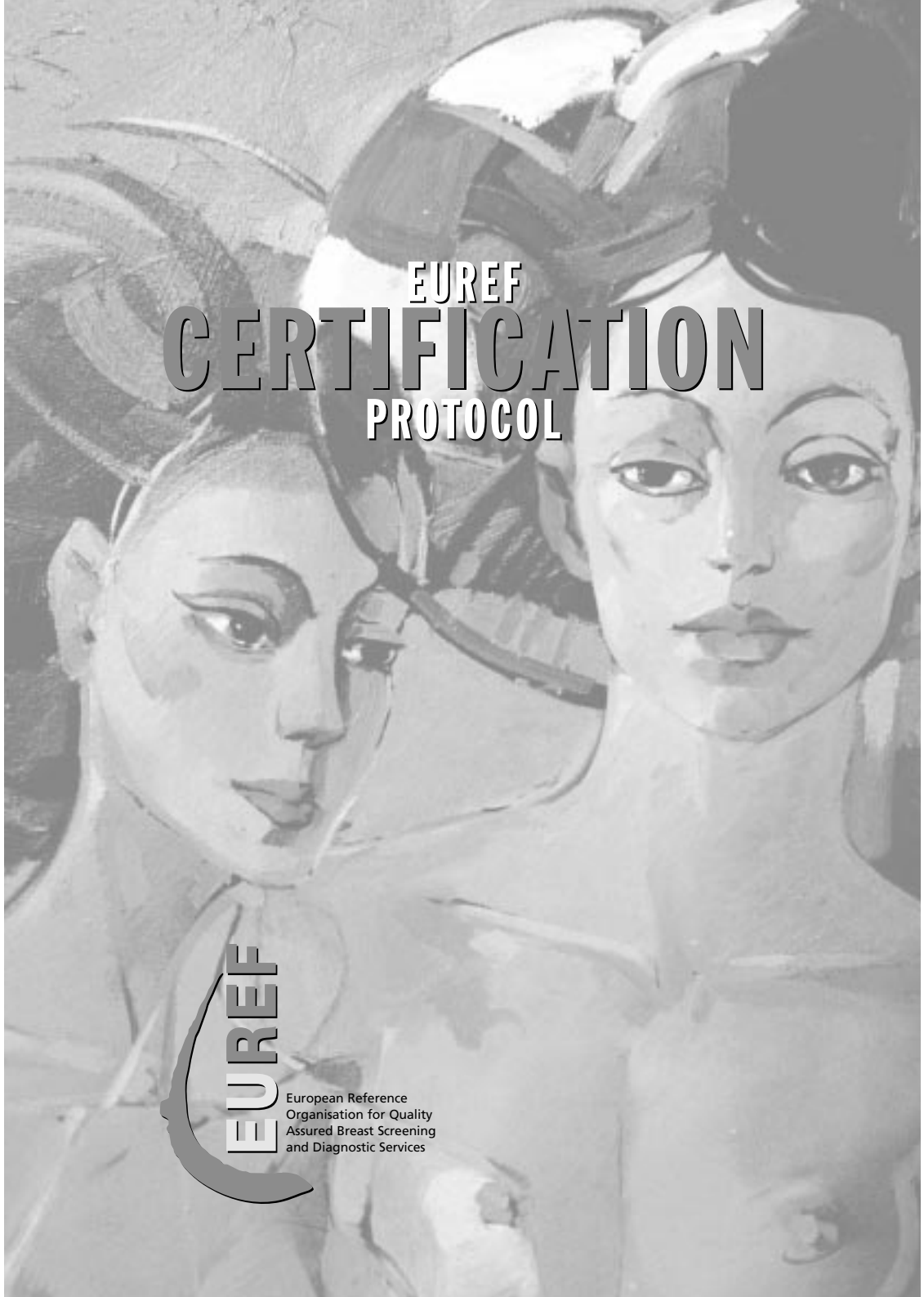

EUREF CERTIFICATION PROTOCOL

EUREF

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Assured Breast Screening
and Diagnostic Services

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EUREF CERTIFICATION PROTOCOL

Executive Summary

Mammography (x-ray examination of the breast) is a widely used imaging procedure - undergone by some 5 - 10 million women per year in the European Member States. The main benefits are those of reassurance of normality, early detection of breast cancer and reduction in mortality from breast cancer by mammography screening. The potential harm in terms of the 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 and skilled professional staff will negate the major benefits of screening and result in poorly effective and cost ineffective mammography services. We believe that positive steps are necessary to abolish such practice and that it is important to help consumers, health care professionals, government authorities and other interested parties to identify high quality mammography services appropriate to women's needs.

