EUREF REQUIREMENTS FOR BREAST SCREENING AND DIAGNOSTIC UNITS

1 Executive Summary

Mammography (x-ray examination of the breast) is a widely used imaging procedure - undergone by at least 26 million women per year in the European Member States. The main benefits include early detection of breast cancer leading to a reduction in mortality from breast cancer by mammography screening, reduction in the extent of breast cancer treatment allowed by early diagnosis, and reassurance of normality. The potential harms in terms of creation of unnecessary anxiety and morbidity, untoward economic costs and the use of ionising radiation should not be underestimated.

Use of sub-optimal equipment by insufficiently trained or skilled professional staff will negate the major benefits of screening and result in poorly effective and cost ineffective mammography services, and lead to disease over- or under-estimation, or false reassurance of normality in women with breast cancer. Positive steps are necessary to abolish such practice and it is important to help women, health care providers, medical professionals, government authorities and other interested parties to identify high quality mammographic services, whether these be providing screening or diagnosis.

Certification allows tangible and demonstrable recognition of adherence to a recognised quality system and achievement of satisfactory outcomes. It will take into account the special requirements of both breast diagnostic and screening services. The EUREF certification programme was originally developed for the European Commission in cooperation with the European Network of Breast Screening, competent departments of the European Commission, European agencies and other interested national authorities in the Member States and published in the European Guidelines in 2006 (2). Over ten years later advances in medical practice together with extensive certification experience and further guidance on certification processes from the European Commission have mandated revision of the original protocol.

Requirements are described for three chosen categories, two for the provision of **breast screening programmes** and one for the provision of **breast diagnostic units.** These categories encompass a range from a high quality basic breast diagnostic service up to a programme performing population based screening to advanced European Reference Centre level.

2 Introduction

Europe currently leads the world in implementation of organised population based breast cancer screening programmes using mammography of demonstrable high quality. The experience gained in these activities across the Member States has

demonstrated the complex technical, organisational and professional aspects of maintaining at a high level both sensitivity and specificity of screening. It is particularly important to maintain an appropriate balance between the beneficial effects of breast screening (including reduction in mortality from breast cancer) and potentially harmful effects (such as over-diagnosis and creation of anxiety). In order to achieve this aim, the need for the highest quality service delivery of breast screening, its interpretation and management together with back-up from support diagnostic mammographic services has become increasingly recognised and proven by published scientific results concerning small cancer detection resulting in mortality decrease (1).

In 1988 the European Commission funded Europe Against Cancer Programme initiated a Pilot Project Network for breast screening in the Member States. This would examine and develop the methodologies for breast cancer screening in different health care environments, share knowledge and experience, provide a common logo under which the Network could move forward as one, and provide a wealth of reliable information for political decision making in each Member State as to the future organisation of any national breast screening programmes.

Following this, EUREF - The European Network of Reference Centres for Breast Cancer Screening - was set up in order to facilitate and co-ordinate training and provide epidemiological and physico-technical support for the screening centres, with the ultimate aim of bringing each of the network members to Reference Centre status within its own country. In 2003 EUREF further refined its role towards certification and is now redefined as the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services.

Such initiatives have been highly successful in the production of sequential editions of the European Guidelines for Breast Cancer Screening. The fourth edition of these was published in 2006, produced by EUREF in conjunction with EUSOMA and the European Breast Cancer Network, and used by governments as a basis for many breast screening programmes throughout the Member States (2).

The significant benefits of successful implementation of such a process in improving outcomes and cost effectiveness of health care services has been underlined and supported by subsequent European Parliament Resolution of 2006, 2008 and Declaration 2015 (3,4,5).
Special requirements for voluntary certification of breast screening programmes and breast diagnostic services – the EUREF Certification Protocol – were developed by EUREF in co-operation with the European Network of Breast Screening and competent departments of the European Commission. These were published as Chapter 11 in the newly titled European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis in 2006 (2).

It has long been regarded as unsatisfactory to dissociate the quality requirements for screening and diagnostic services. Even though differing emphasis is placed on certain processes and requirements of each system, there is a sufficient need for similar standards of technical and professional expertise in order to provide benefits for all women, with or without breast symptoms.

