facilities (include toilet facilities for those individuals with a disability)** |       |
| **Patient shower facilities (where appropriate)** |       |
| **Catering facilities** |       |
| **Sterile services facilities** |       |
| **Radiology facilities -****General radiology diagnostic rooms****Computed Tomography(CT) suite** **Magnetic resonance imaging (MRI) suite****Other radiology facilities** |       |
| **Laundry facilities** |       |
| **Any other facilities not covered above-** |       |

1. **Hospital information - staff providing hospital services including surgical services**

|  |  |
| --- | --- |
| **4.1** | **Give numbers of staff in hospital in the categories listed below****\*Please indicate specialty where appropriate\*** |
| **Medical practitioners under practicing privileges-****Consultant surgeons** **Consultant anaesthetists** **Consultant physicians** **Surgical Assistants**  | Provide detailed information       |
| **Private doctors** |       |
| **Doctors employed by the hospital** |       |
| **Resident medical officers(RMOs)** |       |
| **Management staff****Identify roles-** |       |
| **Allied health professional staff****Identify roles-** |       |
| **Ward nursing staff**  |       |
| **Theatre nursing staff** |       |
| **Operating theatre technicians**  |       |
| **Other theatre support staff-****Identify roles-** |       |
| **Recovery nursing staff** |       |
| **Critical Care unit staff****Identify roles-** |       |
| **Day procedure unit nursing staff****Identify roles-** |       |
| **Outpatient nursing staff**  |       |
| **Radiology staff****Identify roles-** |       |
|  | **Pathology staff** |       |
| **Support staff-****Catering** **Administration** **Estates****Domestic****Laundry****Other** |       |
| **RQIA comments:**  |

**5. Staffing arrangements**

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| --- | --- | --- | --- |
| **5.1** | **Reg.18**  |  | Provide detailed information  |
| **Describe arrangements to ensure there is sufficient numbers of staff in various roles to fulfil the needs of the hospital and patients** |       |
|  |  | **Describe the staffing structure for surgical services that defines lines of accountability, specifies roles and details responsibilities for areas of activity** |       |
| **Describe the process in place for the following:*** **an induction programme which is appropriate to the role**
* **supervision and annual appraisal**
 |       |
| **Describe the arrangements to ensure:*** **that all staff receive appropriate training to fulfil the duties of their role including professional body Continuing Professional Development (CPD)**
* **staff receive mandatory training in accordance with** [**RQIA training guidance**](https://www.rqia.org.uk/RQIA/files/23/234ed963-4957-4002-9886-109285fb2692.pdf)
* **staff receive appropriate training when new procedures are introduced**
 |       |
| **Describe the arrangements for monitoring the professional registration status with the regulatory body (e.g. GMC, NMC, HCPC) of all clinical staff.** |       |
| **Describe the arrangements in place for monitoring the professional indemnity for the service and of all staff who require individual indemnity cover.** |       |
| **Describe the arrangements in place to ensure each private doctor has:*** **confirmation of identity,**
* **current General Medical Council (GMC) registration**
* **professional indemnity insurance**
* **qualifications in line with service provided**
* **evidence of ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC**
* **an appointed responsible officer(RO)**
* **evidence of arrangements for revalidation**
* **is aware of their responsibilities under GMC Good Medical Practice**
* **Is the hospital a designated body?**
* **If so provide the name and contact details of the RO**
 |       |
| **RQIA comments:** |

**6. Recruitment and Selection**

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| **6.1** | **Reg.19****Reg. 21** |  | Provide detailed information |
| **Describe how you ensure recruitment and selection is in accordance with Regulation 19 (2), Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.****Is there a comprehensive recruitment and selection policy and procedure in place Regulation 19 (2), Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended?****Describe how you ensure there is an up-to-date staff register maintained and retained in keeping with Regulation 21.****Describe how you ensure that recruitment and selection records are retained in keeping with Regulation 21 (3) Schedule 3 Part II** |                      |
| **RQIA comments:** |

