**Stakeholder Consultative Process**

***This form may be used to submit feedback regarding the HSE Strategy for Laboratory Services 2025-2029 [Outline Draft Recommendations] document.***

***Please return completed form by CoB Friday 3rd May to: jane.boxberger1@hse.ie***

* ***General comments regarding the strategy document and principles are invited below. Please type responses and return as a Word document.***
* ***In addition, each recommendation is individually referenced to facilitate more specific feedback as appropriate. Please use the spaces provided, keeping comments and suggestions as succinct and relevant as possible.***
* ***As the document will be fully updated following review of all feedback received, we would ask that you kindly overlook any formatting or typographical concerns and focus solely on the substance of the recommendations themselves.***

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| **Completed by:** | **Name:**  | **On behalf of: (*group or organisation if relevant*)** |

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| **SECTION ONE: Context and Background (pp 1-5)** |
| **General Comments/Suggestions:** |

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| **SECTION TWO: Key Principles Guiding the HSE Laboratory Strategy**  |
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| *1.* | *HSE Laboratory services should adapt on an ongoing basis to support and to drive the agenda of healthcare reform to provide integrated care and support the function of the Health Regions.*  |  |
| *2.* | *HSE should continue to provide clinical and non-clinical laboratory services to support decision making in patient care, screening for disease, surveillance, public health purposes and policy formulation*  |  |
| *3.* | *HSE considers laboratory services as a core health service function that should be delivered by HSE operated services to the greatest extent that is practical taking account of service quality, turn-around-time and cost.*  |  |
| *4.* | *HSE considers that laboratory services should generally be provided by services that are integrated in a manner that links with where the person is cared from and across the patient journey in primary, community and residential/hospital/hospice care. Service quality, integration and sustainability are key elements in decisions regarding the degree of centralisation versus decentralisation of services. Centralisation is not an end in itself.*  |  |
| *5.* | *HSE provides access to clinical laboratory services to healthcare practitioners working for HSE and HSE affiliated services, for healthcare practitioners working in partnership with the HSE or with other public services. Providing comprehensive services to General Practice is a key part of the service.*  |  |
| *6.* | *Access to HSE clinical laboratory services is based on need and clinical or public health priority and not on ability to pay. Laboratory services may be provided to private healthcare providers under contract/service level agreement provided this does not limit access or impact on turn-around times for HSE, HSE affiliated and other publicly funded services*  |  |
| *7.* | *The goal is to provide equitable access to essential laboratory services that are quality assured, are delivered when and where needed and in an environmentally and financially sustainable way. This approach reflects the value proposition of the strategy.*  |  |
| *8.* | *The HSE seek to discourage inappropriate and unnecessary testing as this can be harmful to people tested and is contrary to the goal of a sustainable health service.*  |  |
| *9.* | *Effective use of information and communications technology is fundamental to the delivery of an effective and sustainable laboratory service and to support surveillance of communicable and non-communicable disease.*  |  |
| *10.* | *Given the sensitivity of much of the data, managed laboratory services must comply with legal obligations with respect to data protection*  |  |
| *11.* | *Samples such as tissue and body fluids collected from people should be transported, stored, processed and disposed of in a manner that is respectful and consistent with good practice.*  |  |
| *12.* | *Where consolidation or centralisation is required to improve patient services it is expected that this can be achieved in a manner that avoids or minimises relocation of staff through use of remote working from an existing base and relocation of posts (and associated workload) as posts fall vacant*  |  |

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| **SECTION THREE: Recommendations**  |

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| 1. **Quality**
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| *a.* | *All HSE laboratories and near patient testing services should operate a quality management system consistent with appropriate standard such as the EN ISO 15189 (2022) or EN ISO 17025 standard.*  |  |
| *b.* | *Clinical laboratory services on a single site should operate a single quality management system for all disciplines provided on that site. In addition, it is appropriate for smaller laboratories that operate within a laboratory network/unit to be included in a network wide quality management system whenever practical do so.* |  |
| *c.* | *Achievable, context specific, HSE target turn-around-times (TATs) should be specified for common and critical laboratory services. These targets should be defined by clinical requirements rather than current capacity. HSE laboratories should measure their performance against those targets and report their performance to users of laboratory services.*  |  |
| *d.* | *Context specific retesting intervals for tests should be defined where appropriate.*  |  |
| **Section 1 – General Comment (Quality):**  |
| 1. **Workload Management**