Since the European Guidelines on quality assurance in breast cancer screening and diagnosis were written, over a decade has elapsed and considerable advances have taken place in both imaging and tissue sampling techniques. It has now become necessary for EUREF to up-date and revise its requirements for breast screening and diagnostic units, taking these and other factors into account. Revision is also warranted in the light of EUREF's extensive training experiences gained over the past 25 years with regard to organisational aspects and programme results at local, regional and national levels.

The internationally renowned EUREF Physical-Technical Steering Group including members of 6 European countries is constantly tracking new developments in imaging techniques, setting up Quality Assurance and Quality Control protocols for mammography equipment, carrying out type testing and certifying equipment from multiple manufacturers upon voluntary request. Maintenance of Image Quality is paramount for satisfactory outcomes in this field and therefore members of the Steering Group play a key participating role in the certification of screening and diagnostic services (6).

3 Breast screening versus diagnostic activity.

When considering the differing requirements for a breast diagnostic unit and breast screening, it is important to understand the wider organizational and epidemiological support that will be necessary for a successful population based screening programme together with the different emphasis placed upon performance indicators and professional working requirements.

Population based breast screening programmes are built upon numerous clearly defined requirements that are far reaching in both their set-up and the influence they will exert on delivering an efficient and effective service. These include the ability to provide adequate coverage of eligible women, a careful balance of sensitivity and specificity, timeliness and expertise of assessment of subtle screen detected lesions, audit, documentation and completeness of data, result management, rigorous multi-disciplinary professional working practices and excellent physico-technical standards, as highlighted in chapter 4 of this paper. All these and more must be in place and functioning perfectly in order to provide a reduction in mortality from breast cancer as part of an overall benefit to the population served, while at the same time taking all necessary measures to reduce the potential harms caused by screening.

Diagnostic services are predominantly required by women reporting symptoms, and though the accuracy of diagnosis and timeliness are just as desirable and the benefits of multidisciplinary team working just as beneficial, the same degree of organizational and epidemiological structures do not need to be in place. Assessment processes may follow a different pathway, performance targets are different, as are professional working practices. The need for availability of an entire range of equipment will vary depending upon the size of unit and its interaction with other larger centres. Smaller unit size does not however excuse poor standards or performance. Symptomatic

women will have a higher likelihood of breast cancer being present than a screening population, and they require effective diagnosis. In addition, an unspecified number of women undergoing opportunistic breast screening will pass through such diagnostic services.

Breast Centres may of course provide both services as it is unlikely that large screening centres will not be involved in diagnostic activity. Also in a decentralized health care system smaller diagnostic type breast clinics or offices may provide an excellent screening service as part of a larger breast screening programme, where there will be pathways laid out for central support by way of double reading and centralized quality assurance including supervised quality control mechanisms. The required degree of such support will be determined by local guidelines and based upon the size and expertise of the individual unit and its results. However, under any circumstances the diagnostic unit itself will benefit greatly from the quality loop feed-back mechanism that is an essential part of any properly organised breast screening programme.

The processes and pathways leading to adequate treatment of lesions detected by either screening or symptomatic services is of course essential.

4 EUREF categories in breast cancer screening and diagnosis

Three categories are described:

1. **European Reference Centre for Breast Screening**
2. **Loco-regional Breast Screening Programme**
3. **Breast Diagnostic Unit**

Different categories should be acknowledged from an individual Breast Diasgnostic Imaging Unit, up to a facility that is capable of acting as a European Reference Centre for population based breast screening activities. Reference will be made to whether the programme is working in a centralised or decentralised setting.

Also in a decentralised setting all participating offices (Diagnostic Breast Imaging Units and Diagnostic Breast Assessment Units) will be required to form part of the centralized physico-technical and professional quality control requirements as described, and comply with all relevant criteria. The mammographic image quality will be assured, as will the experience of the second radiologist performing centralised double reading. Volume requirements as stated in the following sections are regarded as the absolute minimum required to allow the production of adequate diagnostic quality images. Greater numbers may not guarantee higher quality, but are much more likely to be associated with a significantly higher level of professional skill and physico-technical excellence. For this reason, higher volume throughputs are strongly recommended. In all cases a mammogram refers to a full set of mammograms performed on a woman,

and should not under any circumstances for the purposes of numerical advantage be counted in terms of individual mammographic exposures.

