

Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021

Table of Contents

Enacting Formula

Part 1 PRELIMINARY

1 Citation and commencement

2 Definitions

3 Application of Regulations

4 Specific services provided under licence

Part 2 REQUIREMENTS RELATING TO PERSONNEL

5 Skills and competencies of Clinical Governance Officer for applicable licensee

6 Duties and responsibilities of Clinical Governance Officer

7 Appointment of section leader

8 Duties of section leader

9 General requirements relating to personnel

Part 3 PROCESSES, EQUIPMENT AND FITTINGS

10 Quality management system

11 Equipment and fittings

12 Referral, etc., needed before services provided to patients

Part 4 SAFETY REQUIREMENTS

13 Safety programme

14 Radiation safety programme

15 Chemical hygiene plan

16 Licensee must ensure personnel comply with safety plans and programmes

17 Personal protective equipment must be provided

Part 5 REQUIREMENTS SPECIFIC TO NUCLEAR MEDICINE ASSAY SERVICE

18 Specific personnel

19 Instructions for collection of specimens

20 Acceptance and rejection of specimens

21 Handling and transport of specimens

22 Tests must have clinical utility

23 Tests must be accurate

24 Standards for reagents

25 Documentation relating to tests

26 Quality control of tests

Part 6 REQUIREMENTS SPECIFIC TO NUCLEAR MEDICINE IMAGING SERVICE

27 Specific personnel

28 Facilities and equipment

29 Handling of images

30 General safeguards for examinations

31 Specific safeguards — use of contrast agent or radiopharmaceuticals

32 Specific safeguards — use of anaesthesia or sedation

33 Safety policies regarding pregnant women

Part 7 REPORTING OF RESULTS

34 Who is qualified person

35 Written reports of examinations must be issued

36 Contents of reports

37 Urgent notification of reports in emergency

38 Identification and review of incidental or abnormal findings

39 Notification of error

40 Processes to ensure prompt reporting

Part 8 MISCELLANEOUS

41 Outsourcing prohibited

42 Nuclear medicine assay licensee — records to be kept for each specimen

43 Nuclear medicine assay licensee — records to be kept for each test

44 Nuclear medicine imaging licensee — records to be kept for examinations

45 Keeping of other records

46 Price transparency

47 Display of charges

48 Offence

No. S 1039

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES
(NUCLEAR MEDICINE ASSAY SERVICE AND
NUCLEAR MEDICINE IMAGING SERVICE)
REGULATIONS 2021

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

- “applicable service” means a nuclear medicine assay service or nuclear medicine imaging service;
- “Clinical Governance Officer” means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;
- “collaborative prescribing practitioner” has the meaning given by regulation 56C(6) of the Private Hospitals and Medical Clinics Regulations (Rg 1);
- “diagnostic radiographer” means a duly qualified allied health professional who is registered under the Allied Health Professions Act 2011 to practise radiography;
- “duly qualified allied health professional” has the meaning given by section 3 of the Allied Health Professions Act 2011;
- “examination” means a radiological examination of an individual conducted by a nuclear medicine imaging licensee at the licensed premises of or in the licensed conveyance used by the licensee in connection with the provision of a nuclear medicine imaging service;
- “General Regulations” means the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021);
- “image”, in relation to a nuclear medicine imaging service, means an image produced in the course of the provision of that service;
- “irradiating apparatus”, “radioactive material” and “radioactive substance” have the meanings given by section 2(1) of the Radiation Protection Act 2007;
- “licensee” means a nuclear medicine assay licensee or a nuclear medicine imaging licensee;
- “medical laboratory technologist” means an individual who holds at least a diploma or degree in biomedical science, biological science or medical technology;
- “nuclear medicine assay licensee” means a person who holds a licence to provide a nuclear medicine assay service;
- “nuclear medicine imaging licensee” means a person who holds a licence to provide a nuclear medicine imaging service;
- “nuclear medicine technologist” means an individual who holds at least a diploma or degree in nuclear medicine technology;