MLSA SUBMISSION TO CORU SEPTEMBER 2018

Consultation on Medical Scientists' Registration Board Draft Bye Laws

- Code of Professional Conduct and Ethics Draft Bye-Law
- Return to Practice Draft Bye-Law
- Application for Registration Draft Bye-Law
- Restoration to the Register following Removal By Request Draft Bye-Law
- Restoration to the Register following Cancellation of Registration Draft Bye-Law

MLSA Submission to CORU Medical Scientists' Registration Board

September 2018

The Medical Laboratory Scientists Association is the sole trade union representing over 1500 Medical Scientists in Ireland who provide laboratory services to Health Service Executive and Public Voluntary Hospitals, Private Hospitals and laboratories, the Irish Blood Transfusion Service and Universities in Ireland. This submission was prepared on behalf of the MLSA Executive Committee in response to CORU's public consultation in August-September 2018 on five draft documents from the Medical Scientists' Registration Board.

Participants were asked to comment on the draft documents by answering several questions in an online survey format. The MLSA completed the online survey and this separate submission is a more easily readable format of the answers submitted online. The MLSA submission should be read in conjunction with the draft documents referred to and the specific questions asked in the online survey. The survey questions to which the MLSA commented are reproduced in dark blue text below, followed by the comments and observations submitted.

The consultation related to the following documents of the Medical Scientists' Registration Board:

- Code of Professional Conduct and Ethics Draft Bye-Law
- Return to Practice Draft Bye-Law
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Code of Professional Conduct and Ethics Draft Bye-Law

5. Are there any specific responsibilities which relate to your profession in the areas of conduct, performance or ethics, which have not been captured by this Code? Please provide comments below.

Use of the term "service user" in a laboratory context

This is a general observation about the document terminology but is made with particular reference to the following points of the Code:

- 2.1.d obtain the consent of a service user before discussing confidential information….
- 9.d Transfer any records relating to the service user….
- 11.a take personal responsibility for obtaining consent from the service user…
- 14.1 ensure that if a service user suffers an adverse event…….
- 18.g understand that service users generally have a right to obtain copies of their records…..

The document uses the term "service user" throughout. For most health care professionals, this term would normally refer to the patient but in laboratory standard operating procedures it has commonly been used to refer to the clinicians who refer specimens for testing because they are the users with whom the medical scientist interacts. The terminology of "service user" and references to managing the health and wellbeing of the service user, obtaining consent from the service user,

transferring records to the service user and informing the service user of an adverse event may therefore confuse the issue.

Most medical scientists have little direct contact with patients and usually rely on requesting clinicians and laboratory consultants to liaise between laboratory and patient on these matters. Medical scientists do not receive training or supervised practice in patient interaction or taking notes on such interactions. The healthcare professional taking the specimen is responsible for obtaining consent, except for a small number of investigations for which the laboratory might require explicit written consent from the patient. Patients requesting laboratory results are usually referred to their treating clinicians so that results can be explained and interpreted for them by a clinician. Laboratory quality management systems require laboratories to record and report all incidents that adversely affect patients, but this disclosure is again usually made to the requesting clinician rather than the patient.

Medical scientists must keep the interests of patient service users at the centre of their work and act in their best interests but how this is done in the laboratory context may differ from services involving direct patient contact.

CONDUCT

Point 2: Respect the confidentiality and privacy of service users

2.2.c: Inform the service user of the disclosure of confidential information (as required by law)

As an example of where the lack of direct contact between the medical scientist and the patient service user could leave the medical scientist in conflict with the proposed code, medical scientists are involved in the mandatory reporting of notifiable diseases to the Health Protection Surveillance Centre (HPSC). This is a statutory requirement in the interests of public health and is done on behalf of the clinical director of the laboratory. It is not feasible for medical scientists to notify each patient of this disclosure; nor does it seem necessary because the treating clinician also has a duty to report to the HPSC and should notify the patient of this requirement when communicating the result to the patient.

