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Scotland

Inspections
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To drive improvement

Announced Inspection Report – Ionising Radiation (Medical Exposure) Regulations 2017

University Hospital Crosshouse, Kilmarnock
NHS Ayrshire & Arran

10-11 May 2022

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Contents

About our IR(ME)R inspections 4

Summary of inspection 6

What we found during our inspection 8

About our IR(ME)R inspections

Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** brings a consistency to our quality assurance activity by basing all of our inspections and reviews on a set of fundamental principles and a common quality framework.
- **Our quality framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations 2017 to the quality framework.

How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

What we look at

We want to find out:

- how the service complies with its legal obligations under IR(ME)R 2017 and addresses the radiation protection of persons undergoing medical exposures, and
- how well services are led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality framework.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection to the University Hospital Crosshouse, Kilmarnock, NHS Ayrshire & Arran, on Tuesday 10 and Wednesday 11 May 2022. We spoke with a number of staff including the operational IR(ME)R lead, the responsible IR(ME)R lead, radiographers, the medical physics expert and a health and safety officer. The inspection team was made up of two inspectors.

University Hospital Crosshouse offers plain film, computerised tomography (CT) mamography and nuclear medicine. The focus of this inspection is the imaging department.

What we found

What the service did well

- NHS Ayrshire & Arran has effective governance arrangements in place in relation to IR(ME)R. Strong leadership is provided by the operational IR(ME)R lead, the head of medical imaging and department leads who supports the implementation of IR(ME)R.
- A positive safety culture is in place that supports the sharing of learning from incidents and we saw excellent communication between all staff.
- Employer's procedures are clear and all staff we spoke with demonstrated good knowledge of the procedures and how to apply them in practice.

What the service needs to improve

- A formal letter of entitlement must be sent to referring GP practices.

Detailed findings from our inspection can be found on page 8.

What action we expect NHS Ayrshire & Arran to take after our inspection

This inspection resulted in one requirement and three recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.
https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx.

NHS Ayrshire & Arran must address the requirement and make the necessary improvements as a matter of priority.

We would like to thank all staff at the radiology department, University Hospital Crosshouse, for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires those who refer patients to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify the procedure is necessary, must be adequately trained and entitled to do so. Entitlement is given to each person involved in the process by the employer (NHS board).

What we found – fulfilment of statutory duties and adherence to national guidelines

Entitlement

The process of entitlement sets out the scope of practice an individual can carry out, such as the types of referrals and their roles. Their scope of practice depends on the individual's qualifications, role, training and experience. It can also change over time following additional training or moving to a new role. An individual's scope of practice is set out formally by the operational IR(ME)R lead and aligned training document. The individual is required to work within this scope of practice.

Employer's procedures EP1 (Entitlement of duty holders for medical exposures) provides guidance on the entitlement process. The operational IR(ME)R lead is responsible for entitling all those who refer patients for medical exposures. Employer's procedures EP2 (Procedure to identify individuals entitled to act as referrers, practitioners, operators and medical physics experts and a description of their duties) provides guidance on the basic qualifications required by different staff groups to be entitled as a referrer, practitioner and operators.

All radiologists who are Fellows of the Royal College of Radiologists are entitled to carry out justifications and clinical evaluations. A radiologist is a doctor who is specially trained to interpret diagnostic images, such as x-rays and CT scans.

Radiographers, depending on their training, are entitled as operators to carry out justifications and plain film clinical evaluations, including a recently qualified radiographer who can report on chest x-rays.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. The operational IR(ME)R lead is also responsible for entitling a range of healthcare professionals to act as referrers for medical exposures within their defined scope of practice. The operational IR(ME)R lead and imaging lead assess and approve non-medical referrers' scope of practice and they could clearly describe this process.

A full list of all non-medical referrers, including their scope of practice, is available on the NHS board's intranet site. All non-medical referrers must complete regular audits – a selection of non-medical referrers are asked to share their completed audits in order to maintain their entitlement. We saw evidence that an individual's entitlement can be revoked if they fail to carry out these audits.

Referral

Referrals are received by the radiology department from a variety of sources from within University Hospital Crosshouse, from other hospitals and from the community. Referrals are made using an electronic referral systems. Paper referrals are used when the electronic system is not working, from community services and the hospitals outwith NHS Ayrshire & Arran. Paper referrals are scanned onto the radiology information system.

