Government of **Western Australia**
RADIOLOGICAL COUNCIL

DESIGN REQUIREMENTS

for

Radioisotope Laboratories and Nuclear Medicine Facilities

This document details the design requirements applied to radioisotope laboratories and nuclear medicine facilities in Western Australia using unsealed radioactive substances.

The requirements are based on compliance with the Radiation Safety Act 1975 and Australian Standards:

AS/NZS 2982:2010 Laboratory Design and Construction

AS/NZS 2243.4:2018 Safety in Laboratories, Part 4: Ionizing Radiations

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Dose Limits and Constraints

Schedule I of the Radiation Safety (General) Regulations 1983 sets out the dose limits and maximum permissible exposure levels for radiation workers and members of the public.

The Radiological Council applies more conservative dose constraints to the assessment of premises structural radiation protection; these are 10% of the occupational and 50% of the public annual effective dose limits (2 mSv and 0.5 mSv respectively).

These conservative dose constraints acknowledge that the dose limits have been consistently reduced over time and apply the ALARA principle, as recommended by the International Commission on Radiological Protection.

Radiation Shielding

The structural radiation shielding of a radioisotope laboratory or nuclear medicine facility must ensure that the Council's dose constraints will not be exceeded for the proposed use.

Wherever possible the major shielding component for radioactive stock material and prepared radioactive doses should be provided by local shielding at the source.

It may be determined for some radioisotope laboratories that local shielding will ensure the dose constraints are not exceed, and therefore structural shielding may not be necessary.

Dose rates within a room and between rooms are reduced by distance and shielding. Distance is of importance in reducing the level of structural shielding potentially required. Rooms where radioactive substances are used which are closely adjacent to high occupancy areas may require a higher level of shielding of the walls to ensure dose constraints are not exceeded.

For nuclear medicine facilities, the occupational constraint applies to areas occupied only by nuclear medicine radiation workers and their patients, the public dose constraint is applied to all other areas. Once injected with a radioactive dose the patient also constitutes a source from which radiation emanates. An appropriate patient self-absorption factor may be applied in calculating the required level of structural shielding. In addition, a dedicated area needs to be available for patients who must wait a lengthy amount of time between radiopharmaceutical injection and imaging.

For laboratories containing a generator (e.g. Mo-99/Tc-99m), additional local shielding to that of the transport container may be required depending on proximity to occupied areas and structural shielding of the laboratory. The area designated within the laboratory for a generator must be segregated such that the area can be isolated if necessary.

DESIGN AND FITOUT

The design and fitout of radioisotope areas in nuclear medicine facilities and radioisotope laboratories must comply with the requirements of AS/NZS 2982 and AS/NZS 2243.4.

Radioisotope laboratories must be graded in accordance with AS/NZS 2243.4; the result will be either a low, medium or high-level laboratory. The standards above then specify the requirements relevant to each level of laboratory. Table 3.4 of AS/NZS 2243.4 provides a summary of some of these requirements.

For nuclear medicine, layout and proximity of radioisotope areas must be such that doses can be transported from the dispensing laboratory to the imaging or injection room as directly as possible and avoiding traffic paths. Areas where injections of radiopharmaceuticals are intended to occur must comply with the relevant design requirements for low level laboratories (ventilation, surfaces, finishes, flooring etc.). Consideration will also need to be given when grading nuclear medicine laboratories that contain equipment for the aseptic production of radiopharmaceuticals (such as hot cells). The entire laboratory may not need to meet all design requirements for a higher graded lab, depending on the hazards offset by using such equipment.

Depending on the type of facility, there may also be applicable Good Manufacturing Practice (GMP) requirements. Particular consideration will need to be given to any conflict between the GMP and radiation safety requirements.

The plumbing and ventilation design aspects are addressed below.

Plumbing

Liquid radioactive waste (if aqueous and not prohibited due to other factors) may be disposed of down an approved sink and radioactive waste line, with appropriate dilution as specified in Regulation 31 of the Radiation Safety (General) Regulations.

Sections 3.9 and 9 of AS/NZS 2982 and section 8.3 of AS/NZS 2243.4 detail drainage requirements. Note that AS/NZS 2982 also requires compliance with AS/NZS 3500.

Essentially, to prevent contamination and overflow into other areas, the radioactive waste line must be separate from all other drain lines and, except for waste lines from toilets, to enter the main sewer line outside the building through a disconnector gully.