We have therefore developed a European programme for:
Voluntary certification of high quality mammography services

This certification allows tangible and demonstrable recognition of adherence to a recognised quality system and will take into account the special requirements of both symptomatic and screening services. It has been developed for the European Commission by EUREF in co-operation with the European Network of Breast Screening programmes, competent departments of the European Commission, European agencies and other interested national authorities in Member States.

Methodology and criteria are described for four chosen categories of certification, two for the provision of diagnostic mammography services and two for the provision of mammography screening programmes. These categories range from the ability to produce an adequate quality mammogram up to a centre performing population screening to European Reference Centre level.

Introduction

Europe currently leads the world in implementation of organised population based breast cancer screening programmes using mammography of demonstrable high quality. Considerable progress has been made with effective population based screening in several Member States. The experience gained in these activities has demonstrated the complex technical, organisational and professional aspects of maintaining an appropriate balance between the beneficial and potentially harmful effects of mammography. This need for a high quality service in mammography and breast screening has become increasingly recognised over recent years. Attention to technical detail has been scientifically demonstrated to increase cancer detection rates and in particular to increase detection of small invasive cancers[1], a major pre-requisite for maximising mortality reduction from breast cancer screening by mammography.

Training and adherence to audit have played a significant part in such advances. One of the lessons learnt is that effective mammography screening cannot be established in the framework of opportunistic screening within a symptomatic mammography service. It is essential to have in place high quality diagnostic mammography services, which may or may not participate within a fully organised quality assured breast screening process. Benefits and advances gained by quality assured screening programmes working to recognised high standards should be introduced into programmes that are less experienced and also into the realms of diagnostic mammography.

In 1988 the European Commission funded Europe Against Cancer Programme initiated a Pilot Project Network in the Member States. This would examine and develop the methodologies of breast cancer screening in different health care environments, share knowledge and experience, provide a common logo under which the Network could move forward together, and provide reliable information for political decision making in each Member State as to the future of any national breast screening programmes. After the first few years, the pilot projects matured into a more quality based network for breast cancer screening, with funding only provided for quality improvement initiatives. EUREF - The European Network of Reference Centres for Breast Cancer Screening - was set up in order to facilitate and co-ordinate training in these screening centres. EUREF would provide epidemiological and physico-technical support and ultimately have the aim of bringing each of the network members to Reference Centre

status within its own country. The breast screening network has received funding from The Europe Against Cancer programme and up until now the provision of such funding for quality assurance measures, the co-ordinating of training by EUREF and the site visits performed by consultants to the programme have been the major means by which a quality service has been documented and recognised. EUREF has now further refined its role towards certification, guidelines and training and is redefined as the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services.

We regard it as crucial that adherence to a quality system receives tangible and demonstrable recognition by way of certification. Certification of health care services is an endeavour receiving increasing attention from government agencies, professional bodies and health care purchasers and providers in Europe. There is an increasing awareness of the benefits of this process in improving the outcome and the cost effectiveness of health care services through successful implementation of quality assurance systems. The inference from certification is two fold. Firstly that a certain level of performance has been achieved, secondly that a certificate may be withdrawn if standards are not maintained. In order to ensure that previous standards have not deteriorated, it is suggested that re-certification must be obtained every five years.

Certification in this instance may be defined as the granting of documentation in the form of a certificate bearing the EUREF logo and signed by a suitably senior Executive within the EUREF organisation. The certificate will be time limited and will state that a recognised visiting team of professionals, approved by EUREF, has visited the unit/organisation concerned and has found it to have achieved satisfactory standards to the level of certification granted in accordance with the protocol and published European guidelines.