 |
| *a.* | *The HSE laboratory service should provide services to those healthcare practitioners registered to practice in the jurisdiction of Ireland who are eligible to request HSE laboratory services. Those healthcare practitioners for whom registration is not currently available should also have access to HSE laboratory services within their scope of practice if they are working within the HSE or other public services.*  |  |
| *b.* | *Each laboratory service unit (one site or multisite) should have a Clinical Director and laboratory manager to manage the overall service.* |  |
| *c.*  | *Within the laboratory service unit each major clinical laboratory discipline (such as clinical biochemistry, haematology, histopathology, immunology, microbiology, transfusion) should have an appropriately qualified person identified as clinical lead for that discipline with the authority and responsibility to manage that element of the service and to account for it to the clinical director. The discipline clinical lead will be a Consultant Pathologist or Scientist with appropriate training and competence in the discipline concerned. The discipline lead should account to the Clinical Director for range of services provided taking account of relevant national guidance and practice norms.*  |  |
| *d.* | *The Clinical Director of the laboratory unit, in consultation with the laboratory manager, discipline clinical leads, laboratory users and senior managers and taking account of relevant guidance should determine the requirements (sample type, clinical details) for access to testing including limitations on access and criteria for sample rejection.* |  |
| *e.* | *The Clinical Director, Laboratory Manager and discipline clinical lead should ensure that information on the range of services provided, requirements for tests and target TATs for key tests are readily accessible to users of laboratory services.*  |  |
| *f.* | *Laboratory services to General Practitioners registered to practice in Ireland should be provided as provided for in the 1970 Health Act.*  |  |
| *g.* | *All users of laboratory services practising outside of HSE or HSE associated facilities should provide relevant details of their practice location, contact details and hours of operation to the laboratory service to support traceability and reporting of results.* |  |
| *h.* | *Services that are provided by HSE laboratory services should be supported by a body of evidence of clinical relevance and of assay performance. Tests that are not supported by evidence should not be offered as routine services. This should not impede research and development relating to assessing the value of new services.* |  |
| *i.* | *Where demand exceeds service capacity the Clinical Director of the laboratory unit in consultation with the Laboratory Manager and discipline leads should have the responsibility and authority to identify to users of laboratory services which services must be curtailed to ensure that the quality of the service is not compromised by the volume of samples submitted.* |  |
| *j.* | *If service restrictions are necessary they should be communicated in the first instance to relevant senior management and then to laboratory users. Service restrictions should be based primarily on clinical need and take account of relevant national standards and guidance. Service restrictions should not be based on prioritisation of one hospital over others or prioritisation of one geographical area served by the laboratory over other hospitals or areas served. Prioritisation cannot be based on an assumption that tests submitted from the community are of lower priority that samples submitted from the hospital setting.* |  |
| **Section 2 – General Comment (Workload Management):**  |
| 1. **Sample Collection Services**
 |
| *a.* | *Laboratory services should develop or extend phlebotomy services for hospitals as part of the laboratory service and within the laboratory governance.* |  |
| *b.* | *Blood sample collection should be performed by phlebotomists with requisite skills in communication with the patient regarding the process and the collection of high quality samples with minimum discomfort for the patient.* |  |
| *c.* | *Laboratories should consider broadening the scope of the phlebotomy service to include collection of other samples including oral fluid, nasopharyngeal and other respiratory samples, skin scraping, hair and nail clippings, urine and faeces samples and wound samples.* |  |
| *d.* | *Laboratory services should provide access to phlebotomy services for patients referred by their GP service on the basis that it is particularly difficult to collect adequate blood samples from the patient.* |  |
| **Section 3 – General Comment (Sample Collection Services):**  |
| 1. **Organisation**
 |
| **4.1** | **Services to support care in the community** |
| *a.* | *Planning for service developments in the community should take account of the laboratory services required to support the development and how these will be accessed and delivered.* |  |
| *b.* | *Laboratory services for people cared for in primary and community care should have the same priority as laboratory services for people cared for in hospital. Although the clinically required turn-around-time is context and test specific, services for people cared for in primary and community care should be recognised as equal in priority with services provided to people cared for in hospital.* |  |
| *c.* | *Laboratory services for people cared for in primary and community care should provide a facility for GPs and others practising in the community to readily identify samples that require urgent attention and rapid reporting.* |  |
