



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

|   |                                       |
|---|---------------------------------------|
| Name of Medical Radiological Installation:    | Aut Even Hospital LTD                 |
| Undertaking Name:                             | Aut Even Hospital LTD                 |
| Address of Ionising Radiation Installation:   | Freshford Road, Kilkenny,<br>Kilkenny |
| Type of inspection:                           | Announced                             |
| Date of inspection:                           | 07 January 2020                       |
| Medical Radiological Installation Service ID: | OSV-0006293                           |
| Fieldwork ID:                                 | MON-0028248                           |

## About the medical radiological installation:

Aut Even Hospital LTD provides diagnostic and fluoroscopic medical ionising radiation services in general X-ray and in the operating theatre. General X-ray is provided primarily for orthopaedic and medical services for inpatients and outpatients. Over 4,000 general X-ray procedures are carried out each year at the hospital. The Theatre C-Arm unit is used to provide a fluoroscopy service with over 1,000 procedures carried out each year. This service is predominantly used for image guidance in pain management and orthopaedic joint injection.

## How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users<sup>4</sup> to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

## About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

### **1. Governance and management arrangements for medical exposures:**

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<sup>1</sup> Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA’s findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

**2. Safe delivery of medical exposures:**

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

**This inspection was carried out during the following times:**

| Date                   | Times of Inspection  | Inspector       | Role    |
|------------------------|----------------------|-----------------|---------|
| Tuesday 7 January 2020 | 09:00hrs to 15:15hrs | Noelle Neville  | Lead    |
| Tuesday 7 January 2020 | 09:00hrs to 15:15hrs | Kirsten O'Brien | Support |

## Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership, governance and management arrangements in place at the hospital with systems and processes detailing a clear allocation of responsibility for the protection of service users. The Chief Executive Officer (CEO) was a member of the hospital's Radiation Safety Committee. This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which reported to the Board of the hospital.

From the records reviewed and discussions with management and staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Inspectors were also assured that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and medical physics expert were involved in the optimisation process. There was an area of potential further improvement identified in respect of the alignment of hospital's radiation safety procedures to current legislation, specifically Regulation 4 and Regulation 5. This should be updated to ensure they are reflective of day-to-day practice and ensure clarity regarding roles and responsibilities of staff within the hospital.

Medical Physics Expert (MPE) involvement in medical radiological practices was evident, with the level of involvement in line with the services provided at the hospital. Management and other staff stated that they had adequate access to MPE cover. Although there were contingency arrangements for the continuity of MPE expertise, inspectors were informed that this was not formalised. Additional documentation of the contingency cover would provide additional assurances to HIQA.

Notwithstanding the recommended improvements to documentation, inspectors were assured of the governance and management arrangements in place in Aut Even Hospital LTD to oversee patient protection.

## Regulation 4: Referrers

The hospital's radiation safety procedures reviewed by inspectors stated that medical radiological procedures may only be carried out on the basis of a referral from a referrer. On the day of inspection, referrals for medical radiological procedures were accepted from registered medical practitioners and inspectors were also informed that radiographers were entitled to refer for supplementary views within medical exposures where necessary. Inspectors spoke with staff who demonstrated a clear understanding of the referral process. The hospital received referrals in electronic and hard copy format from internal and external sources. A sample of referrals viewed by inspectors were in line with the regulations and the

referrer was consistently identifiable.

While the hospital was compliant with this regulation, inspectors found that the hospital's radiation safety procedures should be reviewed and updated to definitively identify those that can act as a referrer within the hospital.

Judgment: Compliant

### Regulation 5: Practitioners

Documentation viewed by inspectors stated that medical exposures may only take place under the clinical responsibility of a practitioner. Inspectors reviewed a sample of records in relation to medical exposures on the day of inspection and found that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures as per the regulations.

While the hospital was compliant with this regulation, inspectors found that the hospital's radiation safety procedures should explicitly define who can act as a practitioner within the hospital.