4.1 European Reference Centre for Breast Screening

In this context “European” refers to the performance of a centre according to the best European standards as opposed to its geographical connotations. In addition to the requirements listed and the fulfilment of published targets and conditions at organisational, professional and physico-technical levels (refer to European guidelines for quality assurance in breast cancer screening and diagnosis – Epidemiology chapter) (2), the Centre must be considered capable of providing consultation services and training both internally and externally. It will be expected to function on a more global level of furthering the processes of mammographic quality improvement regionally and nationally, both justifying and promoting the values of population screening by mammography for breast cancer.

A European Reference Centre for Breast Screening requires that all diagnostic breast imaging units and diagnostic breast assessment units operating within the screening programme meet the required standards. (refer to European guidelines for quality assurance in breast cancer screening and diagnosis – Epidemiology chapter) (2)

The following basic criteria will be required from a European Reference Centre for Breast Screening:

A) General

• Perform at least 15,000 mammograms a year
• This will usually indicate an area and age defined target population of at least 45-60,000 eligible women.
• Have undergone at least two full screening rounds
• Have nominated a Programme Director with overall responsibility for the programme, having the authority to suspend unsatisfactory smaller units in a decentralised system, where repeated attempts at image quality improvement have failed. The Director should lead a Quality Assurance team, holding regular (at least two times a year) minuted meetings to discuss programme quality issues of the main unit, also those pertaining to subsidiary screening provider units if decentralized.

B) Invitation scheme

• Operate a personalised invitation system and/or a promotional campaign as well as an organised system for re-inviting all previously invited and screened women.

C) Physico-technical quality control

• Have a centralised physico-technical quality control service
• Comply with all physico-technical criteria set out in the Supplement S1 of the European Guidelines (6) and ensure that adequate technical and professional quality assurance procedures are carried out in all units participating in the programme.
• Have adequate and state of the art equipment in all units dedicated to the use of digital mammography, with all necessary facilities for full and complete assessment of women with screen detected abnormalities
• Have adequate and dedicated viewing conditions allowing the comparison of current and previous images.

D) Radiographers

Have at least two radiographers, carrying out each 1000 mammograms a year complying with what indicated in the European Guidelines for quality assurance in breast cancer screening and diagnosis (refer to European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition – summary document) (7)

The radiographers, technologists or other members of staff performing the mammographic examination must have had at least 40 hours of training specific to the radiographic aspects of mammography and regularly participate in External Quality Assessment Schemes and radiographic update courses.

These persons must be able to perform high quality mammograms. There should be a nominated lead in the radiographic aspects of quality control.

E) Radiologists

Employ trained radiologists, i.e. a person who has had at least 60 hours of training specific to mammography

• Have a double reading system, in which each radiologist must read at least 5,000 mammograms per year.

In case of a decentralised programme, the second reader has to be a fully trained and experienced radiologists reading at least 5,000 mammograms per year

• The reading radiologists must take full responsibility for the image quality of the mammograms reported and ensure that where necessary images are repeated until they be of satisfactory standard.

F) Referral, assessment and feedback

• Keep a formal record of referrals, mammogram results, assessment processes and outcomes including tissue sampling and surgical procedures.
• Have an approved protocol for referral of women with screen detected abnormalities within both centralised and decentralised screening programmes to centres with adequate and full assessment facilities
• Process feedback of data and results to the professional staff involved in the programme.

G) Pathology support

• Have organised and specialist cyto / histopathological support services with the ability to obtain the routinely used immuno-histopathological tests for breast lesions.

H) Multidisciplinary activities

• Participate in regular multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services, including the radiologist(s), pathologist and preferably the surgeon, breast care nurse and radiographer. Keep formal records of the discussion and management decisions of the meeting, which must be filed with the patient records.

I) Identification and peer review of interval cancers and screen-detected cases

• Have a formal mechanism for identification and peer review of interval cancers and screen-detected cases, which will require communication with the appropriate Cancer Registry. Keep a record of interval cancer review results.

