



Healthcare
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Announced Inspection Report – Ionising Radiation (Medical Exposure) Regulations 2017(IR(ME)R)

Borders General Hospital
NHS Borders

4–5 November 2019

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Healthcare Improvement Scotland Ionising Radiation (Medical Exposure) Regulations
Inspection Report
Borders General Hospital, NHS Borders: 4–5 November 2019

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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 of care 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 of care 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 and addresses the radiation protection of persons undergoing medical exposures, and
- how well the service is led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with the Ionising Radiation (Medical Exposure) Regulations and its performance against the Healthcare Improvement Scotland quality of care 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 Borders General Hospital, NHS Borders, on 4 and 5 November 2019. We spoke with a number of staff including the Chief Executive, IR(ME)R lead, radiologists and radiographers. The inspection team was made up of two inspectors.

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

The Clinical Director Radiology manages all radiology services. A radiologist has been appointed an IR(ME)R lead and provides leadership and oversight for the implementation of IR(ME)R within the Board. To support the lead radiologist a senior radiographer has been nominated an IR(ME)R lead for radiographers. The IR(ME)R leads work together to ensure that the Board meets its obligations under IR(ME)R.

What we found

What the service did well

There was a positive safety culture within the radiology team for radiation protection of persons undergoing medical exposure.

Prior to our visit, NHS Borders had carried out a self-evaluation of their medical exposure to ionising radiation safety arrangements and had developed an action plan to address areas of improvement.

All staff were fully aware of their roles and responsibilities in relation to radiation protection of persons undergoing medical exposure.

There was good evidence of audits being undertaken. Following the entitlement process, audit improvements were made to the process to ensure the appropriate documentation was in place.

What the service needs to improve

We found that the governance arrangement for developing and changing employer's procedures and associated documents was not clearly defined.

There was a lack of clarity of the role and responsibilities of the different staff groups and committees.

There were no procedures or guidance for staff to undertake continuous education or training in relation to IR(ME)R, following qualification.

The membership and function of the optimisation group needs to be formalised to ensure the involvement of key staff at all times.

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

What action we expect NHS Borders to take after our inspection

This inspection resulted in five requirements and one recommendation. Requirements are linked to compliance with IR(ME)R 2017. 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.
www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare.aspx.

NHS Borders must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at the radiology department, Borders General Hospital, 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 that those who refer for a patient to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify that 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.

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

Entitlement

NHS Borders' employer procedure (EP 1) states 'All Duty Holders must be officially 'entitled' to work in their capacity as 'Referrer', 'Practitioner' or 'Operator' (or a combination of these) within NHS Borders. The entitlement process will be overseen by the NHS Borders IR(ME)R lead and Chairman of NHS Borders Radiation Safety Committee on behalf of the Employer.'

As entitlement is a process required by the regulations, the individual's scope of practice is set out in a formal letter. An individual's scope of practice can change over time, such as following additional training.

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. The clinical directors are authorised by the IR(ME)R lead to entitle clinicians in their team. Entitlement is administered through the human resources department. NHS Borders has identified that some of the entitlement letters sent to medical clinicians have not been returned to acknowledge their scope of practice, as per

the NHS board's procedure. At the time of inspection, this was actively being addressed with human resources.

Radiographers are entitled, depending on their training, to act as operators and carry out justifications of plain film x-rays. The lead radiographer maintains the entitlement records for radiographers in their own team

All medical staff are entitled to refer all imaging other than iodine therapy. All dentists who hold an entitlement certificate are entitled as a referrer for dental radiographic images.

NHS Borders do not use locum radiographers or radiologists to support the delivery of services. However, if that position changes all locum staff will be subject to the same procedures and training as permanent staff.

Referral

A referral can only be made by a person who is entitled to do so. Referrals will come into the radiology department from a variety of sources, both within the hospital and from the community. Referrals are made internally through the electronic radiology information system. External referrals are made by email or on paper. The information from email and paper referrals are scanned into the radiology information system by the clerical staff.

