EUSOMA accreditation of breast units

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ABSTRACT

EUSOMA (European Society of Mastology) is the organisation representing Breast Cancer Specialists in all disciplines, covering all aspects of breast cancer from risk and prevention, through diagnosis and treatment of the primary tumour, follow-up, treatment of recurrent and advanced disease, pathology, reconstruction, psychology and audit. EUSOMA Guidelines have been published on several aspects of breast cancer and are on service provision as well as giving clinical guidance and providing the basis for audit.

1. Background

EUSOMA (European Society of Mastology) is the organisation representing Breast Cancer Specialists in all disciplines, covering all aspects of breast cancer from risk and prevention, through diagnosis and treatment of the primary tumour, follow-up, treatment of recurrent and advanced disease, pathology, reconstruction, psychology and audit. EUSOMA have been published on several aspects of breast cancer and are on service provision as well as giving clinical guidance and providing the basis for audit.

The EUSOMA Guidelines "The Requirements of a Specialist Breast Unit" has been very well received. The basis behind stated objective and outcome measures were that units should be defined; delivering all the services for breast disease; staffed by specialists in breast cancer in all disciplines; a sufficient case volume for cost effective working, working must be in multidisciplinary fashion in all areas; there must be patient support; processes and outcomes must be audited; both at delivery and at follow-up. A revised edition of these Guidelines is to appear in the 4th edition of the European Guidelines for Quality Assurance in Breast Cancer, published by the European Commission.

There is evidence that the current Guidelines have influenced practice in several European countries and that specialists in breast care strongly support the concepts of accreditation. The Florence and Hamburg statements, voted on by delegates to the European Breast Cancer Conferences, stressed the importance of working in specialist multi-disciplinary units.

EUREF (The European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services) has produced the European Guidelines for Quality Assurance in Mammography Screening, supported and printed by the European Commission, which has been influential in member state government planning for screening and has established a European programme: "Voluntary certification of high quality diagnostic breast imaging and breast screening services". EUREF has already carried out certification visits to a number of units.

In addition to breast specialists (through EUSOMA) demanding specialised Units, the European patient advocacy organisation, EUROPA DONNA, has been supporting and lobbying for the Guidelines for specialist breast units since their publication by EUSOMA in 2000 and considers specialist breast units to be of the utmost importance in enabling...
women throughout Europe to access the best care and treatment possible. Accreditation of specialist breast units will be essential in ensuring that units meet guideline requirements, so that women can select appropriate facilities for diagnosis and treatment. This organisation will be influential in demanding that Units ensure their standards by seeking EUSOMA Accreditation and in widely disseminating knowledge of which units are Accredited.

EUSOMA has therefore implemented the process of Voluntary Accreditation, with the aim of assuring a high quality breast service across Europe, for the benefit of women in all the member states.

The screening component of any Unit or screening service not linked to breast units are separately assessed by EUREF.

2. Need for accreditation

A difficulty faced by patients and referring doctors is how to recognise which units have genuine claims to designate themselves specialist units, hence the need for a process of accreditation.

Health matters remain the responsibility of individual governments. It is anticipated that it would be extremely difficult to bring about a universal process of accreditation, agreed and demanded as mandatory in all countries. However if EUSOMA Accreditation becomes widely sought then it will become de facto a necessary requirement for a breast unit professionally led and demanded by patients. Hospitals will be eager to claim that they have specialist breast units and specialists will wish to show that they work in recognised units; therefore a process of voluntary Accreditation by EUSOMA has been established. It should be noted that the present EUREF Accreditation of screening units is also a voluntary system.

Specialists in breast disease are those who best understand what is needed in a Breast Unit and what is required for efficient and high standard working. EUSOMA is the European Association of specialists in breast disease.

3. EUSOMA accreditation: structure

3.1. European Advisory Committee

Membership:
- EUSOMA
- EUREF Chairs
- EUROPA-DONNA
- Federation of European Cancer Societies (FECS) representative

This committee has no executive powers and is designed to act as liaison in support of EUSOMA Accreditation and to inform women of the advantages of Accredited Units. For this reason EUSOMA will invite to the Advisory Committee as observers, an MEP and a nominee from the European Commission.

The EUSOMA Accreditation Coordinator will act as Adviser.

