Regulatory Compliance for Healthcare Facilities

Introduction

amec foster wheeler

Amec Foster Wheeler

- Multidisciplinary engineering and architectural design firm
- Specialty consulting
    - Regulatory compliance
    - Third party reviews and inspections
    - Enhanced commissioning

Regulatory compliance insights gained from recent healthcare projects including:

- VCCC
- nRAH

Licencing of healthcare facilities:

- Building surveyor using National Construction Code / Building Code of Australia
- Department of Health using Department of Health and Human Services building design requirements

What about specialist areas that may exist within a healthcare facility where licensing over and above Dept. of Health or occupancy permit is required?

What are the specialist areas?

Who is the regulator that licences the area?

What facility design guidance is provided to enable compliance with licensing requirements?

What is the process for facility licensing undertaken by the regulator? Cost? Timing? Documents to support application?

Specialist Areas within Healthcare Facilities

Pharmacy

- dispensing pharmacy
- compounding pharmacy (radiopharmacy, cytotoxic pharmacy, sterile manufacturing suites)

Cyclotron (for radiopharmaceutical manufacture)

The above areas are subject to **State Pharmacy Authority** licensing or **Therapeutic Goods Administration (TGA)** licensing.

State pharmacy authorities: responsible for licensing hospital pharmacy department premises and retail/community pharmacies for dispensing medicines to the public.

Pharmacy Board of Australia: responsible for licensing of pharmacists that operate pharmacies.

State pharmacy authorities each publish a guideline/code regarding the requirements of pharmacy premises and their operation.

Variation exists between the requirements outlined in state pharmacy authority guidelines/codes.

Where does state pharmacy authority compounding facility licensing end and Therapeutic Goods Administration (TGA) facility licensing start?

If an areas within a healthcare facility is used for the production/compounding of medicines and the medicines are not sold to other healthcare facilities or pharmacies then the state pharmacy authority licences the facility.

If an areas within a healthcare facility is used for the production/compounding of medicines and the medicines are sold to other healthcare facilities or pharmacies then the TGA licences the facility.

State pharmacy authorities use different codes/guidelines…

Some state pharmacy authorities have adopted the **PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments** - this shares many requirements with the **PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products** (Rev PE 009-8) that is used by the TGA to provide guidance on pharmaceutical manufacturing facility construction.

What is required for an application to licence pharmacy premises?

- Submission of an application form and associated licence fee.
- Physical inspection of pharmacy premises by the state pharmacy authority.
- Provision of supporting documentation (e.g. premises layout).

Specialist Areas within Healthcare Facilities

- Pathology laboratories
- Histology laboratories
- Tissue banks
- siRNA laboratories
- Other microbiological laboratories used for research purposes
- Animal houses (rats/mice) used for research purposes
- Insectaries used for research purposes
- Aquariums used for research purposes

The above areas could be subject to licensing by the **Office of the Gene Technology Regulator (OGTR)** who is responsible for licencing of facilities where activities using genetically modified organisms (GMOs) are undertaken.

OGTR facility categories:

OGTR Physical Containment Level 1 (PC1)
OGTR Physical Containment Level 2 (PC2)
OGTR Physical Containment Level 3 (PC3)
OGTR Physical Containment Level 4 (PC4)
Risk to human health and environment increases with the level number (Level 1 lowest risk, Level 4 highest risk).

Types of OGTR physical containment facilities:

- microbiological (laboratory)
- animal
- invertebrate (insectary)
- aquatic (aquarium)

What is required to apply for an OGTR facility licence?

- Submission of an application form.
- Establish or have access to an institutional biosafety committee (IBC) that consists of a range of experts in containment including an independent person and exists to ensure compliance with OGTR licence facility legislative requirements.
- Application for facility licence supported by the IBC.
- Provide records of personnel training, testing and validation of equipment used in facility

OGTR PC1 and PC2 facility inspections are carried out by the IBC, OGTR PC3 and PC4 facility inspections are carried out by the OGTR.

The OGTR allows **90 days** to reach a decision to issue/refuse a facility licence or request additional information in support of the licence.

Specialist Areas within a Healthcare Facilities

- Microbiological laboratories used for research purposes
- Animal houses (rats/mice) used for research purposes
- Insectaries used for research purposes
- Aquariums used for research purposes

The above areas could be subject to licensing by the **Department of Agriculture and Water Resources (DAWR)** that is responsible for licencing of “approved arrangements” that allow facility operators to manage biosecurity (quarantine of overseas plant or animal material) utilising their own facility and personnel.

Facilities are categorised by DAWR by the type of quarantine material and the risk level posed to animals, plants and humans if disease is spread to the community or environment.

Types of quarantine material:

- microbiological
- animal
- plant
- insect
- fish

DAWR Biocontainment Level 1 (BC1)
DAWR Biocontainment Level 2 (BC2)
DAWR Biocontainment Level 3 (BC3)
DAWR Biocontainment Level 4 (BC4)
Risk to community or environment increases with BC Level number.

DAWR publishes requirements documents that describe facility requirements for each of the biocontainment levels.

What is required to apply for a DAWR approved arrangement licence?

- Submission of an application form.
- Conduct of a facility compliance inspection.
- Submission of documentation required for the operation of an approved arrangement e.g. standard operating procedures and equipment test records.

Further information about the DAWR approved arrangement application process:

- DAWR does not conduct facility compliance inspections themselves.
- DAWR licences third party assessors to conduct facility compliance inspections on their behalf.
- Upon confirmation of successful facility compliance inspection DAWR reviews documentation relating to approved arrangement operation to confirm quarantine containment can be maintained in operation.
- Upon submission of an application for approved arrangement licensing DAWR makes a decision to approve or refuse the application within **90 days**.
- Following initial inspection (involves both DAWR licences third party assessor and DAWR) periodic inspections and audits are conducted by DAWR alone. Frequency of inspections/audits is dictated by the perceived risk of loss of quarantine containment.

Specialist Areas within Healthcare Facilities

Compounding pharmacy (radiopharmacy, cytotoxic pharmacy, sterile manufacturing suites).

Areas for cellular therapy product manufacture.

If the medicines manufactured are offered for commercial sales to other healthcare facilities or pharmacies then the premises used for manufacturing are subject to TGA licensing.

What is required to apply for a TGA manufacturing facility licence?

- Submission of an application form and payment of an application fee.
- Physical inspection of pharmaceutical manufacturing areas undertaken by TGA inspectors.
- **Provide evidence of validated/qualified systems used for the manufacturing process (building fabric and finishes, air conditioning, equipment, utilities, environmental monitoring).**

According to the TGA website the target timeframe from submission of a compliant application to the issue of an inspection report (for the manufacturing area) is **3 months**.

Timeframes for application processing can exceed the target timeframe - the TGA nominate the inspection date at the time of application submission.

Summary:

- Where the regulator is different from state to state it is necessary to engage with the regulator in the state where the healthcare facility is located to understand the expectations for facility licensing. Particularly if the codes/standards/guidelines state based.
- Significant timeframes can be required for facility licensing application processing and inspections. Early engagement with the regulator (if possible) is desirable to understand the licence application timeframe.
- The TGA facility licensing process is the most onerous with a responsibility by the applicant to demonstrate that:
    - the facility design was approved prior to construction.
    - any changes to the design during construction were approved.
    - the design requirements that dictated the facility construction are borne out in the built facility and that the facility operates as intended

Questions

Thank-you

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