Hospital-based medical staff and community based GP's can refer for all imaging other than iodine therapy. In addition, individuals who are not doctors can also refer patients for plain film (x-ray) and some CT procedures; these are known as non-medical referrers. For an individual to be a non-medical referrer their line manager has to make an application to the IR(ME)R lead (radiographer) with the reason why, and the required scope of practice. This is reviewed and if permission is given, they are entitled by the IR(ME)R lead (Radiologist) and their details added to the radiology information system. Non-medical referrers include radiographers, physiotherapists, occupational therapists, specialist nurses and speech and language therapists. When a non-medical referrer makes a referral this is clearly identified in the radiology information system. This allows the radiographers to crosscheck these names against the approved non-medical referral list. We reviewed a number of records and confirmed that this system was in place. Radiographers confirmed that they could access a list of non-medical referrers to check their scope of practice, if required to do so, prior to carrying out a procedure.

Justification

Radiologists review all referrals other than plain film to ensure that there is sufficient information to be able to justify the referral. They would also choose the correct protocol for the medical exposure of ionising radiation.

Radiographers can only justify plain film (x-ray).

We were told that if there was insufficient information, the radiologist or radiographer would contact the referrer to request further information. The additional information would then be added to the referral to allow a justification to be made. Where additional information is not provided, or the referral is inappropriate and justification cannot be approved, the referrer will be contacted and informed of the decision.

Records

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

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

The radiography staff could describe the checks they would undertake prior to recording information and where they would get the dose information.

What needs to improve

NHS Borders had identified, following an audit, that some of the doctors had not returned signed copies of their entitlement documents as per the employers procedure. NHS Borders are currently in the process of ensuring all entitlement letters are signed and returned, in line with their employer's procedures.

Requirement

- No requirements.

Recommendation

- 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.

NHS Borders has a duty under IR(ME)R to develop written procedures commonly referred to as employers procedures. These are intended to provide a framework under which professionals can practice. NHS Borders has responsibility for ensuring that they involve relevant specialists in their production. Once these procedures are in place, steps must be taken to ensure they are complied with.

What we found - safe delivery of care

Safety Culture

We asked the radiographers, consultant radiologists, IR(ME)R lead, lead radiologist, medical director and director of nursing about the culture within the radiology department. Everybody we spoke with was positive about the safety culture within the department. We were told that staff work supportively and there is an open culture. We were told that consultants and senior staff were approachable and there was a supportive leadership. There was a positive approach to staff seeking clarity and requests for further information if required. We were told that there was a positive collaborative learning environment and there was feedback, discussions and reflection from incidents and audits.

Employer's Procedures

NHS Borders has level 1 and 2 employer's procedures that ensure correct patient identification. All staff spoken with were familiar with the procedures. Staff told us how they would ask the questions to correctly identify a patient, and what to do if the patient could not communicate in English. Staff have access to interpretation services.

Staff told us the measures they use to confirm the identity of patients who could not provide this information themselves. This would include instances where the patient was unconscious or did not have capacity to consent. We were told that in unusual cases, temporary identification measures are used by the NHS board, for example, in trauma cases when a patient cannot be identified at the time of a request for an x-ray. Staff were also clear that they would not proceed if a patient's identity could not be confirmed.

To support patient identification, NHS Borders has developed information posters for patients to read. These posters prompt a patient to speak up if they did not expect a scan. We saw these posters on the walls in the diagnostics department and they were clear and easy to understand.

Staff also told us that they would ask all patients to confirm if they knew why they had been referred to the radiology department. This information would be cross-referenced with the information on the radiology information system. Staff told us that, if required, they would do further checks or check with the referrer. We were told that this system was introduced to reduce the potential for incorrect referrals. We noted that NHS Borders has very few incidents of incorrect referrals.

Making enquiries of individuals who could be pregnant

There is an employer's procedure to correctly identify individuals who could be pregnant. We were told that as part of every exposure where the patient is capable of child bearing, NHS Borders staff always ask if the patient could be pregnant. If the patient can confirm they are not, the patient will sign a declaration and this is scanned onto the radiology information system. All the staff we spoke with described the process and where this information is recorded. The staff spoken with were also aware of the employer's procedures and where they would go to for support and advice if required.