**7. Safeguarding**

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|  |  | **Adult safeguarding****Are there policies and procedures are in line with the regional** [**Adult Safeguarding Prevention and Protection in Partnership policy (July 2015)**](https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/adult-safeguarding-policy.pdf) and [**Northern Ireland Adult Safeguarding Partnership operational handbook June 2017**](https://niopa.qub.ac.uk/bitstream/NIOPA/7268/1/NIASP-Operational-Manual-July-2017.pdf)**.****Describe the arrangements for:*** **an identified an adult safeguarding champion (if required)**
* **an identified safeguarding lead**
* **how staff are made aware of who the safeguarding lead is**
* **Staff training in keeping with** [**Northern Ireland Adult Safeguarding Partnership Training Strategy 2013 (revised 2016)**](https://www.volunteernow.co.uk/app/uploads/2022/05/NI-Adult-Safeguarding-Partnership-Training-Strategy-and-Framework.pdf)
 |       |
| **7.2** | **Reg.16** | **Children and young People****Are policies and procedures are in line with the regional** [**Co-operating to Safeguard Children and Young People in Northern Ireland, (August 2017)**](https://www.health-ni.gov.uk/publications/co-operating-safeguard-children-and-young-people-northern-ireland) **and** [**Safeguarding Board for Northern Ireland (SBNI) Procedures Manual (November 2017)**](http://www.proceduresonline.com/sbni/) | Provide detailed information       |
| **Describe the arrangements for:*** **an identified children and young people’s safeguarding champion (if required).**
* **an identified safeguarding lead for children and young people**
* **how staff are made aware of who the safeguarding lead is.**
* **Staff training in keeping with** [**SBNI Child Safeguarding Learning and Development Strategy and Framework 2020 – 2023.**](https://www.safeguardingni.org/sites/default/files/2021-01/SBNI%20LDSF%20Sept%202020-23%20Final.pdf)
 |       |
| **RQIA comments:** |
| **7.3** | **Reg.16** | **Describe the arrangements to ensure the following:*** **Staff are knowledgeable about safeguarding, familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.**
* **All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation; written records must be retained.**
* **Where shortcomings are highlighted as a result of an investigation, learning arising is assessed, implemented and quality assured.**
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| **RQIA comments:** |

**8. Management of Medical Emergencies**

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| **8.1** | **Reg.34** | **Are there policies and procedures in relation to the management of medical emergencies and resuscitation are in place (to include a risk assessment, training arrangements, provision of equipment, emergency medication, checking procedures, how to summon help, incident documentation and staff debriefing)?****Describe the arrangements to ensure:*** **Emergency medicines and equipment are in place in accordance with** [**British National Formulary**](https://bnf.nice.org.uk/) **(BNF) and the** [**Resuscitation Council (UK)**](https://www.resus.org.uk/library/2021-resuscitation-guidelines)
* **A robust system for checking expiry dates of medicines and equipment by an identified individual.**
* **Medicines required for resuscitation or other medical emergency are clearly defined and are regularly monitored. These medicines are readily accessible in suitable packaging and available for use at all times.**
* **Accessible records are maintained relating to the regular monitoring of medicines required for resuscitation or other medical emergencies.**
* **Resuscitation equipment is checked and restocked to ensure all equipment remains in working order and suitable for use at all times. Checks are carried out daily by a designated person and recorded.**
 | Provide detailed information                                |
| **8.1** | **Reg.34** | **Are there policies and procedures in relation to the management of medical emergencies and resuscitation in place (to include a risk assessment, training arrangements, provision of equipment, emergency medication, checking procedures, how to summon help, incident documentation and staff debriefing)?****Describe the arrangements to ensure:*** **Emergency medicines and equipment are in place in accordance with** [**British National Formulary**](https://bnf.nice.org.uk/) **(BNF) and the** [**Resuscitation Council (UK)**](https://www.resus.org.uk/library/2021-resuscitation-guidelines)
* **A robust system for checking expiry dates of medicines and equipment by an identified individual.**
* **Medicines required for resuscitation or other medical emergency are clearly defined and are regularly monitored. These medicines are readily accessible in suitable packaging and available for use at all times.**
* **Accessible records are maintained relating to the regular monitoring of medicines required for resuscitation or other medical emergencies.**
* **Resuscitation equipment is checked and restocked to ensure all equipment remains in working order and suitable for use at all times. Checks are carried out daily by a designated person and recorded.**
 | Provide detailed information                                |
| **RQIA comments:** |
| **8.2** | **Reg.34** | **Describe the process to ensure:*** **Management of resuscitation and medical emergencies is included in staff induction and update training is provided annually. This training is updated in line with RQIA training guidance and includes paediatric advanced life support training (if relevant).**
* **Staff have knowledge and understanding of managing resuscitation and medical emergencies.**
* **There is at least one person with advanced life support training (ALS) on duty at all times (if relevant).**
 |        |
| **RQIA comments:** |
| **8.3** | **Reg 35** | **Describe arrangements for management of blood loss / critically anaemic patients** **in accordance “**[**Preventing transfusion delays in bleeding and critically anaemic patients” SHOT HSC SQSD 8/4/22**](https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-shot-hsc-sqsd-6-22.pdf)**.****Describe emergency equipment and medication available in the event of a massive blood loss:*** **massive blood loss box/tray**
* **Describe the patient transfer out arrangements to a Health and Social Care (HSC) hospital in the event of a medical emergency or serious post -operative complication**
* **Is there a patient transfer out policy and procedure in place?**
* **Describe how staff are made aware of the patient transfer out arrangements**
 |                           |

