

#### **Clinical Audit in Nuclear Medicine**

## OSDG Symposium Innsbruck 6. Mai 2013

Siroos Mirzaei
Wilhelminenspital, Wien
Institut für Nuklearmedizin mit PET-Zentrum

www.nuklearmedizin-wsp.at http://uems.eanm.org/

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# **UEMS**

(http://uems.eanm.org/)

- UEMS has existed for more than 50 years and is the political representative organisation for medical specialists in the European Union and associated countries.
- UEMS defined the basic principles in the field of training of medical specialists to obtain a comparably high level of knowledge to allow free movement of specialists between member countries.
- Specialist Sections for each of the disciplines practiced in the member states were created to <u>coordinate and harmonise</u> the training and for the recognition of medical specialists.
- The UEMS created European "Boards", working groups of the Specialist Sections, to guarantee optimal care by bringing the training of medical specialists to the highest possible level in the specialty concerned.





## Combining efforts to improve delivery ...

... in <u>2003</u> the <u>UEMS Section and</u> the <u>European Board of Nuclear Medicine</u> merged "in order to unify and facilitate activities, mainly to improve and harmonize the training of nuclear medicine throughout European countries to the highest possible standards", as stated in <u>Article 1 of the Statutes</u>.

25-02-2012

Durval C. Costa, MD, MSc, PhD, FRCR





### www.osdg.at

# UEMS/EBNM Executive Committee President, Secretary/Treasurer, Board Member

**UEMS** Structure

Fellowship Committee & Syllabus Committee CME Accreditation Committee

Accreditation Committee

#### **UEMS/EBNM Presidents**

1990 - 1993 Desmond Croft, UK

1994 - 1997 Bernard Bok, FR

1998 - 1999 Wolfgang Becker, DE

2000 - 2003 Alberto Cuocolo, IT

2004 - 2007 Angelika Bischof Delaloye, CH

2008 - 2009 Thomas Nunan, UK

2010 - 2011 Drazen Huic, HR

2012 - 2015 Durval Costa, PT





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Department of Nuclear Medicine University Clinic - The Norwegian Radium Hospital Montebello 0310 OSLO NORWAY



#### Committee Member:

- A. Boubaker, LAUSANNE, CH D. Fuster, BARCELONA, ES
- Kulakiene, KAUNAS, LT
- Z. Özcan, IZMIR, TR
- D. Huic, ZAGREB, HR

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#### Education & Syllabus Committee - ESC

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#### Committee Member:

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#### CME Accreditation Committee

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#### Committee Member:

- R. Baum, BAD BERKA, DE D. Costa, LISBON, PT
- P. Jarritt, CAMBRIDGE, UK T. Krause, BERN, CH
- L. Pavios, SZEGED, HU

#### Committee for Accreditation of Nuclear Medicine Departments and Training Centres

#### S. Mirzaei

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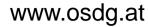
#### Committee Member:

A. J. Hilson, LONDON, UK A. García-Burillo, BARCELONA, ES N. Mutlukoca, BODØ , NO P. Van Boxem, FLEURUS, BE G. C. Vivian, PLYMOUTH, UK M. Bajo, LUND, SE

Corresponding Member: F. Giesel, HEIDELBERG, DE J. Prior, LAUSANNE, CH A. Jiménez Heffernan, HUELVA, ES I. Sippo-Tujunen, HUS, FI

N.G. Hartman, LONDON, UK S.E. Bouzoucef, ALGIERS, DZ

A. Ciarmiello, LA SPEZIA, IT









### **UEMS/EBNM**

**Committee for Accreditation of Nuclear Medicine Departments** 





It has been estimated (UNSCEAR, 2000) that worldwide there are about 2000 million x-ray studies, 32 million nuclear-medicine studies and over 6 million radiation therapy patients treated annually, and the numbers are constantly increasing.

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# Directiva del Consejo 97/43 EURATOM

(Comisión Europea de Energía Atómica)

« Council Directive on Health Protection Against the Dangers of Ionizing Radiation in Relation to Medical Exposure »

(Directiva del Consejo Sobre la Protección Sanitaria Contra los Peligros de las Radiaciones Ionizantes en Exposiciones Médicas)

**Auditorías Clínicas** 

**Quality Management Audits in Nuclear Medicine Practices** 

**Update 2013** 





#### **Directive 97/43/EURATOM (MED-directive)**

#### Article 2:

Clinical audit: a systematic review on medical radiological procedures which seeks to improve the <u>quality</u> and the <u>outcome</u> of patient care through structured review whereby radiological practices, procedures and results <u>are examined against agreed standards</u> for good medical radiological procedures, with modification of practices where indicated and application of new standards if necessary.

#### Article 6:

Clinical audits shall be carried out in accordance with national procedures.

There has been a high variation in the implementation of clinical audit in legislation of different EU countries.







# La auditoría clínica debería abordar los tres elementos principales de las prácticas de atención sanitaria:

Estructura lo que se necesita El enfoque de las auditorías clínicas se centra en la evaluación de Proceso lo que se hace La investigación médica basada en la evidencia evalúa la práctica Resultados lo que se espera en términos de

# NM - Clinical Auditor EANM/UEMS/IAEA

- March 27-28/ 2010, 12 Participants
- June 26-27/2010, 10 Participants
- October 7-8/ 2010, 22 Participants
- A total of 44





# Implementation in Finnish legislation Radiation Act 592/1991 Section 39 c (amendment 1142/23.12.1998)

The responsible party (= the licensee) shall arrange a systematic assessment of the medical use of radiation (clinical audit), in which:

- 1. a review is made of examination and treatment procedures followed, of radiation exposures and of the results of examination and treatment,
- 2. these are compared with known good examination and treatment procedures, and
- 3. measures considered necessary are proposed for improving practices and preventing unwarranted exposure to radiation.







