

CervicalCheck Scoping Inquiry – Supplementary Analysis and Report

Terms of Reference

Further to the issues reported on by the Scoping Inquiry;

- A. Examine further the facts and details of:
- i) The additional laboratories involved in CervicalCheck work which came to light during the work of the Scoping Inquiry – their nature, ownership, extent of activity, quality and accreditation arrangements, governance structures, and other relevant matters;
 - ii) The circumstances which led to these laboratories undertaking work for CervicalCheck;
 - iii) The extent to which CervicalCheck / the NSS / the HSE were aware of, and approved, workload being transferred to other sites;
 - iv) The effectiveness and operation of procurement and contracting of laboratory-based cervical cytology services;
 - v) The use of Schedule 13 of the 2010 contract under the heading ‘Storage and Disaster Recovery Plan’;
 - vi) The respective and comparative merits and limitations of the standards achieved by each of the laboratories, and whether there is equivalence between the standards reached and ISO 15189;
 - vii) The intent and understanding of parties to the laboratory contracts in respect of ISO 15189.
- B. Incorporate further relevant elements if identified during the the course of the supplementary analysis.
- C. Consider the implications of the above issues for quality and safety.
- D. Report to the Minister of Health on the matters above and making recommendations to address the issues arising.