Judgment: Compliant

### Regulation 6: Undertaking

The hospital had a clear allocation of responsibilities for the radiation protection of services users undergoing medical exposure to ionising radiation. The lines of governance and clinical oversight were communicated to inspectors by management and other staff during the inspection. In addition, documentation reviewed, including a hospital organogram, outlined the reporting structures in place within the hospital. The Chief Executive Officer (CEO) was a member of the hospital's Radiation Safety Committee. This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which reported to the Board of the hospital.

Judgment: Compliant

### Regulation 10: Responsibilities

Systems and processes were in place in the hospital to ensure that all medical exposures took place under the clinical responsibility of a practitioner. Inspectors noted that the practitioner and medical physics expert (MPE) were involved in

the optimisation process and the referrer and practitioner were involved in the justification process. Only those recognised as practitioners conducted medical exposures at the hospital, so further documentation of individuals delegated the practical aspects of a medical exposure was not required.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

A contractual arrangement was in place to provide Medical Physics Expert (MPE) services to the hospital by an off-site MPE. In relation to contingency arrangements for MPE expertise, inspectors were informed that a formalised arrangement was not in place to access the service of an alternative MPE should the hospital's contracted MPE not be available. While management and staff stated that they had adequate access to MPE cover, further clarification of the contingency cover would provide additional assurances to HIQA. However, inspectors were satisfied that the hospital had the necessary arrangements in place to ensure continuity of medical physics expertise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Documentation reviewed by inspectors and discussions with management and staff, indicated that the Medical Physics Expert (MPE) had contributed aspects of this regulation which were relevant to the medical radiological practice including the optimisation process, diagnostic reference levels (DRLs), quality assurance of medical radiological equipment and training of staff in relevant aspects of radiation protection. The hospital's radiation safety procedures outlined that the MPE also carried out the separate role of Radiation Protection Adviser (RPA) within the hospital.

Judgment: Compliant

### Regulation 21: Involvement of medical physics experts in medical radiological practices

Medical Physics Expert (MPE) involvement in medical radiological practices was evident, with the level of involvement in line with the services provided at the hospital. Inspectors were satisfied from documentation reviewed and discussions with management and staff, that the MPE was available for consultation and advice

on matters relating to radiation protection concerning medical exposure.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors found that the hospital had assurances in place to ensure that effective and safe medical exposures are provided to service users in compliance with the regulations. This included evidence of the use of diagnostic reference levels, written protocols for each type of procedure carried out and posters relating to pregnancy and the risks associated with radiation exposure available in the Radiology Department. A number of clinical audits were conducted at the hospital including Pregnancy Status Check, Justification and Effective Communication and Dose Area Product (DAP) reviews for X-ray. An up-to-date inventory, and quality assurance and reports were provided to inspectors, which showed that an appropriate quality assurance programme was in place.

Areas of good practice were identified by inspectors including a feature of the hospital's radiology information system (RIS) which displayed a prompt, notifying staff to check the pregnancy status of the person undergoing the medical exposure. The hospital used an electronic system to record radiation incidents which also had the ability to trend incidents.

Inspectors identified some areas requiring improvement in relation to Regulation 8 and Regulation 13 which were accepted and acknowledged by management and staff. Inspectors reviewed a sample of records and spoke with staff and found that justification in advance was not documented for procedures carried out at the hospital. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

In addition, inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. In respect of Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure. Overall, inspectors were satisfied that the areas noted to require improvement did not represent a safety concern to service users.

## Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of the inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures which took place in the hospital was available for review since the implementation of a new radiology information system (RIS) in January 2018.

Information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure on posters in the waiting area of the Radiology Department. Staff informed inspectors that they could access information relating to the dose level associated with a procedure, should a patient ask about this.

The hospital's radiation safety procedures stated that medical exposures should not be carried out unless clinically justified and also outlined shared responsibility amongst key personnel for adherence to the justification procedures in place. Inspectors found that while justification was conducted by appropriate individuals as defined in Regulation 5, documentation should be updated to reflect day-to-day practice at the hospital.