**9. Infection Prevention and Control (IPC) and decontamination procedures**

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| **9.1** | **Reg.15(3) (4)****(5) (7)** |  | Provide detailed information  |
| **Are there Infection prevention and control (IPC) policies and procedures are in place in keeping with** [**The Northern Ireland Regional Infection Prevention and Control Manual**](https://www.niinfectioncontrolmanual.net/)**.?** **Describe:** |       |
| **RQIA comments:** |
| **9.2** | **Reg.15(3) (4)****(5) (7)** | **Describe the arrangements to ensure IPC measures are in accordance to best practice and minimise the risk of hospital acquired infection for patients.****Are there arrangements to carry out an IPC expert/advisor audit of the service as part of registration process?****Describe** **Are there arrangements to carry out microbiological studies of the theatre/ treatment room areas where proposed surgical procedures will be performed as part of the registration process?****Describe**  |                 |
| **RQIA comments:** |

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| **9.3** | **Reg.15(3) (4)****(5) (7)** | **Describe the decontamination arrangements for the following:*** **Surgical instruments**
* **Medical devices**
* **Endoscopy equipment**
 |       |
| **RQIA comments:** |
| **9.4** | **Reg.18(2)** | **Describe IPC staff training including:*** **Aseptic Non-Touch Technique(ANNT) training**
 |       |
| **RQIA comments:** |
| **9.5** | **Reg.15(3) (4)****(5) (7)** | **Describe IPC governance arrangements to include:*** **IPC lead**
* **IPC committee (or equivalent)**
* **IPC audits**
* **Access to IPC specialists for example external IPC consultant, microbiologist, Public Health Agency**
 |       |
| **RQIA comments:** |
| **9.6** | **Reg.15(3) (4)****(5) (7)** | **Describe COVID-19 arrangements to ensure the following:****Staff should have knowledge and understanding and adhere to the most up to date Department of Health (DoH) guidance.****The websites listed below:*** [**Public Health Agency (PHA) Covid-19 webpage**](https://www.publichealth.hscni.net/covid-19-coronavirus)**:**
* [**Northern Ireland (NI) direct Covid-19 webpage**](https://www.nidirect.gov.uk/information-and-services/health-and-wellbeing/coronavirus-covid-19)**:**
* **are routinely reviewed**
 |       |
| **RQIA comments:** |

**10. Surgical Services**

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| **10.1** | **Reg.37** |  | **Provide detailed information**  |
| **Are there policies and procedures for surgical services are in accordance with best practice guidelines as defined by professional bodies and national standard setting organisations including the World Health Organisation (WHO)** [**Surgical Checklist**](https://iris.who.int/bitstream/handle/10665/44186/9789241598590_eng_Checklist.pdf?sequence=2&isAllowed=y) **and Surgical Pause** [**Implementation manual WHO surgical safety checklist 2009**](https://www.who.int/publications/i/item/9789241598590)[**Royal college of surgeons- Good Surgical Practice guide 2025**](https://www.rcseng.ac.uk/-/media/Files/RCS/Standards-and-research/GSP/Good-Surgical-Practice-Guide-2025.pdf)**Describe** |       |
| **Describe the arrangements for scheduling of patients for surgical procedures** |       |
| **Describe staffing arrangements for theatre** |       |
| **Are surgical assistants with practising privileges assisting in surgical procedures?****Is a there a written log of each occasion the surgical assistant is involved in surgical procedures in place?** |       |
| **Describe how informed consent is obtained in accordance to best practice**  |       |
| **Describe how the mental capacity of the patient is assessed*** **What are systems and processes in place to identify where there may be evidence of lack of mental capacity?**
* **is there a model of consultation, which facilitates an assessment of capacity in line with legal expectations?**
 |       |
| **RQIA comments:** |

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| **10.2** | **Reg.37** |  | **Provide detailed information**  |
| **Describe the pre-operative arrangements for patients undergoing surgical procedures** |       |
| **Describe the intra -operative arrangements for patients undergoing surgical procedures, including:*** **management of intraoperative fluids**
* **invasive line labelling**
* **completion of the surgical register.**
 |       |
| **Describe the post -operative arrangements for patients undergoing surgical procedures, including first stage recovery.** |       |
| **Describe the arrangements for the prevention of venous thromboembolism (VTE) in line with best practice.** |       |
| **Describe the arrangements for pathology services:** * **Are there policies and procedures on the management of specimens?**
* **an adequate range of pathology services are available to meet the needs of the patients attending the independent hospital;**
* **appropriate arrangements are made for the collection, and (where pathology services are provided outside the hospital) transportation of specimens; and the patient from whom a specimen was taken and such specimen, is identifiable at all times**
 |                 |
| **Describe the arrangements to ensure submission of information to:*** **The National Joint Registry**
* **Breast and Cosmetic Implant Registry (BCIR)**
* **Private Healthcare Information Network(PHIN)**
 |       |
| **RQIA comments:** |

**11. Inpatient Services**

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| **11.1** | **Reg.15** | **Describe the patient pathway at ward level*** **Nursing care**
* **Medical care**
* **Allied health professional care**
 |       |
| **Describe arrangements to provide adequate nutrition for inpatients in accordance to their dietary requirements** |       |
| **Describe arrangements to ensure** **patient’s privacy and dignity is respected at all times.** |       |
| **Describe arrangements to ensure patients’ rights to make decisions about care and treatment are acknowledged and respected.** |       |
| **Describe arrangements to ensure patients are treated and cared for in accordance with legislative requirements for equality and rights.** |       |
| **Describe discharge planning and management arrangements** |       |
| **RQIA comments:** |