| *d.* | *Laboratory services for people cared for in primary and community care should be provided in a way that ensures that all laboratory requests can be made electronically (order communications). Results should be reported electronically and be accessible to the healthcare worker and be comparable whether the person is being cared in the community or the hospital.* |  |
| *e.* | *There should be consistent clinical guidance, advisory services for and governance of laboratory services for people when they are cared for in primary and community care and when they are cared for in hospital.* |  |
| *f.* | *Laboratory services for people cared for in primary and community care should include effective logistics for safe, efficient and timely collection and transportation of samples taken in the community to the laboratory.* |  |
| *g.* | *Laboratory services for patients cared for in primary and community care should be provided by a laboratory in a conveniently located hospital laboratory where the community service provided in this location meets the needs of people cared for in the community. This approach supports integrated service delivery across patient journeys.* |  |
| *h.* | *Laboratory services for patients cared for in primary and community care should be provided by a laboratory service that is separate from the nearby hospital (for example from a Health Region laboratory) if the nearby hospital laboratory does meet the needs of the service, for example if it cannot achieve appropriate TATs.* |  |
| *i.* | *The HSE in consultation with General Practitioners should define a minimum test catalogue that should be available as routine service to all General Practitioners from the HSE or HSE funded laboratory service subject to provision of the required request details.* |  |
| **Section 4.1 – General Comment (Organisation – Services to support care in the community):**  |
| **4.2** | **Services to support care in the hospital** |
| *a.* | *Planning for service developments in the hospital should take account of the laboratory services required to support the development and how these will be accessed and delivered.* |  |
| *b.* | *The planning and delivery of laboratory services for patients in hospital should take account of the turn-around time required to meet clinical need in different contexts, for example ICU.* |  |
| *c.* | *The planning and delivery of laboratory services for patients in hospital should take account of the impact of the range of services and turn-around-time on patient flow through Emergency Departments and facilitation of patient transfer and discharge.* |  |
| *d.* | *The planning and delivery of laboratory services for patients in hospital should support hospital wide quality of care and patient safety programmes including medication safety and infection prevention and control.* |  |
| *e.* | *Laboratory services should address the needs of co-located mental health, maternity and paediatric services as well as general adult services.* |  |
| **Section 4.2 – General Comment (Organisation – Services to support care in the hospital):**  |
| **4.3** | **Services to support Clinical Programmes** |
| *The HSE has a growing number of national clinical programmes that provide for integrated care of patients. The planning of care by these national integrated programmes with regard to their use of clinical diagnostic laboratory services should ensure that the laboratory capacity to meet the demands of the integrated care service can be met.* |  |
| **Section 4.3 – General Comment (Organisation – Services to support Clinical Programmes):**  |
| 1. **Clinical Laboratories including Reference Laboratories**
 |
| *a.* | *Clinical laboratory services should normally be delivered as an integral part of the HSE. Outsourcing should be considered as an alternative only where the service is so specialised that delivery within the HSE is not reasonably practical or in a context where the required quality and turn-around-time cannot be met within the HSE at reasonable cost. In that case, the arrangements should address the need for resilience to manage risks related to dependence on a single laboratory. The requirement related to outsourcing as set out in the Haddington Road Agreement must be adhered to.* |  |
| *b.* | *The HSE Laboratory Services should be structured in three levels (1) hospital level, (2) Health Region level and (3) National level.* |  |
| **Section 5 – General Comment (Clinical Laboratories including Reference Laboratories):**  |
| **5.1** | **Hospital Level Laboratory Services** |
| *a.* | *A menu of laboratory services defined as core for that hospital in the context of the services provided at the hospital should normally be delivered by an on-site hospital level laboratory or near patient testing service. This is to support rapid turn-around time and to ensure that the core laboratory service team are integrated as partners in delivery of care. Other services should be delivered from a Health Region or national service if this meets clinical requirements in a cost-effective and sustainable manner.* |  |
| *b.* | *Efficient arrangements for exchange of information (electronic) and transport of samples between laboratories should be in place to achieve effective integrated function of hospital level, Health Region and National services as a network.* |  |
| *c.* | *Small scale hospital laboratory services providing services that must be provided at hospital level to achieve clinically acceptable turn-around time should be managed and governed as spokes of a laboratory service unit based on a larger hub laboratory service unit. The hub laboratory may be a larger hospital laboratory or the Health Region laboratory. (For this purpose, laboratories with about 50 staff or less are considered small scale).* |  |