We discussed referrals for patients who were known to be pregnant. The radiography staff told us that the benefit and risk conversation was sometimes recorded in the referral information. When there was no information available, the radiographers would contact the referrer to confirm that the risk and benefit conversation had been undertaken. A record of this conversation would then be made onto the radiology information system.

In theatres, NHS Borders' procedure states 'In certain circumstances when the procedure must proceed on clinical grounds and the patient is pregnant, the risk/ benefit analysis must be discussed with a consultant radiologist and the result recorded in the patient's notes'.

NHS Borders' procedure states that the practitioner is to provide appropriate information to the operator. However, the procedure did not clarify who, what and where information should be recorded in the radiology information system, in order to provide sufficient information for the operator to proceed.

What needs to improve

As part of the justification process, the radiologists will need to demonstrate the risk/benefit for the foetus exposure has been considered. NHS Borders must ensure that the appropriate risk benefits conversations are recorded and the operator is provided with the appropriate documented information before proceeding with an exposure. Consideration should be given to how the information is to be provided and where it should be recorded by the referrer.

Carers and comforters procedures

NHS Borders has carried out a review to monitor compliance with IR(ME)R. NHS Borders' action plan identified the need to update their carers and comforters level 2 document. NHS Borders told the inspection team that they were awaiting further guidance from the Society of Radiographers before proceeding.

What needs to improve

Due to unknown timelines from the Society of Radiographers to produce their updated guidance, NHS Borders should not delay the review of its current carer and comforter's guidance and undertake the review as soon as practical.

General duties in relation to equipment

NHS Borders has a draft policy on 'Equipment and Quality Assurance.' The policy details the responsibilities for maintaining an inventory list and the quality assurance provisions for NHS Borders to fulfill its responsibilities under IR(ME)R. We were shown an equipment inventory list which details all the diagnostic and nuclear medicine equipment. This inventory highlights equipment that is due for replacement and is used to trigger an application for funding to replace it.

We were told about the quality assurance procedures for equipment and shown the records of the quality assurance checks. These assurance checks are carried out by radiography staff daily, weekly and monthly. Staff were able to describe the process for when a piece of equipment fails a quality assurance check. This includes asking for support from the medical physics expert and calling the engineer out to repair a piece of equipment.

We saw that when an engineer visits there were clear handover procedures in place to ensure the equipment was quality assured before it is put back in to

service. All staff could describe this handover procedure and completed records were available on the department.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. All the operators we spoke with could describe how they would select the correct protocol for the intended purpose. The radiologists we spoke with described how they calculate image quality with as low as dose as was reasonably practical when justifying an exposure. They also told us they would always consider if there is an alternative to ionising radiation.

The equipment used to expose patients to ionising radiation have a variety of protocols that help deliver standardised exposures. Exposures can be modified for adults and children and take account of different body sizes.

We were told of a recent NHS Borders study on the use of the mini C-arm. This equipment is used in theatres for small area exposures such as hands and feet. This piece of work was undertaken in partnership with the radiologists and the medical physics expert. NHS Borders has now agreed a new lower Dose Reference Level (DRL). As more dose data is gathered on the mini C-arms, it is anticipated that the medical physics expert will be able to produce more accurate DRL's in the future.

What needs to improve

The lead radiographers told us about a review involving plain film (x-ray) imaging. The review did not involve a change to the dose but did involve a review of the software that affects clinical evaluation. The reporting radiographers who clinically evaluated these images led the review. However, neither the medical physics expert nor a radiologist were consulted as part of the review group.

Accidental or unintended exposure

NHS Borders have an employer's procedure called *Reporting of Incidents Involving Accidental or Unintended Exposure or Overexposure*. The procedure provides information on the reporting and investigating of IR(ME)R incidents. NHS Borders has identified an area of improvement to review the process of how patients are informed after an incident or accident. This process links to the NHS board's Duty of Candour.

We were told that the learning outcomes from incidents are shared with the radiology staff to support learning and that learning is shared through team

briefs and team meetings. The IR(ME)R lead (Radiology) also receives a monthly report on the incidents that have occurred.