Such requests for certification have been received by the EUREF office in Nijmegen from various centres within and outside the Breast Screening Network. We believe that it is important for EUREF to respond to these requests and to extend its activity in this manner. By so doing it will increase its commitment to quality assurance activities throughout Europe and will bring benefit from its extensive team of associated experts to those European areas not currently experienced in high quality mammography.

Some workers believe that the way forward in this matter is to undergo the process of obtaining the ISO 9000 Standard. Experience in the UK Breast Screening Programme has shown that this methodology is not optimal for the purpose required in breast cancer screening. The voluntary accreditation system for mammography in the United States organised initially by The American College of Radiology demonstrated most effectively how such a system rapidly takes hold and may become mandatory in the short to medium term. Ultimately, 'purchasing power' from general practitioners, women's groups or health insurance agencies is likely to be of great significance. Certification can act in support of this.

All requests for certification will be of a voluntary nature until such time in the future that the European Commission or other authorities consider this to be mandatory. These certification activities should not be detrimental to any worthwhile local quality initiatives taking place in units or programmes, and as far as possible should eventually become integrated with, and work alongside initiatives being taken at national level by recognised authorities in each Member State.

Screening versus diagnostic activity

It is important to distinguish clearly between the differing requirements for a diagnostic service (predominantly symptomatic) and a screening programme (predominantly asymptomatic). It is important to avoid confusion between the wider organisational and epidemiological support that will be necessary for a screening programme and to some extent the differing facilities and skills that may be required between both services.

We are committed to recognising and protecting the considerable skills and expertise acquired by numerous funded screening programmes as part of the Europe Against Cancer Breast Screening Network, and already quality assured by EUREF.

To this end we have separated the certification categories between screening and diagnostic activity. We intend to further clarify this issue by issuing certificates, which will be marked as EUREF DIAGNOSTIC or EUREF SCREENING. The issuing of a EUREF DIAGNOSTIC Certificate will therefore make no judgement or reference to the ability to perform screening, likewise the possession of a EUREF DIAGNOSTIC certificate in no way implies that the EUREF organisation considers this unit as suitable to

perform screening activities. EUREF SCREENING Certificates will only be available to organised population based screening programmes, not to individual 'screening' units outside a screening programme.

Certification categories

Four certification categories are described:

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

In addition to the above four certification categories an **EUREF advisory visit** will also be offered on request. Such a visit may take place prior to the commencement of a screening programme, or within the first 3 years of its existence. The aim of such an EUREF advisory visit is to assess whether the design and practice of the programme is in line with the recommendations of the European Guidelines. The visiting team will in addition highlight any possible shortcomings of the programme and offer appropriate advice and support to overcome these. Such an advisory visit may also be seen as a pre-certification visit for the categories 3 and 4.

Different categories of certification should be acknowledged from the ability to produce an adequate quality mammogram in an individual mammography unit, up to a facility that is capable of acting as a European Reference Centre for population screening activities. Reference will be made to whether the programme is working in a centralised or decentralised setting.

It is quite possible that a Diagnostic Mammography Unit or a Breast Assessment Centre may individually form part of a Loco-regional programme or European Reference Centre. However in a decentralised screening programme it is acknowledged that the participating offices may not individually achieve complete Diagnostic Mammography Unit or Breast Assessment Centre standard. However all participating offices under these circumstances will be required to form part of the centralised physico-technical and professional quality control requirements as described, and comply with all relevant criteria.

Under these circumstances 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.

Category 1 Euref certification protocol of a Diagnostic Mammography Unit

This level reflects the ability of any office or clinic to provide mammographic image quality of satisfactory physico-technical and professional standards according to published criteria in the European Guidelines[(2)]. EUREF will be satisfied as to the performance levels of equipment, radiographic staff, radiological staff and physics support services as laid out in the European Guidelines. Adequate and regular Quality Control procedures will be followed.

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

A) General

- Perform at least 1,000 mammograms per year.
- Keep a record of mammogram results and monitor numbers of women referred for further assessment and for assessment outcomes.

B) Physico-technical

- Have dedicated equipment specifically designed for application in diagnostic mammography e.g. mammography system with magnification ability and dedicated processing, and be able to provide adequate viewing conditions for mammograms.
- Comply with the physico-technical protocol in the European Guidelines.