**12. Governance arrangements**

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| **12.1** | **Reg 7****Reg. 8****Reg.17** | **Is there a Statement of Purpose prepared in accordance with Regulation 7, Schedule 1 of The Independent Health Care Regulations (NI) 2005, which contains all relevant information as specified in Regulation 7, Schedule 1 of The Independent Health Care Regulations (NI) 2005?****Is there a Patient Guide which meets the requirements of Regulation 8 of the Independent Health Care Regulations (NI) 2005?****Has a copy of the Statement of Purpose and the Patient Guide been sent to RQIA?****Describe the management and governance systems in place to ensure the overall quality and safety of services provided.****Example- organisation structure, governance committees,** |                           |
| **Describe the arrangements in place in relation to medical governance in accordance with the GMC guidance document:** [**Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors’**](https://www.rqia.org.uk/RQIA/files/e6/e63ece9f-d6a3-415f-9721-383e0d8d0f32.pdf)**.** |       |
| **Describe the arrangements in place to ensure that all surgical procedures are undertaken per the guidance and standards produced by Royal College of Surgeons and National Institute of Clinically Excellence (NICE).** |       |
| **Describe the management of policies and procedures****Including** * **the ratification process,**
* **ensuring policies/procedures are centrally indexed and retained in a manner which is easily accessible by staff**
* **that policies and procedures are reviewed at least every three years**
 |       |
| **RQIA comments:** |

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| **12.2** | **Reg.17(5)** | **Describe the management of incidents or near misses** |       |
| **RQIA comments:** |
| **12.3** | **Reg.23** | **Describe the management of complaints** |       |
| **RQIA comments:** |
| **12.4** | **Reg.17** | **Describe arrangements for carrying out a structured audit programme including clinical audit** |       |
| **RQIA comments:** |
| **12.5** | **Reg.15(1)** | **Describe the arrangements for managing:*** **safety alert**
* **professional alerts/learning letters**
* **DOH letter**
 |       |
| **RQIA comments:** |
| **12.6** | **Reg.17** | **Describe the arrangements to establish and manage a risk register.** |       |
| **RQIA comments:** |

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| **12.7** | **Reg.17** | **Describe the arrangements for granting, reviewing, suspending and withdrawing practising privileges to include:*** **there is clear policy and procedure in place in relation to practising privileges**
* **ensuring all relevant medical practitioners have practising privileges agreements in place with a defined scope of practice**
* **clear review arrangements, how and who is responsible**
* **Arrangements are in place for senior management/ governance board to regularly scrutinise practising privileges arrangements as recommended by the Independent Neurology Inquiry (INI)**
* **The establishment should ensure their organisation website references what is expected of consultants by publishing criteria for practising privileges.**
 |                                |
| **RQIA comments:** |
| **12.8** | **Reg.17** | **Describe patient consultation (patient satisfaction survey) arrangements about the standard and quality of care and environment which is carried out at least on an annual basis.** **How are the findings shared with staff and patients?****How are the findings used to drive improvement?** |                 |
| **RQIA comments:** |
| **12.9** | **Reg.17** | **Describe the role of the Medical Advisory Committee (MAC) to include: terms of reference, participants, frequency of meetings, matters discussed and reports presented to the MAC, action taken,****Is there evidence of Professional Indemnity, Employers Liability and Public Liability insurance in accordance with the services provided?** |            |
| **RQIA comments:** |