A referral can only be made by a person who is entitled to do so. EP4 (Referral procedure and referral criteria) sets out the process and provides guidance about the clinical information required to be included in a referral. The role of the referrer is clearly recorded on the referral and can be checked against their entitlement. When a referral is received by non-medical referrer, radiographers will check the referrer's scope of practice against the list of non-medical referrer's. Radiographers told us this process works well and the list is easy to access. We were told if a referral is received that is outwith an individual's scope of practice, it is rejected.

Junior doctors referring on behalf their responsible consultant for complex exposures must include details of the consultant who has overall responsibility for the referral.

Justification

EP5 (Identification of medical exposures) provides guidance on the justification of exposures. EP2 (Procedure to identify individuals entitled to act as referrers, practitioners, operators and medical physics experts and a description of their duties) clearly states which staff groups can justify medical exposures and that it must be aligned to their training and entitlement.

All staff told us a patient's clinical information is reviewed when a referral is justified, in line with EP4 (Referral procedure and referral criteria). If insufficient information is provided, the referral is returned. A new referral must then be submitted. We were told an external referral must be justified before a patient is offered an appointment. All justifications are recorded on the radiology information system and the practitioner who made the decision is clearly identified. Radiographers check the radiology information system for any previous exposures or duplicate referrals before carrying out an exposure. We are assured staff would choose the correct protocol for the medical exposure and processes are in place to demonstrate staff are entitled to justify, and they are adequately trained to do so.

The radiologist or radiographer will review the image and report their findings (clinical evaluation). All staff we spoke with could describe the process and where this information is recorded. The operator who carried out the clinical evaluation is identified on the report, whether it is a member of staff from NHS Ayrshire & Arran or from the private company that provides out-of-hours radiology services.

Records

During our inspection, we looked at the information recorded on the radiography information system and noted that staff had documented:

- the correct patient information
- details of the referrer and operator
- identification checks
- pregnancy checks
- the recorded dose
- justification, and
- clinical evaluation.

Radiography staff told us about the checks they would carry out before recording information and where they would get the dose information.

What needs to improve

While we are assured processes are in place to ensure referrers are made by those who are entitled to do so, we noted GP practices are not provided with an entitlement letter (requirement 1).

Referrals are currently individually checked by radiology staff to ensure the referrer is within their scope of practice. We discussed changes to the radiology information system that would limit refers to only have access to make referrals within their scope of practice. This would eliminate the risk of referrers seeking exposures they are not entitled to request.

Requirement 1

- NHS Ayrshire & Arran must ensure referring GPs are appropriately entitled to do so.

- No recommendations.

Service delivery

This section is where we report on how well the service is delivered and managed.

Domain 5 – Safe, effective and person-centred care delivery

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

What we found - safe delivery of care

Safety culture

We were told about a positive safety culture. Staff felt confident to report mistakes and near misses and were confident about the procedures for reporting and investigating incidents.

Staff were also clear that learning from incidents is shared to reduce the chance of something similar happening again. Clinical incidents from all NHS Ayrshire & Arran locations are shared with all staff. Staff developed a poster to share themed learning from incidents – this was well received by staff we spoke with.

We saw PAUSE posters prominently displayed in each clinical room in the radiology department to remind staff to take the time when carrying out appropriate checks before carrying out patient exposures. Staff also assured us they are never pressured to rush an exposure.

Employer’s procedures

NHS Ayrshire & Arran has a duty under IR(ME)R to develop written procedures commonly referred to as employer’s procedures. These procedures provide a framework under which professionals can practice. NHS Ayrshire & Arran has a clear structure for the development and update of its employer’s procedures. The NHS board has three levels of employer’s procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 are modality specific across various sites, and
- level 3 are department protocols.

Employer's procedures we reviewed were all clear, up to date and cross-referenced. All staff we spoke with were familiar with the employer's procedures and could find them easily.

Employer's procedures are reviewed at the IR(ME)R compliance meetings, which takes place every month. It is chaired by the head of medical imaging. Any updates recommended by the medical physics expert are also discussed at these meetings. Any changes are signed by the operational IR(ME)R lead and shared with radiology staff by email, at team meetings and through the clinical director's forum to ensure medical staff are aware of relevant changes.

Employer's procedures are stored on the shared drive. A paper copy of the most used procedures is kept in the department. Radiographers are responsible for ensuring these are kept up to date.