3.2. EUSOMA executive

Decisions on the structure and methodology of EUSOMA Accreditation will be made only by the EUSOMA Executive Committee. The Executive appoint the EUSOMA Accreditation Coordinator and the Accreditation Board. In addition to the President at least three positions on the Accreditation Board (a clinician, pathologist and radiologist) should be occupied by members of the Executive. The Executive Committee plays no part in the Accreditation of individual Units.

3.3. Accreditation board

Chairman: Accreditation Co-ordinator (an elected EUSOMA Executive Member or invited to the Executive ex-officio)
President EUSOMA
Surgeon – EUSOMA Member (In addition, another surgeon if neither the Accreditation Coordinator nor the President of EUSOMA are surgeons)
Radiologist – EUSOMA Member
Radiation Oncologist – EUSOMA Member
Medical Oncologist – EUSOMA Member
Pathologist – EUSOMA Member
Pathologist – Invited by EUSOMA to be nominated by European Group for Breast Screening Pathology
Clinical Geneticist – EUSOMA Member
Audit Adviser – EUSOMA Member
Patient Advocate – Invited by EUSOMA to be nominated by EUROPA-DONNA
Patient Support - Breast Care Nurse invited by EUSOMA

3.4. Functions of the accreditation board

3.4.1. It is the responsibility of the Accreditation Board to decide on the Accreditation status of each Unit. The decision of the Board is final and Units will be informed as soon as the Board has agreed their decisions. The EUSOMA Executive Committee is informed of the decisions as a courtesy.

3.4.2. Members of the EUSOMA Accreditation Board are invited onto the Board as individuals and although they may be invited as nominees of other organisations than EUSOMA, their comments and recommendations on the Accreditation status of any one Unit are their own and not those of their organisation. Similarly Accrediting Group Visitors (7.6.1) must submit their own report and not one approved by another organisation.

3.4.3. All communications by Accreditation Board Members must be with the EUSOMA Accreditation Coordinator, through EUSOMA Secretariat. Communications on the Accreditation of individual units will be answered by the Coordinator and if not resolved will be put to the Accreditation Board by the Coordinator.

Any communications on the process of Accreditation (decisions on which are not a part of the Board’s duties) will be passed on to the Executive by the Coordinator, through the EUSOMA Honorary Secretary.
In considering Accreditation status the Board must take note of the object of Accreditation: it is to select the Units capable of delivering a high standard clinical total breast service (see 4.2). Units which deliver such a service must not be denied Accreditation because they do not fulfil every single non-mandatory recommendation made by the Board and based on the EUSOMA Guidelines.

In addition, health care policies vary from one country to another. Although any such considerations must not alter the basic criteria for Accreditation (4.2), account is taken of this in considering recommendations on lesser and therefore non-mandatory points. EUSOMA are inspecting Units for their competence and not whole National Health Care systems e.g. the referral pathway to the Unit may be complex and appear unsatisfactory but that cannot enter into the assessment of the Unit. No objection to Accreditation should be made by a member of the Board unless the reason underlying it is evidence based or based on consensus of experts in the field.

4. General considerations

4.1. The EUSOMA Guidelines “The Requirements of a Specialist Breast Unit” provides auditable recommendations. The ability of a unit to meet these will be the basis of Initial Accreditation.

4.2. Seven basic criteria underlay the judgement of a Unit:
- A single integrated Unit
- Sufficient cases to allow effective working and continuing expertise
- Care by breast specialists in all the required disciplines
- Working in multidisciplinary fashion in all areas
- Providing all the services necessary – from genetics and prevention, through the treatment of the primary tumour, to care of advanced disease and palliation.
- Patient support
- Data collection and Audit

5. Units

5.1. A specialist breast “Unit” is a working entity and does not have to be contained (although preferable) within a single geographical entity, although the constituent buildings must be sufficiently closely sited to allow true multidisciplinary working and all diagnostic procedures to take place at the first consultation; a ‘Unit’ is defined by all aspects of Breast Cancer Care being offered by a multidisciplinary team (MDT) of specialists in breast disease.

5.2. Public hospital and private care may be given in two or more different settings but as long as care is provided by the same MDT, to the same protocols and discussed in the Unit’s multidisciplinary case management meetings (MDM’s) and included in Unit audit, Accreditation may be given of the Unit as a whole.

