Submission to the Oireachtas Joint Committee on Health

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Opening Statement

by

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and

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Good morning Chairman and Members of the Committee.

Thank you for your invitation to attend today.

My name is Sharon McGuinness and I am Chief Executive Officer of the Health and Safety Authority. I welcome the opportunity to meet with the Committee.

I'm joined today by my colleague Adrienne Duff who is programme manager of the Irish National Accreditation Board (INAB) and by Bríd Burke, senior accreditation officer.

By way of introduction, INAB is the national body in Ireland with responsibility for the accreditation of laboratories, certification bodies and inspection bodies.

INAB provides accreditation in accordance with relevant International Organisation for Standardisation (ISO) standards and guides. Accreditation is one component of Ireland's Quality Infrastructure, which includes certification, accreditation and good regulatory practices to ensure national and international standards are met across a range of sectors within our economy and society in general. There are Irish organisations accredited by INAB spanning a wide range of sectors, including healthcare, agri-food, forensic science, vehicle inspections and water quality.

As the Irish body, INAB is part of an international network of accreditation bodies within Europe where each Member State has a single national accreditation body.

INAB was established in 1985 and operates as a Committee of the Health and Safety Authority since 2014. As an operating unit, its role was transferred to the HSA under the Industrial Development Act 2014 which also dissolved Forfás as its original parent body at that time.

Your invitation to us today arises from the second Scoping Inquiry report that includes references to INAB and MedLab Pathology Limited, and around which we are here to provide information to you and to answer any questions you may have.

I would now like to ask my colleague Adrienne Duff to continue our presentation and I will then provide some concluding comments after which we will be happy to take any questions you may have.

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Thank you Sharon and good morning Chairman and members of the Committee. I welcome this opportunity to provide information to you on behalf of INAB.

The Irish National Accreditation Board is a public body and we exist for a public purpose. We provide the national accreditation service on a not-for-profit and non-commercial basis. Accreditation is one component of a network of accreditation, oversight and regulation to ensure standards across a range of sectors within our economy and society in general.

In respect of the matters of interest to the Committee, our role is specific. It is the accreditation of medical testing laboratories to ISO 15189, assessing procedural and technical standards to demonstrate competence to perform cytology screening. As an appendix to our submission, we have included a general overview of the INAB laboratory accreditation process.

When we became aware of the second Scoping Inquiry, we proactively offered to provide information and to assist the review team to the maximum possible in their enquiries to INAB. We co-operated fully with any subsequent enquiries and provided all necessary details and information requested, in a timely manner.

As we now know, the Scoping Inquiry's report identified a procedural lapse which occurred within the INAB accreditation process, specifically in relation to MedLab Pathology Limited and I would like to elaborate on how this took place.

MedLab Pathology was first accredited by INAB in 2011 for cytology screening following an assessment by an independent team of technical experts and this accreditation has been verified annually.

The company's principal location for this operation has always been based in Dublin.

In November 2016, MedLab Pathology Limited contacted INAB by email proposing to hire a cytology screening employee (a cytoscreener) and to locate that person at their laboratory in Manchester.

Following from this notification, INAB considered the information on an internal basis, consulted with technical assessors and was of the opinion that the activities, monitoring and controls that were understood for the cytoscreening (in Manchester) would be in line with ISO 15189.

INAB did inform MedLab Pathology Limited by reply email that, in principle, such a proposal would potentially be acceptable.

The matter of cytoscreening at the Manchester laboratory was not subsequently raised directly again by MedLab Pathology Limited with INAB.

The procedural lapse that arose within INAB is that we did not subsequently and formally follow through on this information.

From November 2016 onwards, INAB continued its usual annual assessments of MedLab Pathology Limited in Dublin which confirmed continued compliance to ISO 15189 each year. On each annual assessment visit, the INAB team comprised a lead assessor to assess the laboratory management system with a Consultant Histopathologist, as a technical assessor.

During the assessments of cytology screening, the INAB technical assessor (Consultant Histopathologist) assessed the competency records of all MedLab screening staff. The lead assessor assessed the laboratory management system. The INAB assessment team raised no major findings during these assessments.

It is worth noting that MedLab Pathology Limited employees, whom were subsequently confirmed as based in the Manchester site, were included in the INAB assessment. However, their exact location was not readily apparent to the INAB assessment team from the records examined.

Following INAB's engagement with the Scoping Inquiry in February 2019, it became apparent that cytology screening at the Manchester site - referred to in MedLab's email to INAB in November 2016 - was in fact fully operational. We now understand from the Scoping Inquiry's report that MedLab Pathology Limited in fact began cytology screening in the Manchester site in February 2016.

We immediately conducted a full and thorough review within INAB in conjunction with our technical assessors. The main outcomes of this were as follows:

1. The competence of all relevant MedLab Pathology Limited staff to perform cytology screening was assessed in detail by our technical assessors each year since 2016 (21/06/16, 18/05/17, 14/05/18).