C) Radiographers

- The radiographers, technologists or other members of staff performing the mammographic examination must have had at least 40 hours of documented training specific to the radiographic aspects of mammography and regularly participate in External Quality Assessment Schemes where available and radiographic update courses. These persons must be able to perform good quality mammograms. One person must take the 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 requirements reads at least 500 mammograms per year.

Category 2 Euref certification protocol of a Breast Assessment Centre

In addition to the standards achieved by the Diagnostic Mammography Unit, a centralised 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 Centre without necessarily having to refer the woman on for further investigation elsewhere.

The following basic criteria will be required from a Breast Assessment Centre:

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 radiographic procedures. Provide cytological examination and/or 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 e.g. mammography system with magnification ability and dedicated processing, and be able to provide adequate viewing conditions for mammograms.
- Comply with the physico-technical protocol in the European Guidelines.
- Have dedicated ultrasound and stereotactic system and needle biopsy device for preoperative tissue diagnosis.

C) Radiographers

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

F) Interdisciplinary activities.

- Participate in multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services.

Category 3 Euref certification protocol of a Loco-regional Screening Programme

In addition to the physico-technical and professional standards required for high quality mammography, it will be necessary to demonstrate a significant level of organisational 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.

Certification of a loco-regional screening programme requires that all mammography units and breast assessment centres operating within the screening programme meet the required standards.

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

A) General

- Perform at least 5,000 examinations a year (the minimum number in the European Guidelines).
- Serve an area and age defined target population of at least 20,000 eligible women.
- Have undergone at least two full screening rounds.
- Ensure that there is a nominated 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.

B) Invitation scheme

- Operate a successful personalised invitation system and/or a promotional campaign as well as an organised system for re-inviting all previously 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 European Guidelines (3rd edition, 2001) and ensure that adequate technical and professional quality assurance procedures are carried out in all units participating in the programme.

- Have adequate and satisfactory equipment dedicated to the use of mammography, and dedicated processing with all necessary facilities for full and complete assessment of women with screen detected abnormalities.
- Have adequate viewing conditions including the use of roller viewers for multiple screen film reading by more than one reader if necessary in the most effective manner.

D) Radiographers

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

E) Radiologists

- Have centralised reading or, in a case of a decentralised programme, centralised double reading by one or more fully trained and experienced radiologists each reading at least 5,000 mammograms per year.
- Ensure that in a decentralised programme with multiple smaller screening offices participating, the central and experienced double reading radiologist judges the mammograms from both the diagnostic and an image quality point of view. This radiologist 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.
- Observe all radiographic image quality criteria.

F) Referral, assessment and feedback

- Keep a formal record of referrals, mammogram results, assessment processes and outcomes.
- Have an approved protocol for referral of women with screen detected abnormalities within a decentralised screening programme 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 cytological and histopathological support services.

H) Interdisciplinary activities

- Participate in multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services.

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

- Have a mechanism for identification and peer review of interval cancers and screen-detected cases. Interval cancer review will also form part of the certification visit.

J) Epidemiology support

- Receive satisfactory epidemiological support particularly with regard to the organisational, implementation and evaluation aspects as described in the European Guidelines - Quality Assurance in the Epidemiology of Breast Cancer Screening[2].
- Collect and monitor data according to the European Guidelines.
- Evaluate and report on the performance of the screening programme on a regular basis.

Category 4 Euref certification protocol of a European Reference Centre for 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 all published targets and conditions at organisational, professional and physico-technical levels, the Centre must be considered capable of providing consultation services and training both internally and externally, being itself already certified as a loco-regional screening programme. 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.

Certification of a European Reference Centre for Screening requires that all mammography units and breast assessment centres operating within the screening programme meet the required standards.

As EUREF certification becomes more widely used, it is anticipated that 'franchised' certification activities will be placed in the hands of a limited number of highly regarded and recognised centres. Only programmes that have achieved level 4 certification will be considered as suitable candidates for this extension of certification within their own Member States. The granting of level 4 certification however does not place any obligation in this regard either on the part of the programme concerned or the EUREF organisation.