**13. Estates - Information about the premises**

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| --- | --- | --- | --- |
| **13.1** | **Reg 25** | **Please confirm that planning permission has been obtained and that the conditions of the same have been compiled within respect of the development ( new works, change of use etc)** | Provide detailed information       |
|  |  | **Please confirm that a notice of passing of plans in compliance with current building regulations has been received and you have received a letter of satisfactory completion of the works from building control.** |       |
|  |  | **Does the hospital have a health and safety policy?** |       |
|  |  | **Are health and safety risk assessments carried out and regularly reviewed.** |       |
|  |  | **Does the hospital comply with Control of Substances Hazard to Health 2002 (COSHH) Regulations?** |       |
| **RQIA comments:** |
| **Fire Safety. Regulation 25 (4) of The Independent Health Care Regulations (NI) 2005** **Standard 24 of The Independent Health Care Minimum Standards 2014** |
| **13.2** | **Reg 25(4)** | **Has the Northern Ireland Fire and Rescue Service (NIFRS) been consulted in relation to the fire safety arrangements?**[**The Fire and Rescue Services (Northern Ireland) Order 2006**](https://www.legislation.gov.uk/nisi/2006/1254/made/data.pdf)[**The Fire Safety Regulations (Northern Ireland) 2010**](https://www.legislation.gov.uk/nisr/2010/325/made/data.pdf) |       |
|  |  | **Is there an up to date Fire Risk Assessment and Fire Management Plan?**[**Fire Safety Risk Assessment Healthcare Premises**](https://www.nifrs.org/wp-content/uploads/2021/02/Healthcare-Premises.pdf) |       |
|  |  | **Is there a fire safety policy which includes an emergency evacuation plan?** |       |
|  |  | **Have all staff received training in fire prevention and the procedure to follow in the case of a fire?** |       |
|  |  | **Will periodic fire evacuation drills be carried out and have all staff taken part in one?** |       |
|  |  | **Is fire equipment maintained in line with best practice guidelines? (E.g. fire alarm system, emergency lighting, fire extinguishers, fire doors)** |       |
|  |  | **Does the practice use piped or cylinders of oxygen?** |       |
|  |  | **If cylinders, are these clearly noted on the fire management plan?** |       |
| **RQIA comments:** |
| **13.3 – Plumbing and Installation** **Regulation 25 (4) of The Independent Health Care Regulations (NI) 2005** **Standard 22 of The Independent Health Care Minimum Standards 2014** |
| **13.3** | **Reg****25(4)** | **Has a Legionella risk assessment based upon the Approved Code of Practice issued by HSENI on control of legionella bacteria in water systems (L8) been carried out and an action plan agreed?** [**Legionnaires' disease Technical guidance. Part 2: The control of legionella bacteria in hot and cold water systems HSG247 (hse.gov.uk)**](https://www.hse.gov.uk/pubns/priced/hsg274part2.pdf) |       |
|  |  | **Have control measures identified in the risk assessment been implemented?** |       |
|  |  | **Have precautions been taken to reduce the risk of scalding at hot water outlets?** |       |
|  |  | **Has the space heating boiler been serviced in the last year** |       |
| **RQIA comments:** |
| **13.4 Electrical testing*** **Regulation 25 of The Independent Health Care Regulations (NI) 2005.**
* **Standard 22 of the DoH Minimum Standards for Dental Care and Treatment 2011.**
 |
| **13.4** | **Reg 25** | **Is the fixed electrical installation safely maintained?**[**Electrical safety and you**](https://www.hse.gov.uk/pubns/indg231.pdf) |       |
|  |  | **Is electrical equipment including fixed and portable equipment safely maintained?**[**Maintaining portable electrical equipment**](https://www.hse.gov.uk/pubns/books/hsg107.htm) |       |
| **RQIA comments:** |
| * 1. **Lift installation**
* **Regulation 25 of The Independent Health Care Regulations (NI) 2005.**
* **Standard 22 of the DoH Minimum Standards for Dental Care and Treatment 2011.**
 |
| **13.5** | **Reg 25** | **Is the lift and/or lifting equipment subjected to regular thorough examinations and is a report from a competent person in accordance with Schedule 2 of The Lifting Operations Lifting Equipment Regulations date in place?** [**Lifting Operations and Lifting Equipment Regulations (Northern Ireland) 1999 (legislation.gov.uk)**](https://www.legislation.gov.uk/nisr/1999/304/made) |       |
| **RQIA comments:** |
| **13.6 Gases*** **Regulation 25 of The Independent Health Care Regulations (NI) 2005.**
* **Standard 22 of the DoH Minimum Standards for Dental Care and Treatment 2011.**
 |
| **13.6** | **Reg 25** | **Are certificates of safety checks by a Gas – Safe registered engineer for the gas installation and gas equipment in place?** |       |
|  |  | **Are there suitable facilities for the storage of gas cylinders including anaesthetic gases** **which comply with current health and safety guidelines?**  |       |
| **RQIA comments** |
| * 1. **Heating and ventilation**
* **Regulation 25 of The Independent Health Care Regulations (NI) 2005.**
* **Standard 22 of the DoH Minimum Standards for Dental Care and Treatment 2011.**
 |
| **13.7** | **Reg 25** | **Are arrangements in place to ensure that ventilation systems are installed and approved by a competent person, in line with Part A of** [**(HTM 03-01) - Heating and ventilation of health sector buildings**](https://www.gov.uk/government/publications/guidance-on-specialised-ventilation-for-healthcare-premises-parts-a-and-b) **and maintained in keeping with Part B of** [**(HTM 03-01) - Heating and ventilation of health sector buildings**](https://www.gov.uk/government/publications/guidance-on-specialised-ventilation-for-healthcare-premises-parts-a-and-b)**.** |       |