2. The Manchester site was under the direct control and management of MedLab Pathology Limited.

3. The staff at the Manchester site were employed by and under the direct supervision of MedLab Pathology Limited.

4. The Manchester site was using identical documentation, work instructions, information technology and reporting mechanisms issued and controlled from the Dublin site.

5. Employees in the Manchester site were included in the overall MedLab quality system and were monitored exactly as employees based in Ireland.

Based on the source and level of control and management of the accredited activities and with the benefit of external advice, we concluded that the cytoscreening conducted at the Manchester site was within the scope of the accreditation of MedLab Pathology Limited. The annual INAB assessments from 2016 also demonstrated that there was a management system which met the requirements of ISO 15189 for all cytology screening performed by MedLab Pathology Limited.

On completion of this review and based on the evidence above, INAB confirmed to the Scoping Inquiry that the cytoscreening conducted at the Manchester site was within the scope of the accreditation of MedLab Pathology Limited.

We subsequently followed up this review with a specific onsite visit to Manchester in April 2019 as part of our annual surveillance visit to MedLab in Dublin. The assessment was completed with an INAB lead assessor and two technical assessors (both of whom are Consultant Histopathologists). The April 2019 assessment confirmed to INAB that the Manchester site was under the direct operation and control of MedLab Pathology Limited and that the laboratory's operations met the requirements of ISO 15189.

Our review satisfied us that the cytoscreening at the Manchester site was accredited under the management system of the MedLab Dublin office. However, for the avoidance of any doubt, we do not think it acceptable to have been unaware of, nor formally notified of, the specific external location of some of MedLab Pathology Limited's cytoscreeners in the Manchester laboratory.

Our internal review determined that a more specific, direct and robust level of communication should have taken place between INAB and MedLab Pathology Limited at the outset.

It is clearly our responsibility to ensure that all applicants for accreditation and accredited bodies keep us fully and clearly informed about proposals to modify or extend their accredited activities so that these proposals can be scrutinised as fully as is necessary before being implemented.

We immediately put in place procedures to rule out any further such occurrence arising. This includes scrutiny of the exact locations of any personnel within organisations seeking accreditation, implementation of new technology to track all such matters throughout our system and checks and balances to monitor our own systems and staff.

In summary, it is the case that MedLab Pathology Limited continues to meet the requirements of ISO 15189.

It is also very important to emphasise that nothing in our review and assessments, or in the Scoping Inquiry report, suggests that the quality of cytoscreening conducted at the Manchester site was of a lower standard to that conducted at the Dublin site.

On a further point of clarification, as the national body in Ireland for accreditation, INAB is permitted to perform assessments in other jurisdictions. This is the case when an Irish based company, accredited by INAB, has established an additional site in another jurisdiction. A similar entitlement exists for other EU based Accreditation Bodies that have site operations based in Ireland.

I will now hand back to the Authority's CEO Sharon McGuinness to conclude our comments.

Thank you Adrienne. The overall matters being enquired into by the Scoping Inquiry are of the highest possible importance to women and society in general and we take them very seriously indeed.

I can categorically reassure the Committee that lessons have been learned, procedures were immediately reviewed and changed, and system improvements have already been implemented. We were and are committed to having a strong and robust system which provides confidence in accreditation.

The Authority regularly reviews overall corporate governance structures to continuously improve our services and we will continue to do so to ensure that we meet the appropriate standards and expectations.

It is INAB's task to ensure, as a professional body, committed to its role and to the transparency required of every public body that they continue to offer professional, independent and impartial accreditation services. Collectively, we are fully resolved and determined that this will continue to be the case now and into the future.

Thank you Chairman and Members of the Committee.

APPENDIX 1

ISO 15189:2012 Accreditation and Laboratories Accredited for Cytology Screening

INAB accredits cytology screening services under the criteria set out by the ISO 15819 Standard and with regard to the quality assurance programme as set out by the National Screening Service (CervicalCheck).

The internationally accepted and recognised standard contains requirements for the competence of medical testing laboratories and details the requirements to be met by laboratories in developing a management system for quality, administrative and technical operations. The provisions of the standard are applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing activities.

The standard requires laboratories to establish and maintain a quality system to manage procedures including document control, complaint handling, contract review, purchasing, audits and investigation into non-conforming testing, provision of medical advice and sample handling.

In addition, the laboratory is required to have policies and procedures to describe training, test methods, validation, quality assurance, reporting and measurement traceability.

Medical laboratories accredited by INAB cover testing in areas such as: clinical chemistry, haematology, histopathology, immunology and microbiology. There are presently 63 medical testing laboratories accredited by INAB, from a total of 237 accreditations in the entire programme. Over the course of 2018, for example, INAB performed over 300 assessments of our organisations.

Laboratories are accredited for a defined range of activities and these are detailed in a scope of accreditation which is publicly available.

The process for the accreditation of laboratories is based on annual surveillance visits with technical experts relevant to the scope of the laboratory's activities. Following the on site assessment and the closure of findings identified, continued accreditation is confirmed.

INAB develops policies and guidance on the implementation of specific elements of ISO 15189:2012 but does not set technical/test method/scheme requirements.

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