Point 5: Comply with obligations regarding registration

5.a Inform the Registration Board within 7 days if your employer or other body has suspended you or placed restrictions on your practice because of concerns about your conduct or competence.

Due to pressures on multi-disciplinary out of hours rosters nationwide, many medical scientists are required by management to work out of hours in disciplines other than their routine work. The level of training required to maintain competence is significant and many laboratories are struggling to maintain multi-disciplinary training and retraining, yet the staff are required to maintain the service. Sometimes non-conformances occur out of hours in such situations and participation in out of hours provision may be suspended until retraining and competency of the individual can be confirmed. In such a case, where the individual is working out of hours in a discipline different from their routine job, the incident in question would not be any reflection on the individual's competency in his/her

routine work. It does not seem fair in such a situation that the medical scientist should have to report to the Registration Board and feel that their entire professional competency is under question.

5.e: Include your CORU registration number in all certificates, reports or other formal documents"

The reports and formal documents for which a medical scientist is most likely to be responsible are computer generated laboratory results and laboratory quality management system documents. It will be difficult and of questionable relevance to include a CORU registration number on either. Many current laboratory information management systems cannot support this requirement. It may be possible with the new MEDLIS system but that remains a distant prospect for most laboratories and any such requirement would need to be agreed in advance with the system provider, Cerner, to be included in the nationally agreed specifications.

PERFORMANCE

Point 9: Act within the limits of your knowledge, skills, competence and experience

9.b: Practise only in areas in which you have relevant knowledge, skills, competence, experience or are appropriately supervised.

Due to pressures on multi-disciplinary out of hours rosters nationwide, many medical scientists are currently required by management to work out of hours in disciplines other than their routine work. The level of training required to maintain competence is significant and many laboratories are struggling to maintain multi-disciplinary training and retraining, yet the staff are required to maintain the service.

Point 10: Keep your professional knowledge and skills up to date

10.1.b Participate in continuing professional development (CPD) on an ongoing basis

Unlike our medical and nursing colleagues, medical scientists to not currently have access to dedicated training budgets or protected time to engage in CPD. Despite a specific provision for medical scientists that the additional hours provided for by the Haddington Road Agreement in 2013 were to be used in part at least for CPD, in most laboratories these hours have been applied solely to cover an extended working day (8am to 8pm) with none allocated for CPD. Medical scientists also struggle to be released and funded for training courses and workshops that they need to undertake to perform their existing roles. Due to the relatively small numbers involved in the profession, there is limited availability of such training courses and participants may need to travel to Dublin or the UK to avail of them. The public service has detailed travel and subsistence expense arrangements in place, but many medical scientists are denied these provisions to attend courses. All aspects of this situation will need to change substantially for medical scientists to fulfil mandatory CPD requirements.

Point 17 Supervise tasks that you delegate to others

17.1.b You must only delegate to a person who you believe to have the knowledge, skills, competence and experience to carry out the task safely and effectively or to a person who is appropriately supervised

17.2 You must not ask anyone to do anything which is outside their knowledge, skills, competence, and experience unless they are supervised in that task by an experienced practitioner.

Laboratories have procedures for the transmission of urgent results to clinicians that have been agreed by the clinical director of the laboratory and notified to clinical service users. Often the requesting or treating clinician may not be directly available and results must be notified to an inexperienced intern doctor, a ward nurse or a general practitioner's clerical staff, who may have little understanding of the result or its significance. In such cases, it must be clearly understood that it is the clinician and not the medical scientist who has delegated the task. The medical scientist cannot be responsible for the competence of the person who has been delegated by the clinician to accept the results on their behalf.

This proviso also applies where clinicians delegate their clerical staff to contact the laboratory seeking verbal reports of complex laboratory results.