| *d.* | *Centralisation of testing at national and regional level from hospital laboratories is appropriate where it supports the delivery of the quality and turn-around-time required with significant benefits in terms of efficiency and cost or reduced environmental impact.* |  |
| *e.* | *Centralisation of laboratory services at regional or national level from hospital laboratories should not compromise quality of preparation and processing of samples, discipline specific medical and scientific interpretation of results, the generation of an integrated report or the role of laboratory services and teams as an integral element of patient care.* |  |
| **Section 5.1 – General Comment (Hospital Level Laboratory Services):**  |
| **5.2** | **Health Region Laboratory Services** |
| *a.* | *Each Health Region should have an identified Medical (Consultant Pathologist) and Scientific (Laboratory Manager) Lead for laboratory services in the Health Region to coordinate the work of all the laboratory service units in the Health Region.* |  |
| *b.* | *Health Region laboratory service units should have robust systems for liaison with Regional Departments of Public Health to support use of laboratory data in surveillance of communicable and non-communicable disease.* |  |
| *c.* | *The Health Region will determine the number of sites at which each laboratory service should be delivered. This should take account of the advice of the Medical and Scientific leads regarding clinically required turn-around-time, the equipment and skill sets required to deliver the service, the volume of service required at each site and the cost-benefit associated with provision from one or a small number of sites.* |  |
| *d.* | *Health Regions should identify which laboratory services should be delivered at by a single regional service. This should be reviewed regularly to take account of changing needs and technology. Designated Health Region laboratory services should be funded and delivered at a regional level.* |  |
| *e.* | *Two or more Health Regions should engage with each other to provide specific laboratory services at a single site where this meets the clinical need in a cost efficient manner and where the service has not been designated for national service provision. In such cases, the Health Regions will agree on the mechanisms to share associated costs. This approach should facilitate the introduction of new technologies and minimise duplication.* |  |
| **Section 5.2 – General Comment (Health Region Laboratory Services):**  |
| **5.3** | **National Laboratory Services** |
| *a.* | *An integrated National Reference Laboratory Service (NRLS) should be established to manage and deliver specified laboratory services in all laboratory disciplines (not limited to infection) as an integrated national service for all HSE and HSE associated services.* |  |
| *b.* | *National Reference Laboratory services should encompass all laboratory disciplines and should provide clinical, technical and IT support for Health Region services, hospital laboratories and Public Health in addition to sample processing. The European Centre for Disease Prevention and Control (ECDC) has defined core functions for microbiology reference laboratories for communicable diseases. Many of those core functions are also applicable for reference laboratory services in other disciplines.* |  |
| *c.* | *The NRLS should be directed by a Consultant Pathologist working with a multidisciplinary medical and scientific team and reporting to the National Director of Public Health as an integral element of Public Health capacity for surveillance of all hazards, planning and emergency response.* |  |
| *d.* | *The NRLS should be funded and managed at a national level as an integrated service designed to meet the needs of the Health Protection and emergency planning and response functions.* |  |
| *e.* | *A multidisciplinary HSE Central Laboratory should be developed. This should be located to support road and rail and public transport links with all areas of the country and therefore is likely to be in the greater Dublin area.* |  |
| *f.* | *The HSE Central laboratory should provide a base for the National Reference Laboratory Service (above), for the National Genetics and Genomics services and other key national services. The HSE central laboratory should also accommodate other laboratory services in the East Coast area for example the Dublin Public Analyst Laboratory and laboratory services currently delivered from the Cherry Orchard campus. Some NRL services may be provided by agreement between the NRLS and one or more Health Region laboratories or Public Analyst Laboratory Services.* |  |
| *g.* | *In addition to confirmatory services for other laboratories, the HSE Central Laboratory should provide a hub for high throughput automated processing of certain sample types and of data to provide services and or surge capacity for Institutional and Regional Laboratories with processing of material and generation of data. This should include capacity to generate images for digital pathology and files of sequence data for further analysis.*  |  |
| *h.* | *The HSE Central Laboratory should work closely with other public service laboratories sharing expertise, technology and data within a “One Health” ethos. This should maximise the synergy and value of public sector service skills, equipment and data for surveillance, action, education, training and policy and leverage scale to achieve best value for money in procurement of services. This also maximises capacity to support Health Protection and emergency planning and response.* |  |
| *i.* | *Health Regions and hospital laboratories may provide national reference services if this is governed by a service level agreement with the HSE NRLS. Laboratories may not self-designate as national services.* |  |