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

A) General

- Perform at least 10,000 mammograms a year.
- Serve an area and age defined target population of at least 20,000 eligible women.
- Have undergone at least two full screening rounds.
- Ensure that there is a nominated 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.

B) Invitation scheme

- Operate a successful personalised invitation system and/or a promotional campaign as well as an organised system for re-inviting all previously 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 European Guidelines (3rd edition, 2001) and ensure that adequate technical and professional quality assurance procedures are carried out in all units participating in the programme.
- Have adequate and satisfactory equipment dedicated to the use of mammography, and dedicated processing with all necessary facilities for full and complete assessment of women with screen detected abnormalities.
- Have adequate viewing conditions including the use of roller viewers for multiple screen film reading by more than one reader if necessary in the most effective manner.

D) Radiographers

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

E) Radiologists

- Have centralised reading or, in a case of a decentralised programme, centralised double reading by one or more fully trained and experienced radiologists each reading at least 5,000 mammograms per year.
- Ensure that in a decentralised programme with multiple smaller screening offices participating, the central and experienced double reading radiologist judges the mammograms from both the diagnostic and an image quality point of view. This radiologist 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.
- Observe all radiographic image quality criteria.

F) Referral, assessment and feedback

- Keep a formal record of referrals, mammogram results, assessment processes and outcomes.
- Have an approved protocol for referral of women with screen detected abnormalities within a decentralised screening programme 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 cytological and histopathological support services.

H) Interdisciplinary activities

- Participate in multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services.

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

- Have a mechanism for identification and peer review of interval cancers and screen-detected cases. Interval cancer review will also form part of the certification visit.

J) Training

Provide training by means of

- Teaching files including interval cancers.
- Training programmes with performance evaluation.

K) Epidemiology support

- Receive satisfactory epidemiological support particularly with regard to the organisational, implementation and evaluation aspects as described in the European Guidelines - Quality Assurance in the Epidemiology of Breast Cancer Screening[2].
- Collect and monitor data according to the European Guidelines.
- Evaluate and report on the performance of the screening programme on a regular basis.

Sources and criteria

The major source for physico-technical and professional standards is the European Guidelines for Quality Assurance in Mammography Screening[2]. Reference has been given to the American Mammography Quality Standards Act and in particular the Small Entity Compliance Guide - An Overview of the Final regulations Implementing the Mammography Quality Standards Act of 1992[3]. Reference is also made, and should be made by any office or programme wishing certification, to Council Directive 97/43/EURATOM[4], referring to the radiation protection of the exposure of individuals as part of health screening programmes.

Methodology

All requests for certification should be made to the organising offices of EUREF in Nijmegen by filing an application form with the Professional Co-ordinator. This form will include preliminary questions, and the applicant should demonstrate that the criteria have been achieved. EUREF will then consider each request and on the basis of the crtirea, the decision whether or not the site in question can be deemed viable for certification will be taken. In this case a site visit will be scheduled, a suitable team will be allocated and an agreed date for the site visit will be set. A protocol will be sent to the local unit laying out the time schedules involved and describing precisely the actions to be followed, the criteria which need to be achieved, and the documents and results that should be available for the visiting team to review. All visits will include a review of films, technical and patient facilities.

The visiting team for the Diagnostic Mammography Unit and Breast Assessment CentreClinic certification will consist of a radiologist, radiographer, physicist and pathologist, with a team leader who may or may not be one of the professional representatives participating in the visit. Visiting teams for Loco-regional Screening Programme and European Reference Centre certification will include the above nominated members with the addition of an epidemiologist. The membership will be stated prior to the visit and will be drawn from a pool of acknowledged experts from recognised centres.

The certification visit will take place at the offices of the unit or organisation requesting certification and it is expected that the relevant senior professionals involved in that programme will also be present. Following the visit and while still on site, the EUREF team will have an informal feedback session with each other. Provisional and brief comments on initial impressions will then be passed on confidentially by the leader of the EUREF team to the Senior Executive present at the local unit. Although the prime purpose of the visit will be to assess the suitability for certification, the visiting team will still make constructive suggestions as to any local improvements which could be made to further best practice.