Point 18: Keep accurate records

18.b.iii "identifiable as being made by you, using your registered name and registration number"

For this to be feasible, laboratory information management systems (LIMS) will need the capacity to record this information. Systems will be required for recording all of this information in the ongoing manual workup of individual samples over several days, potentially by several medical scientists, particularly in disciplines like Microbiology and Histopathology. Current laboratory LIMS cannot support this requirement. Many systems have an audit trail that records who enters each piece of data, using individual login details, but does not record full names or registration numbers. If such a feature is possible with the new MEDLIS system, any such requirement would need to be agreed in advance with the system provider, Cerner, to be included in the nationally agreed specifications. However, addition of such detailed information at every step of a multi-step recording process is likely to overcomplicate the notes, with possible unintended effects on clarity of the record, follow-up testing and ultimately patient safety.

18.g Understand that service users generally have a right to obtain copies of their records, subject to certain limited exceptions.

Notwithstanding patients' rights to access their own medical records, patients requesting laboratory results are usually referred to their treating clinicians so that results can be explained and interpreted by a clinician. Subject access requests are the responsibility of the data protection officer or laboratory manager and not the individual medical scientist.

19. Address health safety and welfare risks

19.b Take any steps necessary to minimise, reduce or eliminate the risk you identify.

This assumes that the individual has the authority and resources to do this. Medical scientists have a duty to report such risks and to try to mitigate them, but some necessary mitigation measures may be outside of their control, in particular measures that require financial resources. As an example relating to exposure to chemical agents, the MLSA knows of medial scientists who have reported levels of hazardous chemicals exceeding maximum occupational exposure limits but have been directed by management to continue to work in these conditions to ensure continued provision of service on site rather than transferring the work to a safe facility.

Point 20. Raise concerns about safety and quality of care

20.b inform an appropriate person or authority if you are aware of systems or structures that lead to unsafe practices which put service users, yourself or others at risk.

The MLSA suggests that the appropriate person to report to in this instance is the medical

scientist's immediate line manager. If the registration board requires the registrant to go beyond this normal governance arrangement, it should specify the relevant appropriate authority.

20.c. Raise the issue outside of the organisation if your concerns are not resolved despite reporting them to an appropriate person or authority.

20.d. report any serious breaches of behaviour or malpractice by yourself or others.

To comply with this, medical scientists will require clear guidelines on who such matters should be reported to.

Point 21. Maintain adequate professional indemnity insurance

As employees of the laboratory rather than independent contractors, medical scientists are currently covered by the indemnity insurance of their employers.

Appendix A

Suggested procedure for decision making

I. Remember that you are accountable, as an autonomous practitioner, for the consequences of the solution or decision that you choose.

Medical scientists are highly trained professionals who must be accountable for their actions; however, but it must also be recognised that they operate within a quality management system where all deviations from standard procedures must be documented. Most medial scientists are not authorised to implement improvements or changes to these procedures unless they are collectively agreed and approved.

Return to Practice Draft Bye Law 2018

5. Is the language used and the layout of the draft bye-law easy to follow and understand?

Yes

6. An applicant who has not practised the profession for any period between 2 and 5 years must complete a period of updating consisting of not less than 210 contact hours. Do you consider this to be appropriate?

The MLSA understands that this is the standard requirement that has been set by all CORU registration boards but believes that it is a heavy requirement for a mainly female profession where many registrants may take career breaks for family reasons. The MLSA already has serious concerns about the level of resources available in laboratories for staff training and believes that this additional requirement will have to be appropriately resourced and planned, especially in a time where there is a recruitment and retention problem and when the profession needs to encourage such people to return to the workforce and to remove barriers to returning to work. The requirements will be more easily fulfilled by medical scientists on career breaks who still retain permanent posts because their employers will also have responsibility for their return to practice. It is not clear how an applicant who does not hold a permanent post will find a laboratory willing to support their supervised practice requirement. This would be particularly difficult for HSE hospitals whose vacant posts are filled by National Recruitment Service (NRS) panels that may cover several laboratories. The MLSA understands that applicants for NRS posts will be required to be on the register before they apply for these panels. A laboratory that wants to support their return to practice in order to employ them will have no incentive to do so if a panel already exists from which vacancies will be filled or if the applicant is more likely to be employed elsewhere once registered.