**14. Medicine management – part 1**

**Standard 25 - Medicines are managed safely, securely and effectively in compliance with legislative requirements, professional standards and guidelines.**

| **Question** | **Yes** | **No** |
| --- | --- | --- |
| **14.1. Do the independent hospital support doctors to practise in line with the GMC guidance on proposing, prescribing, providing and managing medicines and devices?**[Good practice in proposing, prescribing, providing and managing medicines and devices - GMC](https://www.gmc-uk.org/professional-standards/the-professional-standards/good-practice-in-prescribing-and-managing-medicines-and-devices) | **[ ]**  | **[ ]**  |
| Please provide details:  |
| **Provider response:**      |

|  |
| --- |
| **14.2. What services are provided which require the use of medicines?** |
| **Provider response:**      |
| **14.3. Do you have up-to-date written policies and standard operating procedures for the management of medicines which cover all aspects of medicines management within the organisation?**  |
| **Provider response:**           |
| **14.4. What arrangements are in place to ensure that the management of medicines is conducted by qualified, trained and competent staff?**  |
| **Provider response:**      |
| **14.5. Are records of staff training and competency assessment in relation to medicines management maintained?** |
| **Provider response:**      |
| **14.6. Who has overall responsibility for the safe, secure and effective management of medicines?**(Are there clear lines of accountability leading to the Chief Executive or Board where applicable?)  |
| **Provider response:**      |
| **14.7. Who is authorised to obtain prescription only medicines and medicinal products from suppliers and how are these medicines obtained?**  |
| **Provider response:**           |
| **14.8. Who is authorised to prescribe medicines?** |
| **Provider response:**      |
| **14.9. What system is in place to ensure that medicines are prescribed safely in line with evidence based practice, current guidance, local formulary and within the prescriber’s scope of practice?**  |
| **Provider response:**      |
| **14.10. Are regular audits completed to ensure that prescribing is in line with evidence based practice, current guidance, local formulary and within the prescriber’s scope of practice?**  |
| **Provider response:**      |
| **14.11. How are deviations from the current guidance, local formulary and scope of practice escalated and actioned?** |
| **Provider response:**      |
| **14.12. Who is authorised to administer medicines?** |
| **Provider response:**      |
| **14.13. What are the arrangements for the disposal of medicines?** |
| **Provider response:**      |
| **14.14. What is your system to manage drug alerts, medical device alerts and safety warnings about medicines?** |
| **Provider response:**      |

|  |
| --- |
| **14.15. What is your system to manage/ report safety problems relating to medicines, medical devices, blood and defective medicines to the Medicines and Healthcare Regulatory Agency (MHRA)?** |
| **Provider response:**      |
| **14.16. What is your system to manage adverse incidents involving medicines and medicinal products to ensure they are promptly identified, recorded, reported and analysed?** |
| **Provider response:**      |
| **14.17. How do you audit all aspects of the management of medicines?****Are records of audits maintained?**  |
| **Provider response:**      |
| **Question** | **Yes** | **No** |
| **14.18. Are any medicines administered or supplied to service users via Patient Group Directions (PGDs)?**  | **[ ]**  | **[ ]**  |
| If stating yes please give reason and details of the medicines: |
| **Provider response:**      |
| **Question** | **Yes** | **No** |
| **14.19. Do you use any unlicensed and/or off label medicines?** | **[ ]**  | **[ ]**  |
| If stating yes please give reason: |
| **Provider response:**       |
| **14.20. Are medicines prepared immediately prior to their administration from the container in which they are dispensed under appropriate conditions in accordance with their Summary of Product Characteristics?**  | **[ ]**  | **[ ]**  |
| If stating no please give reason: |
| **Provider response:**       |

|  |
| --- |
| **Question** |
| **14.21. Are patients/clients required to self-administer medicines?** | **[ ]**  | **[ ]**  |
| If stating yes, is there a standard operating procedure in place, which includes consent, assessment of patient suitability and staff training? Where are these medicines stored?  |
| **Provider response:**       |
| **Question** | **Yes** | **No** | **N/A** |
| **14.22. Are there procedures in place for the safe storage of prescription pads?**  | **[ ]**  | **[ ]**  | **[ ]**  |

|  |
| --- |
| **Provider response:**       |
| **14.23. How do you obtain confirmation of a patient’s currently prescribed medicines before starting treatment?** |
| **Provider response:**       |
| **Question**  | **Yes** | **No** |
| **14.24. Are there arrangements to check if the patient is taking any over the counter medicines?** | [ ]  | [ ]  |
| **Provider response:**       |

|  |  |  |
| --- | --- | --- |
| **Question** | **Yes** | **No** |
| **14.25. If medicine is needed as part of treatment, is this fully explained to the patient, including:****• the reasons for taking the medication** **• the consequences of not taking the medication** **• any common side effects** **• how to get the medication** | [ ]  | [ ]  |
| **Provider response:**       |
| **Question** | **Yes** | **No** |
| **14.26. Are patients advised pre-and post- treatment in relation to taking or ceasing their currently prescribed medicines?**  | **[ ]**  | **[ ]**  |
| **Provider response:**       |  |  |