Patient identification

Employer's procedure EP7 (Patient identification) provides guidance on the three point identification checks to be carried out for all patients before an exposure. These checks are essential to ensure the correct person is being exposed.

All staff we spoke with could clearly describe the checks carried out before an exposure. They told us they would review the patient's clinical history to check it matched the clinical information received. They would check the site, laterality (part and side of the body to be exposed), the reason for the exposure matched the referral and that this matched the patients understanding. If any discrepancies are identified during the identification checks, radiographers told us they would return the referral to the referrer and await a new referral. Once the patient identification checks are complete, this is recorded the radiology information system.

Risk benefit conversations

Employer's procedure EP6 (Information and instruction to patients) details the procedure for providing information on the risks and benefits associated with the radiation dose from medical exposure. We saw information posters displayed in the radiology department and in changing facilities to inform patients of the low risk of an exposure. Leaflets are sent out with appointment letters to patients receiving higher dose exposures. Operators will also discuss the risks with patients, when appropriate.

Making enquiries of individuals who could be pregnant

Employer's procedure EP8 (Exposure of individuals of child bearing potential) provides guidance for carrying out pregnancy checks before any exposure. All

radiographers we spoke with were familiar with the employer's procedure. They told us everyone aged between 12 and 55, for exposures where the lower diaphragm and upper thigh are directly in the primary beam, are asked the pregnancy status questions.

All radiographers we spoke with confirmed pregnancy checks are always carried out. Records we reviewed showed an inconsistency with the recording of responses. When verbal checks are carried out, the pregnancy check box is also completed on the radiology information system. When written forms are used, they are scanned into the radiology information system. Radiographers do not always complete the required check box – they told us the scanned form provides sufficient evidence.

EP8 clearly states pregnancy must be ruled out before carrying out any exposure. If a patient is confirmed to be pregnant, the referring clinician will make the final decision about whether to proceed. This is communicated verbally to the radiographer. It also sets out how to proceed in different scenarios. Such as, the need to record the justification when a decision is made to proceed with an exposure when a patient is pregnant, or may be pregnant.

Information posters are displayed in the diagnostic department, which also highlights the need to inform a member of staff of any possibility that a patient may be pregnant.

Carers and comforters procedures

Employer's procedure EP22 (Carers and comforters) provides clear guidance on the authorisation of an exposure to a carer or comforter, such as the mother of a child. All staff could describe the measures they would take to encourage carers and comforters to reduce their exposure or leave the room if possible. Dose constraints for carers and comforters are in place, and the carer is given written information about the dose they will be exposed to. A written record is kept of all carers and comforters and the dose they receive.

General duties in relation to equipment

Quality assurance checks are carried out on all equipment and the frequency required is clearly documented and complied with.

A 'super user' approach is in place when training staff on new equipment. Radiographers receive specialist training from the radiography application specialist – once this training is complete, this group of staff are deemed competent to provide training to others. Staff are assessed before using any equipment for the first time, even if they have experience in previous roles.

Quality assurance checks on equipment are completed by radiographers, including bank staff, who are trained to the same level. A training programme has been implemented to ensure all radiographers are trained to carry out quality assurance.

Radiographers told us if an equipment fault is suspected during clinical use, additional quality assurance checks are carried out. If the quality assurance check confirms an issue, the engineer is informed. If the equipment performs well, senior staff are informed. If doses delivered are consistently at, or above, the dose reference levels, it is also reported to senior managers for further investigation.

An equipment register records the name of the manufacture, serial number and year of manufacture for all equipment. An equipment replacement programme is in place and no equipment is more than 10 years old. The medical physics expert is involved in all decisions about new equipment.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable.

The equipment used to expose patients to ionising radiation have a variety of protocols to help deliver standardised exposures. Staff we spoke with were confident about modifying exposures for adults and children and taking account of different body sizes.

The medical physics expert carries out dose audits. This information is used to set local dose reference levels. Where local dose reference levels are not available, national dose reference levels are used. We saw national and local dose reference levels displayed near equipment in the radiology department. Should the recorded value of an exposure be outside agreed limits, an investigation will be carried out. The investigation will consider the patient details, the quality of the image taken, the protocol used and scan range.