Inspectors spoke with staff responsible for the justification of medical exposures who described how each medical exposure was justified. Inspectors reviewed a sample of records and spoke with staff and found that while justification was conducted by appropriate individuals as defined by Regulation 5, the record of justification was not documented for procedures carried out at the hospital. As a result, the hospital was not in full compliance with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

The hospital's radiation safety procedures provided an outline of the process for the establishment and review of diagnostic reference levels (DRLs). Inspectors were informed that DRLs for radiodiagnostic examinations were established, regularly reviewed and used with reference to national DRLs. DRLs relevant to the medical exposures carried out were displayed in the Radiology Department.

Inspectors were informed by staff that an electronic system was used to record patient doses which were reviewed retrospectively on a daily basis as a quality assurance measure. The findings from these dose audits were presented to the

Radiation Safety Committee at meetings held twice a year for review and then compiled at the end of each year. DRLs used at the hospital were found to be consistently below national DRLs. This provided additional assurance to the hospital in relation to the safe delivery of medical exposures.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols were established for each type of standard medical radiological procedure. These protocols were available in both hardcopy and electronic format and staff demonstrated an awareness of and ability to access these to inspectors.

Referral guidelines for medical imaging taking into account the radiation doses were available in hardcopy in the Radiology Department. Inspectors found that while the hospital had referral guidelines, referrers should be made aware of the availability of these guidelines.

Inspectors were informed that a number of clinical audits were conducted at the hospital and viewed a sample of these including Pregnancy Status Check, Justification and Effective Communication and Dose Area Product (DAP) reviews for X-ray. While the results of the audits seen by inspectors demonstrated a high level of compliance, the expansion of the range of clinical audits conducted at the hospital may be beneficial in providing further assurances of compliance with the regulations.

Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. As a result, the hospital was not fully compliant with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that equipment was kept under strict surveillance regarding radiation protection. The testing and monitoring of equipment was listed as a standard agenda item at the Radiation Safety Committee. Documentation reviewed by inspectors showed that appropriate quality assurance (QA) programmes, including regular performance testing had been implemented and maintained for

each piece of medical radiological equipment on the inventory.

Inspectors were informed that the hospital had completed the tendering process for a new piece of general X-ray equipment which was due to be installed in the coming months. This new equipment was due to replace equipment which had exceeded its nominal replacement age in 2013. While the piece of equipment had passed its nominal replacement date, inspectors were informed that it was approved for clinical use and had passed all necessary quality assurance testing. Inspectors were also informed that the hospital had a system for reporting and recording equipment faults and processes were in place to take equipment out of service where it was deemed necessary for patient safety.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors found that the hospital was meeting the requirements of this regulation from the evidence reviewed. The hospital had a policy on protection of patients of reproductive capacity. This policy outlined the process for determining pregnancy status and the process to be followed if pregnancy cannot be ruled out. Staff demonstrated a good knowledge and understanding of the hospital's pregnancy policy. Inspectors viewed a sample of written records documenting pregnancy inquiries made by staff.

The hospital's radiology information system (RIS) had a feature which displayed a prompt, notifying staff to check the pregnancy status of the person undergoing the medical exposure in advance of this exposure taking place. Inspectors found that this feature was a useful reminder to staff to check the pregnancy status of females of childbearing age.

The hospital took measures to increase the awareness of people to whom this regulation applies. Inspectors observed posters in a variety of languages alerting patients to inform staff of their pregnancy status in the waiting area of the Radiology Department. In addition, samples of radiology appointment letters were reviewed by inspectors which included information for female patients on the risk associated with medical exposure during pregnancy.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

The hospital had taken reasonable measures to minimise the risk of accidental or unintended exposures to people using the service. This was demonstrated through

the hospital's procedures, surveillance of equipment and quality assurance and audit programmes.

Inspectors were satisfied that the hospital had an appropriate system for the record keeping and analysis of incidents. An electronic system was in place in the hospital for recording radiation incidents which all staff had access to. Inspectors were informed that the electronic system had the ability to trend incidents and potential incidents. However, due to the low numbers of incidents occurring, it was not possible to carry out trending. Staff demonstrated a good knowledge and understanding of the incident reporting process within the hospital.