| *j.* | *Laboratory services for delivery by the NRLS should be designated by the office of the CCO based on medical and scientific advice from the relevant National Clinical Programmes and other clinical strategies/programmes such as the National Cancer Clinical Programme and the National Women’s and Infant’s Programme. This should be reviewed regularly to take account of changing needs and technology.* |  |
| *k.* | *In general, laboratory services should be considered suitable for delivery by the NRLS if the clinically required turn-around-time can be met adequately by central service provision and (1) the delivery of the service requires specialised equipment or skill sets that need not be duplicated (2) the total volume of service required at Health Region level is low to moderate (3) there is a significant quality or cost benefit associated with centralised provision.* |  |
| *l.* | *Specialised services required from other jurisdictions should be organised and procured at national level with access through the national laboratory services. With roll out of the Individual Health Identifier number, this will help minimise redundancy in testing and with appropriate IT and logistics this should not compromise turn-around-times.* |  |
| *m.* | *Under governance of the Director of the NRLS, the HSE NRLS and Health Region Laboratories will collaborate to maintain plans, skills and capacity to provide an integrated response and to scale up services in the event of a public health emergency.* |  |
| **Section 5.3 – General Comment (National Laboratory Services):**  |
| 1. **Non Clinical HSE Laboratories and Non HSE Public Laboratories**
 |
| *a.* | *In keeping with the report “HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology and Virology Reference Laboratories Review” of February 2022 unified governance should be provided for these services as soon as is practical. In the context of this strategy, the governance for that integrated service should be expanded to include the Public Analyst Laboratories. This will provide a nidus for development of the comprehensive National Laboratory Service recommended in this strategy.* |  |
| *b.* | *The integrated National Public Analyst Laboratory service including the Official Food and Water Microbiology services should be managed by a National Lead Public Analyst at Assistant National Director Level.* |  |
| *c.* | *Over the 5 years of this strategy the food and water microbiology laboratory service should be incrementally consolidated to three sites associated with the three public analyst laboratories in Dublin, Cork and Galway by the unified governance group referred to in 5a. Environmental testing (water, air and surfaces) required for monitoring in HSE healthcare facilities should be included in the remit of these laboratories with agreed context specific turnaround times.* |  |
| *d.* | *The food and water microbiology laboratory service and PAS laboratory service should liaise closely with relevant hospital and clinical services regarding laboratory services required for monitoring the environment (for example water, clean rooms, air) in HSE healthcare facilities.* |  |
| *e.* | *With respect to laboratory services not managed as a National service (for example testing of hospital water samples from washer-disinfector units), each site providing non-clinical analytical services should provide services for the Health Region in which they are based and one other adjoining Health Region. Health Regions will agree on the mechanisms to share associated costs.* |  |
| *f.* | *Non-clinical analytical services should be delivered at a single site where this has significant practical or cost benefits. Health Regions will agree on the mechanisms to share associated costs.* |  |
| *g.* | *HSE should work with other state funded laboratory services related to testing of human samples (for example the State Laboratory, Toxicology Laboratory) to ensure that services support each other and minimise duplication of service provision and embed a “One-Health” approach in their work.* |  |
| **Section 6 – General Comment (Non Clinical HSE Laboratories and Non HSE Public Laboratories):**  |
| 1. **Infrastructure**
 |
| *a.* | *Hospital Laboratories should be based in secure permanent building that are designed and built with flexibility to facilitate install and operate high throughput automated systems and multidisciplinary working of teams. The building should address needs for security, rest and refreshment for staff working unsocial hours.* |  |
| *b.* | *Hospital Laboratories should include a space within the laboratory proper or in the adjoining hospital where tests related to different disciplines can be provided as “stat-lab” services in particular out of hours. This will support team based delivery of critical services required on a 24/7 basis and will reduce personal security concerns associated people working alone for extended periods in isolated facilities overnight and at weekends.* |  |
| *c.* | *Design of new or refurbished buildings for delivery of patient care services, in particular Emergency Departments and Critical Care Units should take account of the potential of near patient testing/“stat-lab”.* |  |
| *d.* | *The HSE should develop at least one Health Region Laboratory in each of six Health Regions to provide those services that are designated by the Health Regions for provision at regional level. The Health Region Laboratories should be designed with surge capacity and ease of expansion to support the HSE Central Laboratory in response to a public health emergency.* |  |
| *e.* | *The HSE Health Region Laboratories should be co-located with a hospital site to preserve a clinical ethos and partnership in-patient care.* |  |
| *f.* | *The HSE Health Region Laboratories should be developed at locations that facilitate access for materials, supplies and deliveries and ease of access for visiting healthcare workers from other HSE services.* |  |