A dose and image optimisation group sets local exposure limits and guidelines to optimise exposure for different procedures. This group meets every 3 months and is chaired by a radiologist. Membership includes representation from all modalities, medical physics expert, radiologists and the operational IR(ME)R lead. A CT image optimisation subgroup and a plain film image optimisation subgroup both feed into the image optimisation group. Local diagnostic levels for a variety of procedures has also been produced, such as for exposures for children. We saw these clearly displayed in the diagnostic department.

We found all staff were aware of the importance of image optimisation and clear about how to escalate any questions or concerns to these groups.

Accidental or unintended exposure

Employer's procedure EP15 (Reporting of incidents involving unintended exposure; overexposure or underexposure of patients) details the procedure to follow when an error takes place. The process of reporting and investigating incidents was well understood by all staff we spoke with. We were told about a culture that supports the reporting of incidents and sharing lessons learned. Incidents are shared throughout the radiology department up to the clinical governance group.

What needs to improve

Employer's procedure EP15 (Reporting of incidents involving unintended exposure; overexposure or underexposure of patients) provides good links to the Duty of Candour, however it does not reference the Royal College of Radiologist's definition of clinically significant (recommendation a).

While some super users training records indicated their competency to train to others, this was not consistently recorded in all training records we saw (recommendation b).

Staff told us they check site, laterality (part and side of the body to be exposed) and reason before carrying out any exposure. The radiology information system has a check box to record this, however staff do not consistently use it. Employer's procedures could be updated to ensure these checks are consistently carried out and recorded.

When the decision is made to continue with an exposure of an individual who may be pregnant, it is only communicated verbally to the radiographer. This could lead to miscommunication and accidental exposure.

While employer's procedures were mostly clear and detailed, a few updates are required:

- Staff told us they ask about site, laterality (part and side of the body to be exposed) and the reason for the exposure as part of the patient identification checks. This is not reflected in employer's procedure EP7 (Patient identification).
- Employer's procedure EP15 (Reporting of incidents involving unintended exposure or overexposure of patients) - the flowchart should be updated to reflect Scottish Ministers are notified through Healthcare Improvement Scotland.

- Employer’s procedure RG7 (Justification and/or authorisation of medical exposures) should be updated to ensure managers’ competency is assessed by a senior member of staff.
- Employer’s procedure RG23 (Quality assurance programme) states equipment is quality assured as appropriate. It should be updated to be clear about when equipment should be quality assured after an engineer’s visit. Staff were inconsistent about when this should happen.
 - No requirements.

Recommendation a

- NHS Ayrshire & Arran should update employer’s procedure EP15 (Reporting of incidents involving unintended exposure; overexposure or underexposure of patients) to demonstrate the process for deciding which incidents are clinically significant and detail the role of clinicians.

Recommendation b

- NHS Ayrshire & Arran should ensure training records clearly indicate whether staff are competent to train others in the use of equipment.

Domain 6 – Policies, planning and governance

High performing healthcare organisations translate strategy into operational delivery through development and reliable implementation of plans and policies, and have effective accountability, governance and performance management systems in place.

What we found – policies and procedures

Each organisation must appoint an IR(ME)R lead who is responsible for the implementation of systems and processes to ensure statutory requirements are being met. NHS Ayrshire & Arran have two IR(ME)R leads:

- the ‘responsible IR(ME)R lead’ is the medical director and is responsible for ensuring that structures are in place for the entitlement of IR(ME)R duty holders for all types of medical and dental exposures, and
- the ‘operational IR(ME)R lead’ is the clinical director of medical imaging who takes a lead role in the practical aspect of ensuring compliance with IR(ME)R procedures. They are also the chair of the NHS board’s radiation safety committee and reports to the responsible IR(ME)R lead on any IR(ME)R related issues.

NHS Ayrshire & Arran's IR(ME)R policy provides clear structure about how IR(ME)R is implemented. It includes the roles and responsibilities for all relevant staff.

What we found - risk management, audit and governance

NHS Ayrshire & Arran have several committees and groups that support safety in relation to IR(ME)R. These include the following.

- An IR(ME)R compliance group chaired by the head of medical imaging. This group meets every month and reviews employer's procedures, inspection reports and identifies any improvements required.
- A hospital radiation safety committee meets every 6 months and discusses IR(ME)R related incidents and policy decisions. It is chaired by the operational IR(ME)R lead and membership includes the medical physics expert, modality leads and health and safety representatives.
- A health and safety wellbeing committee is attended by senior managers and chaired by the human resources director. This is the overarching group for health and safety in NHS Ayrshire & Arran.
- A clinical effectiveness committee receives annual reports, including reports from the operational IR(ME)R lead.