The full written report in draft will be sent by EUREF to the nominated representative of the local unit within six weeks of the date of the visit. A formal reply must be made by the local unit within a further three weeks responding to issues of accuracy or interpretation. Following receipt of this response, EUREF will then issue a final report within two weeks and will state whether certification has been granted or withheld. There will be a mechanism for the right of appeal in cases of dispute.
When all procedures have been satisfactorily completed, full EUREF DIAGNOSTIC or EUREF SCREENING Certification will be issued. This signed certificate will bear the EUREF logo and will state quite clearly the name of the unit or organisation concerned and the category of certification granted. Such a certificate may be displayed by the units or programmes concerned, and the relevant logo utilised on notepaper, reports etc as appropriate.

Frequency of certification

Re-certification should take place every five years with at least one data-updates every two years in between full visits, so that the co-ordinating office may ensure that technical and professional standards are being adhered to.

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3. Small Entity Compliance Guide - An Overview of the Final Regulations Implementing the Mammography Quality Standards Act of 1992. Report to Mammography Facilities and the Public. United States Department of Health and Human Services. October 1997.

4. Health Protection of Individuals Against the Dangers of Ionising Radiation. Council Directive 97/43/EURATOM.
European Commission. June 1997.

The European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF)

Breast screening and diagnostic services have expanded rapidly throughout Western Europe. This growth will accelerate as activity increases in certain Member States of the European Community and is also taken up by Eastern European nations.
The primary benefits of such services include reduction of mortality from breast cancer and better overall management and care of women with breast problems. However, poor quality of service provision may cause harm and can lead to significant negative outcomes in term of morbidity, anxiety, efficiency and cost-effectiveness.
Current European experience is that breast services vary considerably in the quality of organisation, delivery and professional support. Concepts of specialist training, professional guidelines and standards, audit and quality assurance are not widely recognised nor implemented.
EUREF believes it is neither appropriate nor desirable for women in Europe to be subject to such haphazard standards of care when breast cancer is so prevalent and causes such concern. Furthermore, knowledge gained through successful breast screening programmes must be disseminated widely throughout screening and diagnostic services for the benefit of all women.

Experience of national screening programmes and the European Network for Breast Cancer Screening has demonstrated the need for three key activities:

1. **Certification** of breast services,
2. **Guidelines** – the production and regular updating of technical and professional quality assurance guidelines,
3. **Training** – the promotion and organisation of mandatory training programmes for staff in all professional and administrative disciplines related to breast screening and diagnosis.

EUREF commits itself to the furtherance of these activities at a local, regional and national level and will provide support and advice on such issues upon request.

The structure of the EUREF organisation will be as follows:

a. Council,
b. Management Board,
c. Affiliated experts,
d. Administrative office.

The Council will consist of nationally recognised professionals, prominent in the fields of health politics or breast care services. They will provide high level and high profile support for the aims of the organisation both politically and professionally. They will also provide advice to the management board on key issues as required.

The Management Board will be drawn from recognised and experienced staff actively involved in the professional or administrative aspect of breast screening and diagnostic services. They will drive and steer the activities of EUREF, communicate with the Council where necessary and either as a whole or in nominated subgroups receive reports from and oversee the activities of those experts affiliated to EUREF. A designated member of the Management Board will attend Council meetings in order to report activities and to provide a liaison function.

A panel of affiliated experts to EUREF will be drawn up, consisting of at least two recognised and experienced persons from all of the disciplines associated with breast screening and diagnostic services. They will participate in the practical activities carried out by the EUREF organisation, whether they be related to certification, guideline production or training. They and the EUREF organisation will pay due respect to confidentiality issues with regard to the findings and reports arising from any such activity.

EUREF is a pan European organisation, widely drawn from different Member States and is operated on a non-profit making basis. Its name and logo have been registered at a European level. At the present time the administrative office will be located in Nijmegen where facilities and administrative staff are available, although it may be necessary in the future to have subsidiary offices based in other European centres as certification activities expand. EUREF already has considerable experience in the planning and practical performance of certification activities as part of a European Commission funded study.

Amsterdam, January 11, 2001

EUREF

Notes