The draft bye-law also states that *"the applicant must have completed his or her period of updating within the two year period prior to the date of submission of his or her application, unless the Board permits otherwise."* Given that the amount of supervised practice currently proposed will be difficult for an applicant to arrange and once organised will take at least 4 weeks to complete, this severely reduces the two year period that an applicant can be out of practice or off the register for any reason before the more onerous >2year return to practice requirements apply. The MLSA proposes that as long as the applicant applies to return to practice within two years, any supervised practice or formal study element could be completed beyond the two-year period.

7. An applicant who has not practised the profession for any period greater than 5 years must complete a period of updating consisting of not less than 420 contact hours. Do you consider this to be appropriate?

See response to question 6.

8. Do you consider that the composition of the period of updating with regard to supervised practice, formal study and private study as set out in section 4(4) is appropriate?

No. The MLSA notes that the level of supervised practice proposed by the registration board far exceeds the level set out by other CORU registration boards. It is not clear how the individual registrant could satisfy this requirement within current laboratory structures; nor is it clear how laboratories are to support this requirement given that they struggle already with the training of existing staff and medical scientist students. The MLSA would also be concerned that any return to practice training programme would need to be developed and applied in a standardised manner, for the protection of the public and of the applicant.

The level of resources required to keep staff trained and competent to provide a 24/7 service has never been properly assessed or budgeted for. Laboratories have embraced quality management systems and the demands on and complexities of out of hours services grow year on year, which adds to the training required to maintain the competency of existing staff. Several hospital laboratories have withdrawn from offering student training places due to the resources required to provide that training. It is unclear how a further supervised return to practice training requirement could be supported in these circumstances.

The bye law requires that each applicant must have a designated supervisor who will satisfy himself or herself that the applicant has completed the requisite period of updating and sign off the Return to Practice form. The only requirement stated in the bye law is that the supervisor should be a registered medical scientist in practice for a minimum of three years and not subject to any disciplinary sanction under the Act. This is a big responsibility for an individual to take on, yet there is no requirement on what training they should receive for the role, what recognition they should receive for undertaking it or what their legal responsibility is.

9. Do you agree with the criteria for supervised practice contained in Section 5 of the draft bye-law?

No. The MLSA considers that the requirement for 60% of the required contact hours to be supervised practice is unreasonable and is far too onerous on registrants and on individual laboratories. 60% of 210 hours amounts to 126 hours or the equivalent of 3.4 standard working weeks; 60% of 420 hours is 252 hours or almost 8 standard working weeks of attendance by the registrant and of supervision by the staff of the laboratory.

It is also unclear what is meant in this context by "supervised practice". Applicants will not be registered at this point and therefore will not be able to practise as medical scientists and it is unclear what exactly they will be legally able to do. Presumably, they will be unable to make any independent clinical decisions, which limits how much they can do, particularly in more manual aspects of laboratory work. In addition to this training, as is currently the case, once applicants meet the criteria for registration and can be employed as medical scientists, they will still require many weeks or months of further training and supervision before they are competent to practise independently and contribute fully to laboratory staffing. All practising medical scientists are also

continuously monitored and reviewed in their practice by a complex system of internal and external quality control, audit, review and non- conformance reporting that is set out by the laboratory quality management system.

In comparison with the proposed criteria for medical scientists, the current return to practice requirements for opticians do not specify any supervised practice element and the proportions set for other professions ranges from 33.3% to 50%. Many of these healthcare professionals will be operating independently in direct patient contact from a very early stage of their employment, unsupported by the systems of checks and balances that are available to monitor the competence of medical scientists, yet they are deemed to require less supervised practice training than medical scientists.

10. Do you agree with the criteria for formal study contained in Section 6 of the draft bye-law?

The MLSA would have concerns about the availability of and access to the type of courses described in the document in Ireland, especially for some of the more specialised areas of laboratory medicine and any recent developments in practice with which the applicant may be unfamiliar. The issue of the cost of such formal courses could also be a barrier to return to work for applicants without an income at the time of application. It is unclear how and by whom such courses would be provided or what the process would be to deem a course or group learning activity suitable.