Similarly, teams in two different public hospitals may join together but must be seen to be working as a single Unit producing a single dataset.

5.3. There are three ways in which units are organised:

5.3.1. Specialist Breast Units providing all services (including diagnosis) except screening may apply for Accreditation by EUSOMA.

5.3.2. Specialist Breast Units covering all aspects of Breast Care with a Screening Unit Incorporated or Associated. These units may be Accredited by EUSOMA but their screening component is separately certified by EUREF.

5.3.3. Screening Units (or) Diagnostic Units entirely self contained. It is the EUSOMA view that all screening units and diagnostic units should work within a total integrated breast unit structure and that diagnosis and treatment should not be carried out by separate units (a Unit may work as an integrated structure with a recognised multidisciplinary team but have geographical separation of the diagnostic, treatment or screening facilities: under that circumstance they fall into 5.3.1 or 5.3.2).

Nevertheless it is a fact that separate screening and/or diagnostic units are in place. These Units cannot receive EUSOMA Accreditation but may apply to EUREF.

Units considering Accreditation, which are unclear into which category they fall, are asked to seek advice from the Accreditation Coordinator before submitting an application.

6. Initial accreditation, full accreditation and re-accreditation

6.1. Initial Accreditation is on the potential (the capacity) of the Unit to meet the recommendations of the EUSOMA Guidelines “The Requirements of a Specialist Breast Unit” i.e. their buildings, hardware, specialist team, protocols, service provision, data base and audit.

The results of audit cannot be used as a basis for Initial Accreditation since no outcome measures will be available for some years.

6.2. Full Accreditation (and Re-Accreditation after every 5-year interval) will depend on Audit of Performance Indicators (such as pre-operative diagnosis rate, percentage of clear margins in breast conserving therapy) and Outcome Measures (such as Local Recurrence rate after breast conserving therapy). These will be measured on the data collected in the years after Initial Accreditation and transferred to the EUSOMA database.

A Unit may apply for Full Accreditation when it has five years of appropriate data (back data may be suitable for inclusion).

7. EUSOMA initial accreditation: procedure

7.1. EUSOMA Initial Accreditation is activated on electronic request from the Unit: The application form is available on www.eusoma.org. The applicant Unit must be situated within Europe.
7.2. The Unit will receive information on accreditation. After response to this the Unit will be sent a questionnaire on their accommodation, specialist (core) team, working practices, non-core team members, equipment, staffing, protocols, audit and research, set out to match the recommendations in the EUSOMA Guidelines and separate questionnaires on Pathology and Data Collection/Audit.

7.3. A date for a visit is agreed with the Unit and an Accrediting Group is chosen to visit. The group must include a Surgeon (acting as Clinician and therefore also the Visit Coordinator), a diagnostic Radiologist and a Pathologist. To spare expense for Units visited, a maximum of four visitors is taken. The extra visitor from the other disciplines is from the field of patient support. Visitors must be from countries outside of the applicant unit.

Visitors do not have to be selected from the Accreditation Board and other organisations may be invited to recommend visitors for certain disciplines; other than these, Visitors must be EUSOMA members.

7.4. The site-visit has the aim of meeting members of the Unit team in all the core specialities, talking through the replies given on the questionnaires and on arrangements of the working week, ensuring that multidisciplinary working is carried out and talking to some members of the associated services (non-core team).

7.5. Each visit is carried out according to the following schedule:

- 0.00 hrs: Informal meeting of members of the Unit with the visitors over buffet breakfast or sandwich lunch
- 0.30 hrs: Brief presentation by Visit Coordinator on Specialisation in Breast Cancer, Eusoma Guidelines and Eusoma Accreditation
- 0.45 hrs: Meeting with Head of Unit, Clinical Director and Members of Unit Team: at least one representative from each core discipline must be present together with clinical psychologists, breast care nurses, clinical geneticist and reconstructive surgeon. Presentation by the Unit with questions discussed during the presentation.
- 2.15 hrs: Visitors divide to separate tasks
- 3.15 hrs: MDT meeting observed by visit coordinator and the radiology and pathology visitors
- 4.00 hrs: Meeting of the visiting team
- 4.30 hrs: Visit coordinator feed back to the Unit
- 5.00 hrs: Visit ends

Meetings will usually commence at 8 am or 12.00 mid-day.