**15. Medicine management – part 2**

**Standard 26 - Medicines are safely and securely stored in compliance with legislative requirements, professional standards and guidelines.**

|  |
| --- |
| **15.1. Where are medicines stored within the service?** |
| **Provider response:**      |
| **15.2. Who has access to the keys to medicines storage areas?**  |
| **Provider response:**      |
| **15.3. Who has overall responsibility with regard to control of the keys/access to medicines storage areas?** |
| **Provider response:**      |
| **15.4. Do patients bring their own medicines into the service? If yes, are these medicines assessed before use and stored in a safe place and returned to the service user at discharge?** |
| **Provider response:**      |
| **15.5. Are medicines required for resuscitation or other medical emergency clearly defined and regularly monitored?** **Are these medicines readily accessible in suitable packaging and available for use at all times?** **Are these medicines regularly monitored to ensure available and in-date?**  |
| **Provider response:**      |
| **Question** | **Yes** | **No** |
| **15.6.** **Do you have a refrigerator for the storage of medicines?** | **[ ]**  | **[ ]**  |
| **Question** | **Yes** | **No** | **N/A** |
| **15.7. If you store medicines in a refrigerator, is the maximum, minimum and current temperature monitored and recorded on a daily basis (when the practice is open) to ensure that medicines are maintained within the range 2°C to 8°C?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **15.8. Is there a system is in place to ensure that any deviations in temperature from 2°C to 8°C is acted upon and addressed?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **15.9. Is the refrigerator thermometer reset every day (when the service is open)?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **15.10. Is the refrigerator serviced regularly?**  | **[ ]**  | **[ ]**  | **[ ]**  |
| **Question** | **Yes** | **No** |
| **15.11. Do you have a freezer for the storage of medicines?** | **[ ]**  | **[ ]**  |
| **Question** | **Yes** | **No** | **N/A** |
| **15.12. Is the freezer approved, monitored and serviced regularly?**  | **[ ]**  | **[ ]**  | **[ ]**  |
| **Please provide any additional information on the storage of medicines:**       |

**16. Medicine management –part 3**

**Standard 27 - The management of controlled drugs is in compliance with legislative requirements, professional standards and guidelines.**

| **Question** | **Yes** | **No** |
| --- | --- | --- |
| **16.1. Are controlled drugs used within this service?**[**List of most commonly encountered drugs currently controlled under the misuse of drugs legislation - GOV.UK (www.gov.uk)**](https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation) | **[ ]**  | **[ ]**  |
| **If stating no, proceed to section 17 Medicine management –part 4**  |
| **If stating yes, please list which controlled drugs below** |
| **Provider response:**       |
| **Question**  | **Yes** | **No** |
| **16.2. Does the service have an Accountable Officer (AO) with responsibility for securing the safe management and use of controlled drugs in accordance with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009?** | **[ ]**  | **[ ]**  |
| **If yes, please provide the name of the AO** |
| **Provider response:**       |
| **If no, please explain why an AO is not required.** |
| **Provider response:**       |
| **Question** | **Yes** | **No** |
| **16.3. Does the service have a controlled drug licence issued by the Department of Health, unless specifically exempted by the Misuse of Drugs Regulations (Northern Ireland) 2002?** | **[ ]**  | **[ ]**  |
| **If no, please explain why the service is exempt?** |
| **Question** | **Yes** | **No** |
| **16.4. Are there Standard Operating Procedures which cover access, storage, security, destruction, disposal and record keeping of controlled drugs?**  | **[ ]**  | **[ ]**  |
| **Date of last review:**       |  |  |
| **Provider response:**      |
| **16.5. Please describe the internal auditing and monitoring process which evaluates and documents findings in relation to the organisation’s management and use of controlled drugs?** |
| **Provider response:**      |
| **16.6. Please describe the system to alert the AO or where there is no AO, a senior person, of any complaints or concerns involving the management or use of controlled drugs?** |
| **Provider response:**      |
| **16.7. Who is authorised to requisition, dispense and supply controlled drugs?** |
| **Provider response:**      |
| **16.8. Where are controlled drugs ordered/ requisitioned from?**  |
| **Provider response:**      |
| **16.9. Are records of controlled drug requisitions maintained and available for review/inspection?**  |
| **Provider response:**      |
| **16.10. How do you ensure that records of controlled drug requisitions, receipt, supply, administration and disposal are accurately maintained?**  |
| **Provider response:**      |
| **Question:**  | **Yes** | **No** |
| **16.11. Are controlled drugs stored in accordance with the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 and published guidance)?** | **[ ]**  | **[ ]**  |
| **16.12. Is the key to the controlled drug cupboard held separately from all other medicine keys?**  | **[ ]**  | **[ ]**  |
| **16.13. Is there a record of who is responsible for the key of the controlled drugs cabinet?** | **[ ]**  | **[ ]**  |
| **16.14. Please detail the arrangements for the reconciliation of Schedule 2 and Schedule 3 controlled drugs which are subject to safe custody legislation?** |
| **Provider response:**      |
| **16.15. Please provide details of how controlled drugs are administered in the service?**  |
| **Provider response:**      |
| **16.16. Please provide details of how controlled drugs are disposed of in the service?**  |
| **Provider response:**      |