11. Do you agree with the criteria for private study contained in Section 7 of the draft bye-law?

The MLSA believes that private study should be eligible to count for considerably more than 10% - ideally 50% - of the contact hours requirement and that this is how applicants are most likely to be able to learn about new developments since they left practice. Due to training and work pressures on laboratories, applicants will be left to their own devices for large parts of the supposed "supervised practice" and sent to the library to read exactly the same materials they could have sourced at home independently. A recommended reading list drawn up by the Registration Board and updated regularly would be of great value in assisting applicants to update their professional knowledge.

12. Is there anything you believe should be added to this bye-law?

The MLSA believes that the bye law should address the resources required by laboratories to support the return to practice requirements of applicants because current laboratory training resources are already inadequate. The level of supervision by an appointed supervisor for this process, in addition to the stringent requirements already laid down for supervision of student contact hours, means that such supervisors / training officers are unlikely to have much time for routine laboratories duties while involved in this important role.

13. Is there anything you believe should be removed from this bye-law?

No

14. Do you have any other comments on the draft bye-law?

In considering the level of supervision, training and monitoring of all medical scientists on commencing in a post, the limited availability of formal study options especially in recent laboratory medicine developments and the suitability of private study for updating applicants on such developments, the MLSA believes that the optimum proportions for contact hours should be as follows:

Supervised practice: 25%

Formal study: 25%

Private study: 50%

The MLSA also believes that the return to practice requirements combined with the stringent student training requirements may require the appointment of fulltime training officers in larger laboratories and at the very least guaranteed protected time for training officers in all laboratories engaged in these processes.

Application for Registration Draft Bye Law 2018

7. Is there anything that you consider should be amended in this bye-law?

The bye law stipulates that the applicant "shall comply with such requirements of the Board in respect of education, training and continuous professional development as may apply from time to time". The bye law should make it clear whether the applicant will be required to show CPD activity in advance of registering or whether a commitment to participate in ongoing CPD after registration be sufficient to allow the applicant to register.

8. Is there anything you believe should be added to this bye-law?

The MLSA is concerned that the applicants will be required to submit sensitive information including their PPSN number. The registration board should explain the purpose of collecting this information, how will it be used and the data protection policies and security arrangements regarding the maintenance of the register.

Restoration to the Register following Removal on Request Draft Bye Law 2018

8. A person must make a new application for registration if they want to return to the Register:

- More that two years after the date of voluntary removal

OR

- More than 6 months after the annual renewal date where they have been removed from the register for failure to pay the annual fee

Please provide any comments that you have:

The MLSA is unclear which bye-law applies to applicants whose registration expired due to non-payment of fees. The survey questions for the *Removal on Request Bye-Law* cover this instance but the bye law itself makes no reference to removal for non-payment. If this is the case, that circumstance should be specifically referred to in the document so that registrants clearly understand their responsibility to retain their registration and the possible consequences of not doing so.

9. Please provide any additional comments on the draft bye-law here:

The bye law stipulates that the applicant "shall comply with such requirements of the Board in respect of education, training and continuous professional development as may apply from time to time". The bye law should make it clear whether the applicant will be required to show CPD activity in advance of registering or whether a commitment to participate in ongoing CPD after registration be sufficient to allow the applicant to register.

Restoration to the Register following Cancellation of Registration Draft Bye Law 2018

6. Under part 3 (subsection (4)), the criteria which the Council uses when considering whether an applicant should be restored to the register are set out. If you think that some criteria should be amended, added or removed please provide details below.

The bye law stipulates that the applicant "shall comply with such requirements of the Board in respect of education, training and continuous professional development as may apply from time to time". The bye law should make it clear whether the applicant will be required to show CPD activity in advance of registering or whether a commitment to participate in ongoing CPD after registration be sufficient to allow the applicant to register.