7.5.1. Opening session

The presentation by the Unit is discussed as it goes along. Presentations on individual topics must be short and must leave plenty of time for interruptions from the Visitors and be based on the questionnaire. The subjects to be addressed are who are the specialist team in each discipline, their timetables, what are the working arrangements and protocols, case flow, attendance at Multidisciplinary Meetings (MDM’s). Outcomes and results of most performance indicators do not form part of Initial Accreditation and may only be presented briefly. Questions and discussion are continuous throughout. There should be no presentation on techniques (e.g. sentinel node biopsy; use of MRI) nor details of research projects. It is essential that the Head of Unit, the Clinical Director of the Unit and at least one specialist of each core discipline (including data manager) are present (importantly including oncology) and members of certain non-core disciplines (clinical psychology, psychiatric support, clinical geneticist, associated plastic surgeon).

7.5.2. Visitors split to separate tasks

The Visiting Radiologist visits the imaging unit for breast disease and meets the breast radiologists and radiographers (technicians); inspects the location of the diagnostic unit (within the breast unit, in campus, outside campus and distance); the dedicated rooms; the examinations performed and whether these are available on the day the woman first attends for consultation and clinical examination; the equipment; is given the numbers of mammograms, breast ultrasound and MRI's performed each year and who reads MRI's and CT scans (breast radiologists or general radiologists); the number of radiographers (technicians) and whether they are trained in and are dedicated to breast disease; who assess imaging for diagnosis and response of distant metastases. The Visiting Pathologist visits the Pathology laboratory and meets with the pathologists reporting breast disease. The Visitor checks the equipment for routine diagnostic work and for specimen radiography; the staffing levels of secretarial and technical staff; checks that the pathologists are not under undue workload pressures, as this will invariably affect the time available for accurate grading and typing of tumours, the turn around time and ability for multidisciplinary working and intra-laboratory conference (one pathologist should gross and report approximately 4000 histological specimens of average complexity per year). The Visitor must check whether the laboratory participates in technical and diagnostic external quality assurance (EQA) schemes and whether the laboratory is accredited by any National laboratory scheme. If the laboratory is producing receptor results and Her-2 testing by immuno-histochemistry or FISH, then the laboratory should participate in technical assessment of competence in these, such as that provided by NEQAS in the UK.

The existence of adequate transport systems between the laboratory and the clinical facility and operating theatre and adequate communication channels with the clinicians. It is expected that the lead breast pathologist has a major interest in breast pathology, reports to the standard of national or international guidelines and is able to attend conferences or update courses in breast disease.
The Patient Support Visitor meets with those on the team primarily responsible for patient support (psycho-oncologists, clinical psychologists, breast care and/or psycho-oncology nurses, social workers); a representative of any patient volunteer group which is active in helping with support; clinical psychologist and/or psychiatrist who provides back-up on request from the support staff; the person giving support for genetics; the contact person on the Unit for women in long-term follow-up.

The Visitor must have explained by one of the surgeons and one of the support staff the arrangements for support when the initial diagnosis of cancer is given, later the pathological findings and adjuvant treatment and the staff who give support if and when the diagnosis of advanced disease is given.

The visitor must be shown the information literature provided to patients and have someone present who can both translate and explain how the literature is given out i.e. whether it is individualised so that only certain leaflets are given to a patient dependant on the features of the breast cancer.

The Visitor should inspect some of the facilities – the out-patient (ambulatory) clinic, the imaging facilities, the chemotherapy suite and accommodation for patients admitted for surgery.

The support given to patients with learning, visual hearing or language difficulties must be explained to the Visitor.

Enquire whether there are formal assessments of quality of life (QoL) aspects e.g. general QoL questionnaire, of cosmetic outcome (again may be by questionnaire), of side effects such as lymphoedema.

The surgeon (Visit Coordinator) meets with the surgeons, the reconstruction team, the clinical geneticist, the radiation oncologist, the medical oncologist and the Audit officer. Particularly the arrangements are assessed for counselling, investigation and intervention for women asking for advice on their family history; for reconstruction; for follow-up and (unless clear from the preceding session) for the involvement of the Oncologists in the team; how advice on reconstruction is given; the post-operative physiotherapy. If time permits, the surgeon is also given a brief overview of the teaching and research.