| *g.* | *The HSE Central Laboratory and Health Region Laboratories should include facilities for collection of blood and other readily collected clinical samples so that sample collection services for patients may be provided as appropriate.* |  |
| *h.* | *Public Analyst Laboratory infrastructure should be developed or extended as required to accommodate the broader service remit outlined in this strategy.* |  |
| *i.* | *The multidisciplinary HSE Central Laboratory should be co-located with a hospital service to maintain a clinical ethos and to support ongoing clinical engagement of and continuing education for staff working in the Central Laboratory.* |  |
| *j.* | *The HSE Central Laboratory should be designed to provide capacity to redeploy space and expand footprint rapidly in the event of a public health emergency.* |  |
| *k.* | *The HSE Central Laboratory should be designed to facilitate security, secure communication and autonomous function for an extended period in the event of a public health emergency or conflict.* |  |
| *l.* | *The HSE Central Laboratory should accommodate NRLS other than any that may be agreed for delivery under SLA by Health Regions* |  |
| **Section 7 – General Comment (Infrastructure):**  |
| 1. **Information Communication Technology for safe and efficient laboratory service delivery**
 |
| *a.* | *All enhancements and changes to the digital environment within which laboratories operate should be carefully planned to ensure security and continuity of services.* |  |
| *b.* | *Rollout of the national laboratory information system for clinical laboratories should proceed to all HSE laboratories. This should be achieved in three to five years depending on resource allocations.* |  |
| *c.* | *Pending the full implementation of the national laboratory information system, laboratory information systems in Health Regions, should continue incremental progress. Where order communications technology is not present early rollout of the national system should be considered.* |  |
| *d.* | *During the roll out period, any systems deployed in laboratories as interim measures, should be interoperable with the national laboratory information system to achieve the goals of access to patient results wherever the patient attends for care and use of laboratory generated data for health surveillance, planning and management including crisis response.* |  |
| *e.* | *The HSE will be deploying Electronic Health Care Records (EHR) in the future. Laboratory diagnostics should be integrated within the EHR for a patient. The EHR for a single patient has diagnostics from multiple laboratory services across disciplines, laboratory sites (both national and international) and over time. These all contribute to the patient’s longitudinal record, which enables clinicians to assess and optimally manage care.* |  |
| **Section 8 – General Comment (Information Communication Technology for safe and efficient laboratory service delivery):** |
| 1. **Information Governance**
 |
| *a.* | *Information governance should be strengthened to ensure secure seamless sharing of patient laboratory records between healthcare service providers in Ireland. Duty of Care is Duty to Share is the underlying principle and appropriate mechanisms to deliver on this principle should be established so that the laboratory records can be readily accessible to the patient’s chosen healthcare provider.* |  |
| *b.* | *Information governance arrangements should be established to ensure non-patient identifying laboratory information is efficiently shared between HSE and HSE funded healthcare service providers and with Irish or EU public health agencies to support surveillance and policy development.* |  |

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| **Section 9 – General Comment (Information Governance):**  |
| 1. **Automation and New Technologies**
 |
| *a.* | *Automation offers potential to release the existing highly qualified scientific staff from repetitive manual tasks allowing them to deploy and expand their skills to practice at the top of their licence.* |  |
| *b.* | *Automation of all stages of sample preparation and processing should be enhanced in all disciplines facilitated by developments in infrastructure, robotics and IT.* |  |
| *c.* | *The opportunities to enhance automation of processes afforded by the use of digital pathology and artificial intelligence should be developed.* |  |
| *d.* | *Managed service contracts for facilities and equipment have practical advantages and should be used as appropriate* |  |
| *e.* | *Opportunities to improve patient services and reduce cost through automated systems should not be constrained by traditional laboratory discipline boundaries.* |  |

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| **Section 10 - General Comment (Automation and New Technologies):**  |
| 1. **Staffing**
 |
| *a.* | *Consultant Pathologists and appropriately qualified scientists in each discipline should function as part of sub-regional or regional teams as appropriate to support the service. This should provide more equitable access to expertise, more resilient service to patients and more equitable and sustainable rotas for out of hours work. With appropriate IT and harmonisation of practice multi-site team service should not require frequent travel between sites.* |  |
| *b.* | *The productivity of existing Consultant Pathologists and Specialist Registrars should be maximised by reassignment of tasks as appropriate. International experience has examples of success of enhancing skill of non-medical staff to take on tasks in sample processing, interpretation and reporting traditionally limited to medical staff. This aligns with general measures to review productivity across healthcare.* |  |