**17. Medicine management- part 4**

**Standard 28 - Medicines records comply with legislative requirements, professional standards and guidelines.**

|  | **Yes** | **No** |
| --- | --- | --- |
| **17.1. Are medicines records legible and constructed, completed and retained in such a manner as to ensure that there is a clear audit trail?** | **[ ]**  | **[ ]**  |
| **17.2. Are the following medicines records completed?**1. **Medicines requested and received;**
2. **Medicines prescribed;**
3. **Medicines administered;**
4. **Medicines refused;**
5. **Medicines doses omitted;**
6. **Medicines doses delayed;**
7. **Medicines that are self-administered;**
8. **Medicines transferred;**
9. **Medicines disposed of.**
 | **[ ]**  | **[ ]**  |
| **17.3. Is there a system in place to ensure that medicine records are fully and accurately completed on all occasions?**  | **[ ]**  | **[ ]**  |
| **Provider response:**      |
| **17.4. Is there a controlled drug register in place?**  | **[ ]**  | **[ ]**  |
| **Provider response:**      |
| **17.5. Are there robust audit trails in place relating to the management and use of controlled drugs including a record of ordering, receipt, supply, administration and disposal of controlled drugs?**  | **[ ]**  | **[ ]**  |
| **Provider response:**      |
| **17.6. Is there a system to manage any recording errors?** | **[ ]**  | **[ ]**  |
| **Provider response:**      |
| **17.7. Where medicines are prescribed on a ‘when required’ basis, are parameters for use clearly defined in the patient’s records?** |
| **Provider response:**       |

**Appendix 1**

**Independent Hospital Pre-registration Inspections - surgical procedures**

**Documentation List**

|  |
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| **Please have the following documentation available for inspection:** **Policies/Procedures/Protocols/Guidelines** |
| **Governance arrangements/review of the Regulation 26 report (if applicable)** |
| Organisational Structure including the Board of Directors / Trustees |
| The most recent unannounced visit to the premises in line with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, if applicable.  |
| Statement of Purpose and Patient Guide |
| Written terms of reference for the Medical Advisory Committee (MAC) |
| Minutes of all staff meetings, * safety briefs, handovers,
* medical advisory committee (MAC),
* senior management meetings
* mortality and morbidity meetings
 |
| Complaints management – policy and complaints records* Records in relation to complaints received
* Summary of complaints received in the previous 12 months
* Record of complaints audit
 |
| Records of audits undertaken |
| Records in regards to all notifiable events, Serious Adverse Incidents (SAI’s) and safeguarding referrals made and infectious diseases  |
| Risk register |
| Organisational registers as specified in Schedule 3 of The Independent Health Care Regulations (Northern Ireland) 2005 |
| Records in respect of quality assurance, review and development - evidence of quality improvement strategy |
| Safeguarding adults and children policy |
| Raising concerns/Whistleblowing policy |
| Incident management policy |
| ICO registration certificate |
| **Recruitment and selection and staffing arrangements** |
| Recruitment and selection policy |
| Staff register  |
| Staff rota  |
| Staff personnel files recruited to include all information listed in The Independent Health Care Regulations (Northern Ireland) 2005, Regulation 19 (2) Schedule 2, as amended.  |
| Records pertaining to all Private Doctors (PDs)  |
| Staff training records and training matrix for **all** staff including PDs/ doctors with practising privileges  |
| Induction records |
| Supervision and appraisal arrangements |
| Evidence of professional indemnity and professional registration of professional staff |
| **Practising Privileges** |
| Practising privileges policy |
| All private doctors and sample of medical practitioners practising privileges agreements |
| **Records** |
| A register of patients attending PD services |
| Treatment protocols of day surgery services offered in the establishment |
| Sample of each private doctors’ clinical records - if a new PD service we will review the clinical record templates to be completed |
| **Management of medical emergency** |
| Resuscitation policy  |
| Basic life support / Immediate life support/ Advanced life support training records (as applicable) |
| Emergency transfer out procedure  |
| Emergency trolley checklist /monitoring record  |
| **Infection prevention control** |
| External expert IPC report and evidence of action taken |
| IPC Policies and Procedures |
| Deep clean certificate |
| Microbiological studies for theatre and treatment room |
| Cleaning schedules |
| Contract for CSSD services (if applicable)  |
| Policy for decontamination of reusable surgical instruments (if applicable) |
| Contract for clinical waste services |
| **Insurance certificates** |
| Insurance certificates (professional indemnity, public and employer’s liability |
| **Patient consultation** |
| Arrangements to seek patient feedback on the quality of service and treatments offered |
| The summary report detailing the findings of the client consultation, to include action plan to improve the quality of services, if applicable |

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| **Surgical/Theatres** |
| Admission policy |
| Discharge policy |
| Surgery pathway policy |
| Transfer out policy |
| Record of patient surgical pathway |
| Decontamination policies and procedures  |
| Pathology procedure |
| Massive blood loss policy |
| Information leaflets for patients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes |
| Consent procedure |
| Surgical register |
| WHO Surgical Safety Checklist  |
| Theatre staff log(for surgical assistants) |
| Resuscitation policy |