7.5.3. Multidisciplinary meeting

Units are asked to arrange for one of their regular multidisciplinary case management meetings to be held, which the visiting surgeon, radiologist and pathologist observe. The meeting must be a real case discussion meeting and not a demonstration. The post-operative histology should be demonstrated by the pathologist using a projection microscope, relevant x-rays should be demonstrated with explanation and all members of the core team should be present (including the staff responsible for patient support). Those members of the Unit who do not regularly attend these meetings, should not be invited. The visiting team are not present to discuss individual case management nor unit policies and should make no comment during the meeting. If the Unit team has difficulty in holding a genuine MDT meeting in English, the native language may be used, with an English-speaking member of the MDT answering questions for explanations from the Visitors. It is the style of the MDT meeting, the participation of all staff, the method of presentation etc rather than the actual decisions made which the visitors need to see.

7.5.4. Meeting of visitors

After the MDT meeting all the visiting team meets in confidence for 45 minutes.

7.5.5. Feedback

The visit closes with the visit coordinator giving some preliminary feedback to the head of Unit or if the Unit prefers, to all the members of the Unit. Feedback does not include all subjects addressed in the Preliminary Report but does give the Unit some feel as to how they are performing and gives them important warning of problems which will need to be addressed.

7.6. Reaching Decisions on EUSOMA Initial Accreditation

7.6.1. Following the visit the visitors send their reports (see 3.4.2) within two weeks to the Visit Coordinator. Reports are also received from the geneticist, radiation oncologist and audit members of the Accreditation Board (who have reviewed the appropriate questionnaires).

7.6.2. The Visit Coordinator writes a Preliminary Report within four weeks, which may put extra questions to the Unit and to some members of the Accreditation Board.

7.6.3. The Preliminary Report and the extra reports (7.6.1) are sent by the EUSOMA Accreditation Coordinator to the Unit Director, the Board and the Visitors, who may request further information within four weeks of receipt of the Preliminary Report.

7.6.4. Comments from these individuals (and replies to extra questions posed) are received by the EUSOMA Accreditation Coordinator who, based on the replies, may ask the Unit for further information.

7.6.5. Once all necessary information has been received the Accreditation Coordinator writes an Amended Report with a recommendation on Initial Accreditation status, agreed with the visit coordinator.

7.6.6. Individuals (see 3.4.2) on the Board have 28 days to approve or disagree with the recommendation. Failure to register an objection will be taken as assent.

7.6.7. If no objection is received Initial Accreditation (see 6.1 and 9.1-9.2) is awarded (see 3.4.1).

7.6.8. Any objection must have a reason clearly stated, which should cross a basic criterion (4.2) and be evidence based or supported by a published consensus statement (see 3.4.4). Such an objection is forwarded by the EUSOMA Accreditation Coordinator to the Board.

The EUSOMA Accreditation Coordinator is then empowered to make the decision on Accreditation status. He/she will attempt to obtain the unanimous
agreement of the Board. If objections from more than one member remain then a teleconference of the Board will be arranged. If the Board fail to reach unanimity then the Accreditation Coordinator will have to decide by a majority vote: if more than 25% of the Board are against Accreditation then it will be denied.

7.6.9. The Accreditation Coordinator will write the Final Report which will include the Accreditation decision. The Final Report will be sent to the Board (for their record only) and to the Unit with a letter informing them of the decision. In those accorded Accreditation a certificate will be sent. The Conditions of Accreditation (10.1–10.3) will also be sent.

7.6.10. If a Unit wishes to appeal against an adverse decision then a letter must be sent to the EUSOMA Accreditation Coordinator stating the reason for appeal. This will be passed onto the EUSOMA Executive, whose decision will be final (applicant Units should note that Accreditation is Voluntary and not a legal requirement).

8. Full accreditation and re-accreditation

8.1. This will be largely electronic and based on the outcome measures for case management stipulated in the various EUSOMA Guidelines, recorded continuously onto the database designed for the EUSOMA Network.

8.2. Full Accreditation (6.2) may be applied for when a Unit has 5 years of Audit Data, which may include cases treated in years prior to Initial Accreditation.