| *c.* | *There should be equity of access to training and pathways for advancement for all scientists working in the laboratories. This should be supported by consolidating staff training structures and career pathways, grades and pay scales into one professional cadre/scale with differentiated levels that are applied consistently across the HSE and HSE funded services to reflect the skills, role and responsibility associated with the position.* |  |
| *d.* | *At entry level scientific staff recruitment should include a mix of Medical Scientists (multidisciplinary training) and laboratory scientists (including but not limited to Biochemists) graduating from others honours level courses relevant to specific disciplines such as bioinformatics, clinical biochemistry, epidemiology, haematology, histopathology, immunology, microbiology, molecular biology and transfusion science.* |  |
| *e.* | *Advancement from entry level Medical Scientist/ Biochemist/Scientist to senior grades should, as at present, require a higher degree and specified experience and be based on a competitive process.* |  |
| *f.* | *Advancement from senior grades to higher grades should be provided for Medical Scientists/Biochemists/Scientists in all laboratory disciplines and should be based on three pathways clinical, scientific and management (see section 12).* |  |
| *g.* | *Advancement along the chosen pathway should be supported with competitive access to structured defined numbered temporary rotating training posts (similar to the model for basic and higher specialist training in medicine) with support for training programmes and costs.* |  |
| *h.* | *The HSE should define an expanded range of tasks that may be performed by Laboratory Aide staff subject to demonstrated competence. As at present, these post should not require an honours science degree in a relevant discipline for entry. This should assist in ensuring that the available Medical Scientists/Biochemists/Scientists can focus on tasks that require their existing skills and provide opportunities to develop new skills.* |  |
| *i.* | *With the exception of final review and authorisation, the range of task potentially assigned to Laboratory Aides (pre-processing and processing) should only be restricted by the requirement that they have demonstrated competency in accordance with EN ISO 15189 and that there is appropriate scientific or medical supervision of their work.* |  |
| *j.* | *Career progression for Laboratory Aides should be facilitated by competitive access to defined numbered training posts that support them in acquiring the qualifications that make them eligible to compete for entry to Scientist grade posts.* |  |
| *k.* | *HSE Laboratory services should develop a cadre of Engineers, Information Technologists and Administrative Support staff specialising in the optimal costing and delivery of laboratory services and working within the laboratory governance system to support the efficient operation and maintenance of the Central and Health Region Laboratories.* |  |
| *l.* | *HSE laboratory services should recruit and retain a sufficient cadre of permanent phlebotomy staff to provide the core service over an extended working day and weekends and to ensure supervision of temporary staff recruited to support the service.* |  |
| *m.* | *All HSE laboratory staff (medical, scientific and laboratory aide) working in a service that delivers an out of hours service should be required, as appropriate to the needs of the service and their competence, to contribute to the out of hours service as a matter of obligation. To ensure that the full range of essential services required is available 24/7 adequately staffed shifts should be established on a similar basis to other healthcare workers who provide essential 24/7 services.* |  |
| *n.* | *The staffing structures in Public Analyst Laboratories that are currently in place remains generally fit for purpose in the context of the broader remit of the PALs outline in this strategy.* |  |
| *o.* | *Public Health Food and Water Microbiology Laboratories should primarily recruit technical staff with education and skills that prepare them to work in food and water microbiology rather than Medical Scientists or other Scientists with education and skills that prepare them for work in Clinical Laboratory services.* |  |
| *p.* | *Opportunities for training and development should be provided for staff of Public Analyst Laboratories and Food and Water Microbiology Laboratories similar to those provided for laboratory staff in clinical laboratories.* |  |
| **Section 11 - General Comment (Staffing):**  |
| 1. **Education and Training**
 |
| *a.* | *HSE laboratories should maintain and develop partnerships with third level institutions and professional bodies to support undergraduate and post graduate education and training through contributions to the teaching programme and student placements.* |  |
| *b.* | *The existing training structures and career pathways for Medical Staff are broadly appropriate but must be scaled to meet the anticipated demands of the service for Consultant Pathologist appointments.* |  |
| *c.* | *Expanded opportunities for training to advanced practice for scientists within the HSE laboratory services should be provided consistent with the Health and Social Care Professions Advanced Practice Framework 2023. The opportunity to progress to autonomous practice, currently limited to Biochemists, should be available to all scientific disciplines. Scientists at this level will have gained competence to engage in unsupervised clinical scientific practice including independent scientific direction of laboratory services where this meets the requirements of the service.* |  |