The hospital's Radiation Safety Committee standing agenda included a review of incident and accident reports. While the hospital did not have cause to notify the Authority of the occurrence of any incident, management and staff demonstrated a clear knowledge of the process to be followed should the need arise.

Judgment: Compliant

## Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

| Regulation Title  | Judgment                |
|---|-------------------------|
| <b>Governance and management arrangements for medical exposures</b>                     |                         |
| Regulation 4: Referrers   | Compliant               |
| Regulation 5: Practitioners   | Compliant               |
| Regulation 6: Undertaking   | Compliant               |
| Regulation 10: Responsibilities   | Compliant               |
| Regulation 19: Recognition of medical physics experts                                   | Compliant               |
| Regulation 20: Responsibilities of medical physics experts                              | Compliant               |
| Regulation 21: Involvement of medical physics experts in medical radiological practices | Compliant               |
| <b>Safe Delivery of Medical Exposures</b>   |                         |
| Regulation 8: Justification of medical exposures  | Substantially Compliant |
| Regulation 11: Diagnostic reference levels  | Compliant               |
| Regulation 13: Procedures   | Substantially Compliant |
| Regulation 14: Equipment  | Compliant               |
| Regulation 16: Special protection during pregnancy and breastfeeding                    | Compliant               |
| Regulation 17: Accidental and unintended exposures and significant events               | Compliant               |

# Compliance Plan for Aut Even Hospital LTD OSV-0006293

Inspection ID: MON-0028248

Date of inspection: 07/01/2020

## Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

## Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

### Compliance plan undertaking response:

| Regulation Heading   | Judgment                |
|--|-------------------------|
| Regulation 8: Justification of medical exposures   | Substantially Compliant |
| <p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:<br/>This has already been actioned and in practice.</p> <p>A Task has been inserted into the PACS system creating a "Clinical Justification" electronic (E) - questionnaire for the radiographer to complete before progressing to the examination in question.<br/>This E-questionnaire is generated for each individual standard examination.</p> <p>If the Clinical information is sufficient to justify the requested examination, the radiographer selects the "Yes" radio button and submits the E-Questionnaire into the PACS record.<br/>If the submitted clinical information is not sufficient to justify the examination in question then the radiographer will select the "No" radio button.<br/>However, the radiographer may gain additional information, either from the patient or referring clinician and these additional details are recorded in the text box.</p> <p>If the clinical information does not justify the examination the procedure will be postponed/cancelled until justification is achieved.<br/>All stakeholders are informed of postponed/cancelled procedures.</p> <p>If additional information justifies the examination the radiographer also adds the additional clinical information into the "Radiographer Comment" dialogue box in PACS. These comments are always viewable in the PACS reporting platform for the reporting radiologist.</p> <p>The Electronic document is saved to the study in PACS and available for review in the way that referrals, pregnancy status questionnaires etc. are available.<br/>The E-Questionnaire is Date/Time stamped within the PACS</p> |                         |

A monthly Compliance audit is in place to ensure the process is adhered to.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:  
This has already been actioned.

Subsequent to all examinations recording the DAP for the completed examination, the DAP data is a record field in PACS.

This field data is now routinely shown on the validated report below the reporting consultants' digital signature.

## Section 2:

### Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

| Regulation       | Regulatory requirement  | Judgment                | Risk rating | Date to be complied with |
|------------------|---|-------------------------|-------------|--------------------------|
| Regulation 8(8)  | An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved. | Substantially Compliant | Yellow      | 11/02/2020               |
| Regulation 8(15) | An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.                          | Not Compliant           | Yellow      | 11/02/2020               |
| Regulation 13(2) | An undertaking shall ensure that information relating to patient exposure forms part of the report  | Not Compliant           | Yellow      | 11/02/2020               |

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|  | of the medical<br>radiological<br>procedure. |  |  |  |
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