J) Ensure satisfactory epidemiological support

Particularly with regard to the organisational, implementation and evaluation aspects, (refer to Europen Guidelines for quality assurance in breast cancer screening and diagnosis – Epidemiology Chapter) (2)

• Collect and monitor data according to the European Guidelines (refer to Europen Guidelines for quality assurance in breast cancer screening and diagnosis – Epidemiology Chapter) (2)

• Evaluate and report on the key performance data of the screening programme annually.

K) Training

Provide training by means of:

• Teaching files including interval cancers and recalled cases subjected to assessment procedures and pre-operative localisation.

• Training programmes with performance evaluation for radiologists and radiographers

• Training programmes for multidisciplinary diagnostic and treatment teams.

L) Audit and Research

It is expected that a screening programme operating at European level will participate in a full range of audit at least annually documented by a formal report and produce scientific papers published in peer-reviewed journals.

4.2 Loco-regional Breast Screening Programme

Such a Loco-regional Breast Screening Programme covers usually a smaller region with less eligible women compared to a European Reference Centre.

In addition to the physico-technical and professional standards required for high quality breast imaging, it will be necessary to demonstrate a significant level of organizational success with regard to population based mammographic screening, and in addition to meet recognised performance standards and targets widely regarded as essential for successful screening. (refer to Europen Guidelines for quality assurance in breast cancer screening and diagnosis – Epidemiology Chapter) (2)

The following basic criteria will be required from a Loco-regional Breast Screening Programme:

A) General

• Perform at least 5,000 examinations a year
• This will usually indicate an area and age defined target population of at least 15-20,000 eligible women.
• Have undergone at least two full screening rounds.
• Have nominated a Programme Director with overall responsibility for the programme, having the authority to suspend unsatisfactory smaller units in a decentralised system, where repeated attempts at image quality improvement have failed.

In addition, all basic criteria listed and described in in the sub-chapter 4.1of a European Reference Centre for Breast Screening under **B)** through **J)** are also required from a Loco-regional Breast Screening Programme.

4.3 Breast Diagnostic Unit

In such an assessment unit a centralized system of diagnostic assessment for mammographically or clinically detected lesions must be available. There should be a full range of assessment facilities provided in order to allow complete and adequate work up by the Unit without necessarily having to refer the woman on for further investigation elsewhere.

The following basic criteria will be required from a Diagnostic Breast Unit:

A) General

• Perform at least 2,000 mammograms a year. • Be able to perform physical examinations and ultrasound examinations as well as the full range of radiologic procedures, such as core biopsy sampling under radiological (including stereotactic) or sonographic guidance.

• Monitor data and feedback of results.

• Keep a formal record of mammogram results, assessment processes and outcomes.

B) **Physico-technical**

• Have dedicated equipment specifically designed for application in diagnostic mammography and breast imaging, a digital mammography system with magnification ability, and be able to provide adequate viewing conditions for mammograms

• Have dedicated ultrasound and stereotactic system and needle biopsy device for preoperative tissue diagnosis.

• Comply with the physico-technical protocol set out in the Supplement S1of the European Guidelines (6).

C) Radiographers

• Breast Diagnostic Unit must have at least two radiographers, carrying out each 1000 mammograms a year complying with what indicated in the European Guidelines for quality assurance in breast cancer screening and diagnosis (refer to European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition – summary document(7)

The radiographers, technologists or other members of staff performing the mammographic examination must have had at least 40 hours of training specific to the radiographic aspects of mammography and regularly participate in External Quality Assessment Schemes and radiographic update courses. These persons must be able to perform good quality mammograms.

There should be a nominated lead in the radiographic aspects of quality control.

D) Radiologists

• Employ a trained radiologist, i.e. a person who has had at least 60 hours of training specific to mammography and who in volume reads at least 1,000 mammograms per year.

E) Pathology support

• Have organised and specialist cyto / histopathological support services with the ability to obtain the routinely used immuno-histopathological tests for breast lesions.

F) Multidisciplinary activities.

• Participate in regular multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services, including the radiologist(s), pathologist and preferably the surgeon, breast care nurse and radiographer. Keep formal records of the discussion and management decisions of the meeting, which must be filed with the patient records.

5 References

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