| *d.* | *The scientific training programmes for scientists in clinical laboratories and technical staff in non-clinical laboratories (Food and Water and Public Analyst) should make full use of EU funded training opportunities and should support training to doctorate level in specific scientific and data analysis skills relevant to the development and delivery of laboratory services.* |  |
| *e.* | *The managerial training programmes for scientists in clinical laboratories and for technical staff in non-clinical laboratories should provide training including relevant qualification in health services management.* |  |
| *f.* | *Participation in educational activities with partner institutions should be recognised as a part of the work of all laboratory staff. Staff should have protected time to participate in these activities assigned to them.* |  |
| *g.* | *Given the importance of life-long learning, continued professional education is essential and should be supported for all laboratory staff.* |  |
| *h.* | *Education and training should be provided to support all staff in developing the Irish language skills required to support compliance with the requirements Official Languages Act 2023.* |  |
| *i.* | *As part of their diagnostic stewardship laboratory services should provide ongoing education and training and tools to support laboratory service users to make appropriate use of laboratory services and to support communication on these issues with patients.* |  |
| **Section 12 – General Comment (Education and Training):**  |
| 1. **Research, Innovation, Development and Audit**
 |
| *a.* | *Research, innovation, development and audit should be considered an integral part of HSE laboratory service delivery as essential to support improvement of service.* |  |
| *b.* | *All staff should be supported to participate in research, innovation development and audit as part of their work* |  |
| *c.* | *HSE laboratories should develop partnerships with third level institutes, regulators and industry to support research, innovation and development.* |  |
| *d.* | *With appropriate consent and controls, the HSE central and regional laboratories should develop and maintain a bank of material (biobank) for use in research and development* |  |
| 1. **Financing of Laboratory Services**
 |
| *a.* | *HSE laboratory services should be financed by a laboratory services revenue budget clearly defined within the overall institution /governance unit that hosts the laboratory service unit. In most cases, the host institution will be a hospital or a group of hospitals that function as a laboratory service unit within a Health Region. The revenue budget should cover human resources, laboratory supplies, cost per unit managed service contracts and other laboratory specific services. This will support greater transparency in relation to costs of provision of laboratory services and ensure that service demand is managed within a defined resource.* |  |
| *b.* | *HSE laboratory service units should have defined capital funding for acquisition of laboratory equipment based on the laboratory service priorities. This will support greater transparency in relation to costs of provision of laboratory services and ensure that service demand is managed within a defined resource.* |  |
| *c.* | *Reimbursement on a fee for service model of diagnostic laboratory should not generally be adopted, as it tends to incentivise overuse of testing, undermine diagnostic stewardship, to and to detract from the view of laboratory services as partners in care as distinct from simply test providers.* |  |
| *d.* | *All new service developments proposed by the laboratory service unit or other clinical services should include a defined financial provision for each Health Region and laboratory service unit supporting the new service that becomes part of the budget for the laboratory providing that service. This should address revenue and capital funding requirements.* |  |
| *e.* | *HSE laboratories should not seek to fund their operation by competing with private providers to provide diagnostic laboratory services to actors external to HSE and HSE affiliated services.* |  |
| *f.* | *HSE laboratories should provide diagnostic or analytical services to private healthcare providers on request in particular where they can offer specific services that are not otherwise readily accessible. The private provided should cover the full cost of the service with fees generated should be used to support the laboratory service.* |  |
| *g.* | *HSE laboratories should provide diagnostic services to other Health Regions in particular where they can offer specific services that are not otherwise readily accessible. The Health Regions should agree a mechanism to ensure that funding follows the service provision.* |  |
| *h.* | *HSE laboratories that are designated and funded as national reference laboratory service providers should not charge fees to for the reference laboratory services they are have been designated to provide. Fee per service for reference laboratory services deters laboratories from submitting samples to reference laboratories and therefore undermines the public health function of reference laboratories.* |  |
| *i.* | *Agreements for service provision from private laboratory providers should be coordinated at Health Region or National level to manage costs by ensuring that alternative provision from other HSE laboratories is explored and that the HSE fully uses the volume of service it procures to leverage best value for money.* |  |
| **Section 14 - General Comment (Financing of Laboratory Services):**  |
| **Any additional feedback relevant to the recommendations & principles outlined in the Laboratory Strategy Document may be included here:** |
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