These groups are supported by the dose and image optimisation groups.

Contracted services

A private company provides radiology services out of hours. Radiographers and medical staff can contact the company for advice. The operational IR(ME)R lead assumes responsibility for the experience medical registration for radiologists. A copy of their scope of practice and entitlement is shared with the NHS board. All justifications are assigned to an individual and their details are recorded on the radiology information system.

Clinical audit

Employer's procedure EP20 (Clinical audit) details the audit activity relating to IR(ME)R. Audits are completed each year and results are provided to the operational IR(ME)R lead for inclusion in the NHS board's annual clinical governance committee report. Any unsatisfactory results included in the report are re-audited by the head of service 6 months later and the results shared with the operational IR(ME)R lead.

The scope of audits cover:

- entitlement
- training records to support entitlement
- referrals
- justifications
- clinical evaluations
- all written procedures
- incidents, and
- dose.

Radiologists also carried out peer review on justifications, including those justified by the out-of-hours contracted service.

We were told all audit results are used to drive improvements. We saw an example where operational changes were made to the placement of the detector plate to underneath the incubator, rather than underneath the child, when x-raying young children. This meant the child did not need to be moved, which led to a reduced risk of infection.

What needs to improve

While we saw a robust variety of audits being carried out, we did not see documentation identifying all audits carried out and the required frequency (recommendation c).

- No requirements.

Recommendation c

- NHS Ayrshire & Arran should update its employer's procedure on clinical audit to demonstrate the scope of audits to be carried out. It should include what should be audited, the frequency and by whom.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

What we found - staff recruitment, training and development

Expert advice

Medical physics expertise is contracted from NHS Greater Glasgow and Clyde. They provide expert advice in relation to compliance with IR(ME)R. They are involved in a variety of areas such as:

- commissioning of new equipment
- acceptance testing of new equipment
- local dose reference levels
- dose monitoring, and
- analysis of incidents.

Staff told us the medical physics experts often visit to test equipment and they are easily contactable and available for advice and support. They also provide advice on whether an incident should be reported to Healthcare Improvement Scotland.

The medical physics expert submit reports to the NHS board's radiation safety committee every 6 months. The report details the implementation of IR(ME)R and the services delivered in the previous year.

Training

Employer's procedure EP3 (Training and education) sets out the approach to training. We saw comprehensive training records in place for staff involved in medical exposure to radiation. A radiographer is provided with a comprehensive induction once qualified.

Training has been provided to enhance radiographers' skills and opportunities. The operational IR(ME)R lead teaches senior radiographers to justify under protocol, so they can then disseminate this. One radiographer is being trained to clinically evaluate chest x-rays. They will be required to double report 3,000 exposures before being deemed competent – this is in line with the training expectation of radiologists.

Students are supervised at all times. The tasks students carry out are in line with the relevant stage in their training and the competency they demonstrate. All radiographers we spoke with were clear about the activities of the students they were mentoring.

Radiologists' training and continual professional development is managed through their annual appraisals and medical revalidation process, which takes place every 5 years.

What needs to improve

While the NHS board completed a calculation of the medical physics expertise resource required, the identified shortfall is not yet outlined in a workforce plan. We understand this is being planned and would help identify how to meet the predicated service need.

- No recommendations.
- No recommendations.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of a service to comply with the Regulations. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

Domain 1 – Key organisational outcomes	
Requirement	
1	NHS Ayrshire & Arran must ensure referring GPs are appropriately entitled to do so (see page 11). <i>Regulation 17(1) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Domain 5 – Safe, effective and person-centred care delivery	
Requirements	
None	
Recommendations	
a	NHS Ayrshire & Arran should update employer’s procedure EP15 (Reporting of incidents involving unintended exposure; overexposure or underexposure of patients) to demonstrate the process for deciding which incidents are clinically significant and detail the role of clinicians (see page 17).
b	NHS Ayrshire & Arran should ensure training records clearly indicate whether staff are competent to train others in the use of equipment (see page 17).

Domain 6 – Policies, planning and governance

Requirements

None

Recommendation

- c** NHS Ayrshire & Arran should update its employer’s procedure on clinical audit to demonstrate the scope of audits to be carried out. It should include what should be audited, the frequency and by whom (see page 19).

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, Head of Service Review, kevin.freeman-ferguson@nhs.scot in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

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