8.3. Re-Accreditation is applied every 5 years after Full Accreditation and will again be based on performance indicators and upon long-term outcome measures.

8.4. The data required to be recorded at initial diagnosis and treatment and of the follow-up data, will be available on www.eusoma.org.

It is important to note that one of the absolute requirements to be met for Initial Accreditation is the ability to submit Audit data to EUSOMA: this data is used for Full and Re-Accreditation.

The Unit must have an electronic database in place. If the database is not one already approved by EUSOMA (approved databases will be listed on the EUSOMA website) then a transfer of raw (i.e. individual patient) anonymised data to the QT EUSOMA Model Data Set must be made. Assessment by EUSOMA at Initial Accreditation will depend on the following: transfer can be satisfactorily performed, correct data items are being recorded with the appropriate definitions, if a data analysis system is used to calculate outcomes then the accuracy of that procedure will be assessed.

9. Levels of initial accreditation

9.1. Initial Accreditation

9.2. Conditional Initial Accreditation (defined standards to be met within a set time period and once met, Initial Accreditation will be accorded automatically).

9.3. Fail

10. Conditions of accreditation

10.1. The Unit must submit data (8.4) to the EUSOMA Database for primary breast cancer (details of the patient age etc, detection (screening or symptomatic), diagnosis, primary operative and adjuvant therapies, tumour pathology and biology) and regular follow-up data. Data will be anonymised to EUSOMA (key kept at base Unit). Data accumulated is used for Full and Re-Accreditation (8).

10.2. To maintain Accreditation a Unit must have at least four-Members of EUSOMA (we suggest surgeon, pathologist, oncologist, radiologist). This is because the Unit owns the data collected by EUSOMA (10.3) for their re-accreditation and inspection or use of the data must therefore be controlled by these members. Also the membership fees will cover the costs of data entry, storage and intermittent analysis, on the EUSOMA database and of correspondence with the Units on problems arising in the data.

10.3. On receipt of Initial Accreditation the Unit will become a partner in the EUSOMA Network of Accredited Units (rules of the Network will be defined).

If a Unit no longer complies with these conditions or alters its structure or working practices so as to no longer satisfy the Guidelines or fails Full Re-Accreditation, then Accreditation will be withdrawn.

11. EUSOMA network of accredited units

11.1. The list of Accredited Units will appear on the EUSOMA website together with a short description of the Unit, its expertise and the services offered and (approved by the Unit) the Final Report.

11.2. Partners in the EUSOMA network will own the collected data on the primary tumour (on pathology, treatment and follow-up) submitted to the EUSOMA Data Base to be used for Full and for Re-Accreditation. They will therefore be empowered to decide on which data may be analysed collectively and used for research and standard setting. For such decision making and on publications or research based on the collective data, the Network members will elect a EUSOMA Network sub-committee.

12. EUSOMA executive committee

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<tr>
<th>Prof Luigi Cataliotti</th>
<th>Florence</th>
<th>President Vice President &amp; Accreditation Coordinator</th>
<th>Surgeon</th>
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<td>Prof Marco Greco</td>
<td>Milan</td>
<td>Honorary Secretary Treasurer (also EUREF member)</td>
<td>Surgeon</td>
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<td>Dr Alberto Costa</td>
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<td>Prof Werner Audretsch</td>
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This document was written by Roger Blamey and Luigi Cataliotti and co-authored, amended and approved by EUSOMA Executive Committee. Comments were invited from the officers of EUREF (R. Holland additionally to the above), and The European Group for Breast Cancer Screening Pathology (C. Wells). Paragraphs on procedures during visits were written for Pathology by C. Wells, for Radiology by M. Rosselli Del Turco and for Patient Support by J. Stewart (breast care nurse). Advice on data collection and Audit was given by A. Ponti.

13. EUREF certification (see 5.3.2 and 5.3.3)

EUREF has already defined its own processes for the certification of screening units (see EUREF Certification Protocol) and has its own Certifying Groups. EUREF Certifying Groups have a different composition from EUSOMA Accrediting Groups and include specialists from additional disciplines, e.g. a medical physicist, a diagnostic radiographer (technician) and an epidemiologist.

Requests for EUREF certification should be sent direct to EUREF (www.euref.org).

Conflict of interest statement

None declared.

REFERENCES