Requirement 1

- NHS Borders must ensure that there is a clear procedure for the recording of information to demonstrate the risk/benefit to the foetus and exposure has been considered by the appropriate practitioners. This may be achieved by updating the practical procedure '*Exposure of individuals of Child bearing potential*', to provide clear information on who considered the risk/benefit for to the foetus exposure where this information is recorded. (Regulation 11(3)(d)).

Requirement 2

- NHS Borders must ensure that a practitioner and an operator are involved when optimisation of an exposure is being reviewed. (Regulation 12(1)).

Requirement 3

- A medical physics expert must be involved as appropriate for consultation on optimisation. (Regulation 14(1)).

Recommendation 1

- It is recommended that NHS Borders develop an imaging optimisation group that includes representation from medical physics experts, radiologists and radiographers. The group should have clear roles and responsibilities to provide governance and coordination of any dose optimisation undertaken.

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

The development, review and updating of employers procedures level 1,2, and 3 is detailed in NHS Borders' employer's procedure 19. The governance of the procedures is managed through the IR(ME)R lead and the radiation safety committee. The level 1 employer's procedures can only be changed through the radiation safety committee. We were told that level 2 documents could be

signed off by the IR(ME)R lead and a clinical director and they would advise the radiation safety committee of the changes. Level 3 procedures can be changed and signed off by NHS Borders' modality leads (superintendents). We were told that the IR(ME)R lead (radiographer) manages most of the changes to the level 2 and 3 procedures.

The IR(ME)R leads for radiology and radiography are an integral part of the team and manage many of the operational aspects of implementing IR(ME)R in NHS Borders.

What needs to improve

Employer's procedure 19 needs to be further developed to provide clear roles and responsibilities in relation to the review and updating of employers procedures level 1, 2, and 3. We found unclear accountability of both the radiation safety committee and the IR(ME)R lead radiologist. There should be clear lines of accountability, roles and responsibilities for any changes to the levels 1, 2, and 3 employer's procedures. At the time of our inspection, we discussed with NHS Borders options to address our findings.

What we found - risk management, audit and governance

Outsourced services: governance arrangements

NHS Borders use a private company to provide radiologist services between the hours of 23.00 and 08.00. The clinical director, Radiology, provides oversight of the outsourced service. As part of the inspection, we reviewed the governance information for the outsourced service and discussed the service with the lead radiologist. All radiologists provided by the private company have to be registered with the General Medical Council. The company undertakes its own quality assurance and provides NHS Borders with this information.

Radiographers and medical staff can contact the company for advice. All justifications are attributed to an individual and their details are recorded on the radiology information system. The radiologists provided by the private company will justify exposures and provide clinical evaluations of images. The clinical director, Radiology, carries out a review of all clinical evaluations performed by the radiologists provided by the private company. If any discrepancies are identified these can be raised with the company. These clinical audits provide assurance to NHS Borders on the quality of the purchased service. This level of audit is achieved through the manageable numbers of clinical evaluations and the personal drive of the lead consultant radiologist.

What needs to improve

NHS Borders must develop an employer's procedure that includes the scope of clinical audit of purchased radiologist service. It is recommended that the policy should include what should be audited, the frequency and by whom.

Clinical audit

The IR(ME)R lead (radiographer) coordinates and manages the delivery of the audit programme on behalf of the IR(EM)R lead (radiologist). The scope of audits are included in employer's procedure 21 and cover the following areas.

- NHS Borders Entitlement Process.
- Entitlement Certificate Audit.
- Supplementary Training Requests.
- Radiation incidents.
- Dental audit.
- Orthopaedic Mini II audit.
- Dose Audits.

An annual report of all audits is sent to the radiation safety committee. During our inspection, we reviewed the annual audit and discussed the outcomes with the IR(ME)R leads for radiology, radiography) and the director of nursing. We saw information on a patient pathway audit. We were told that the findings from audits are communicated to staff in a variety of ways, such as staff meetings and emails. We saw that, as a result of an audit, staff practices had changed following the introduction of pregnancy questions. We noted that the NHS board carry out audits annually and on an ad hoc basis. We were told that the next audit will focus on non-medical referrers' referrals.