An exception to the requirement for a separate drain line is a waste line used for the dual purpose of acid drainage and radioisotope waste. Radioisotope drain lines connected directly into the acid drain systems within buildings must conform to the following:

- The acid drains proceed directly to acid treatment and dilution pits, the outlet from which is through a disconnector gully to the main sewer line.
- The pH of the waste is corrected in the acid pits and any suspended solids form a sludge in the bottom that is periodically pumped out to remove such solids.
- All vents from the acid treatment system project through the roof of the building away from air intakes.
- The drain lines display dual labels showing acid and radioisotope warnings.

When disposal of liquid radioactive waste to the sewer is likely to be small and incidental rather than as a primary route, the facility may be exempted from the requirement for a

disconnector gully. For example, this would apply to nuclear medicine facilities where the only significant source of routine radioactive substances disposal to sewer is via the patient toilet.

A flushing sink may be required if liquid radioisotope waste is to be disposed of into the sewer; it is not required if all liquid radioisotope waste is to be stored for decay prior to disposal as non-radioactive waste. Operation of a flushing sink must be hands-free and the flush must completely wet the sink in a non-splashing motion without forming a non-wetted area.

For nuclear medicine facilities, a toilet reserved for radioactive waste from nuclear medicine patients is required. As with laboratory radioactive waste lines, the radioactive waste line from hot toilets must be separate from other types of waste lines until it joins the main sewer line outside the building.

Ventilation

Sections 5 and 9 of AS/NZS 2982 and section 3 of AS/NZS 2243.2 detail ventilation requirements for radioisotope laboratories depending on the level classification of the laboratory. Note that these Standards also require compliance with AS/NZS 1668.2.

Essentially, exhaust air from the radioisotope areas must not be recirculated and must be discharged from the building through exhausts located away from air intakes.

For nuclear medicine facilities conducting radioactive ventilation studies (such as technigas), the following is required:

- compliance with AS/NZS 1668.2 treating any radioisotope discharge as a noxious discharge under the provisions of the Standard; or
- at least a simple emergency ventilation system.

Storage of Radioactive Material

Radioactive material must be stored securely when not in use. The design of a radioisotope facility must incorporate either a dedicated or in situ storage arrangement (as appropriate to the hazard), in accordance with the requirements of Regulations 29 and 30 of the Radiation Safety (General) Regulations and section 5.1 of AS/NZS 2243.4.

AS/NZS 2243.4 specifies maximum dose rates for areas adjacent to the store, however, the Council also applies additional generic dose constraints for the storage of any radioactive material. For areas not listed as per AS/NZS 2243.4, storage must be suitably designed such that the absorbed dose rate in air outside the store in any area accessible to persons other than radiation workers does not exceed 25 µGy/h and no person receives a dose exceeding the appropriate effective dose limit.

Regarding labelling for storage areas and containers, labels must display the radiation warning symbol, words “CAUTION - RADIOACTIVE” and a label identifying its contents, unless otherwise directed by the Council. Labels must be visible, clearly legible and durable for the required life-time.

The storage of radioactive waste is dealt with in section 8 of AS/NZS 2243.4. Shielded waste bins or cupboards may be required for storage of short-lived radioactive waste for decay to non-radioactive waste disposal levels.

APPROVAL OF PROPOSED FACILITY DESIGN

Section 30 of the Radiation Safety Act 1975 prohibits the registration of defective premises and requires the Radiological Council to be satisfied that the premises have been constructed and equipped with the essential services installed and finished to a standard it deems acceptable.

Approval of facility design as detailed in this document must therefore be sought from the Council.

Required Documentation

Documentation should be submitted for preliminary approval in the early stages of laboratory nuclear medicine facility planning to avoid structural alternations being required after completion of the laboratory/facility.

The following documentation must be submitted to the Radiological Council such that it may consider issuing approval for the proposed shielding, plumbing and ventilation design:

1. A report detailing the assessment undertaken to ensure the suitability of radiation shielding for the proposed use of radioactive substances;

    a. For radioisotope laboratories, the report must be signed off by a physicist with experience in radiation shielding design.

    b. For nuclear medicine facilities, the report must be signed off by either an ACPSEM nuclear medicine physicist or a medical physicist with experience in nuclear medicine shielding design.

2. A report of the laboratory grading in accordance with AS/NZS 2243.4 and confirmation of meeting the design fitout requirements of that grade of laboratory. In cases where a lower laboratory grading has been determined to be more appropriate, additional commentary is required to be provided as justification.

3. A report from an appropriate engineer confirming the plumbing will meet the requirements of AS/NZS 2982 and 2243.4. Highlighted and annotated hydraulics plans must accompany the report.

4. A report from an appropriate engineer confirming the ventilation will meet the requirements of AS/NZS 2982 and 2243.4 or the radioisotope areas. Highlighted and annotated ventilation plans must accompany the report.