Requirement 4

- NHS Borders require to develop an employer's procedure that includes the role of clinical audit for outsourced radiologist services. The policy should include what is to be audited and the frequency. (Regulation 7).

Recommendation

- No recommendations.

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

NHS Borders contracts medical physics expertise from NHS Greater Glasgow and Clyde. The medical physics experts are appointed by letter from NHS Borders by the IR(ME)R lead (Radiologist). The medical physics experts provide advice to NHS Borders in relation to compliance with IR(ME)R. They are involved in a variety of areas including commissioning of new equipment, quality assurance of equipment, dose monitoring, training and analysis of events. The medical physics experts provide advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland. The medical physics experts told us that they were currently involved in dose reviews in plain film (x-ray), imaging and CT scans, with data forwarded to Public Health England as part of a national review. An annual report is provided to NHS Borders by the medical physics experts on the services they have provided.

Staff told us the medical physics experts were easily contactable and available for advice and support.

Training

We found that there were comprehensive training records in place for staff involved in medical exposure to radiation. Once a radiographer qualifies, NHS Borders provides induction and ongoing training. We saw records that demonstrated the training had been provided. There were clear training records for operators of equipment in the department and this included CT and plain film equipment. Student radiographers can only work under the supervision of a qualified radiographer. A radiographer's training record is closely linked to their entitlement. We reviewed a sample of records and the entitlement records corresponded to the training records.

Operators must be trained to use the different types of machines as it is not a 'one size fits all' approach. We were told that anyone operating a machine must be trained on the specific equipment. All the radiographers we spoke with said they had received appropriate training and all training records inspected were up to date.

It is the responsibility of the radiographer to maintain their own continual professional development as part of their professional registration.

Radiologist training and continual professional development is managed through their annual appraisals and medical revalidation process and the medical director signs off staff re-validation every five years.

As detailed with the dental employer's procedures, all dental operators and practitioners require to demonstrate that they have obtained the appropriate qualifications, experience and training. A newly qualified or newly appointed staff in dentistry will be assigned an authorised competency assessor; the assigned competency assessor will be responsible for assessing evidence of qualifications, experience and registration with regard to the basic requirements for entitlement.

What needs to improve

There was evidence of continual education for radiologists and radiographers, however, it was not always possible to identify the training that related specifically to IR(ME)R. It was also unclear what was the policy for staff outside radiology, who have obligations under IR(ME)R, in relation to their continual IR(ME)R education. NHS Borders must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R.

Requirement 5

- NHS Borders must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R. (Regulation 6(3)(b)).

Recommendation

- 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 an 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 5 – Safe, effective and person-centred care delivery	
Requirements	
1	NHS Borders must ensure that there is a clear procedure for the recording of information to demonstrate the risk/benefit to the foetus and exposure has been considered by the appropriate practitioners. This may be achieved by updating the practical procedure ' <i>Exposure of individuals of Child bearing potential</i> ', to provide clear information on who considered the risk/benefit for to the foetus exposure where this information is recorded. (Regulation 11(3)(d)) (see page 15).
2	NHS Borders must ensure that a practitioner and an operator are involved when optimisation of an exposure is being reviewed. (Regulation 12(1)). (see page 15).
3	A medical physics expert must be involved as appropriate for consultation on optimisation. (Regulation 14(1)). (see page 15).
Recommendation	
1	It is recommended that NHS Borders develop an imaging optimisation group that includes representation from medical physics experts, radiologists and radiographers. The group should have clear roles and responsibilities to provide governance and coordination of any dose optimisation undertaken. (see page 15).

Domain 6 – Policies, planning and governance

Requirement

- 4** NHS Borders require to develop an employer’s procedure that includes the role of clinical audit for outsourced radiologist services. The policy should include what is to be audited and the frequency. (Regulation 7). (see page 17).

Recommendation

None

Domain 7 – Workforce management and support

Requirement

- 5** NHS Borders must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R. (Regulation 6(3)(b)). (see page 19).

Recommendation

None

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.freemanferguson@nhs.net 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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