# Decree of the MSAH on the medical use of radiation, 423/2000 2/3 Section 21, Performance of audits

The subjects of clinical audits shall include the following:

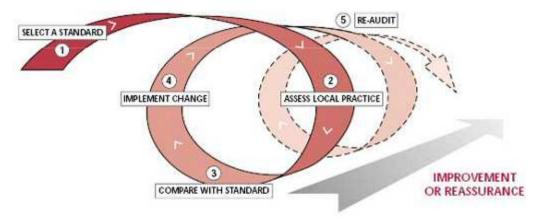
- 1) specification of powers and responsibilities;
- 2) referrals and recommendations guiding the issuing thereof;
- 3) the practice and information flow observed in assessing justifications;
- **4) instructions and practices** pertaining to the performance of procedures involving exposure to radiation;
- 5) equipment for examinations and treatment;
- 6) radiation doses from procedures and the examination and treatment results achieved;
- 7) the quality, recording and flow of information pertaining to procedures;
- 8) staff training;
- 9) the definition and application of quality assurance activities; and
- 10)self-assessments of activities, assessment of results and the use of results.





## The general objectives of clinical audit should be to:

- o Improve the quality of patient care.
- o Promote the effective use of resources.
- o Enhance the provision and organization of clinical services.
- o Further professic



Goodwin R, et al 1996

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- Lunch Meeting during EANM Congresses in Vienna/Birmingham/Lyon...
- Committee meetings 1x/y Vienna

#### Publication:

Why do we need accreditation of nuclear medicine departments? García-Burillo A, Hilson A, Mirzaei S., Eur J Nucl Med Mol Imaging. 2012

Clinical audit in nuclear medicine.

Mirzaei S., Maffioli L., Hilson A., EurJ Nucl Med Mol Imaging 2011







http://uems.eanm.org/index.php?id=49





## **Accreditation process** -ISO-certificate or other equivalent documents - Equipment (NM, devices) - 5 x SOPs **UMES/EBNM** Correct **Verify Iso-certificate Verify NM physician Recognised Stds for SOPs** Rec. accredited **Centre of** Stds met? NO **Competence** →5 x SOPs ✓ YES





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# Miembros del Comité

Committee for Accreditation of Nuclear Medicine Departments

Marika BAJC, Suecia Amparo GARCIA BURILLO, Cataluña Andrews HILSON, Reino Unido Siroos MIRZAEI, Austria Nadide MUTLUKOCA, Noruega Philippe VAN BOXEM, Bélgica Gill VIVIAN, Reino Unido

## **NEW: Corresponding members of the Committee 2012**

- Bouyoucef Salah, Algeria
- Ciarmiello A., Italy
- Giesel Frederik, Germany
- Hartman Neil G; England
- Jimenez-Heffernan Amelia, Spain
- Prior John, Swizerland
- Sippo-Tujunen Inkeri , Finnland
- ...., Mexico/Iran/Südkorea





# Centros acreditados en Europa al 2011

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15 países – 61 servicios

# La Auditoría Clínica en Europa

# En Medicina Nuclear, la Auditoría Clínica

## NO está implementada en:

13. Portugal

15. Eslovaquia

18. Reino Unido

14. Irlanda

España
 Suecia

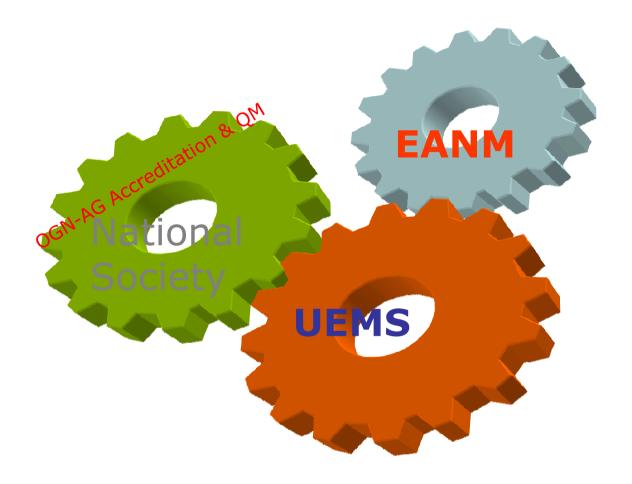
# Austria Bélgica Holanda

- 3. Chipre
- 4. Dinamarca
- 5. Estonia
- 6. Grecia
- 7. Hungría
- 8. Italia
- 9. Lituania
- 10 Luxemburgo

## solo está implementada en:

- 1. Bulgaria
- 2. Rep. Checa
- 3. Finlandia
- 4. Francia
- 5. Alemania
- 6. Latvia
- 7. Polonia
- 8. Rumanía
- 9. Eslovenia

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Quality indicators should be developed when possible as a practical measure of performance. These are useful in particular in internal audits.

The standards of good practices should be reconsidered from time to time with the development of evidence based medicine and RADIOLOGICAL equipment and techniques.

The definition of clinical audit presumes that suitable written criteria for good practice are available for the assessments. In conditions when there are no written criteria available, as a preparatory approach to clinical audit, the assessment could be based on an expert opinion or preferably on a consensus opinion of a relevant expert group. However, this is not recommended as the permanent approach for clinical audits because it does not ensure the uniformity and impartiality of judgements.







It must be strongly emphasised and understood that clinical audit is different from other quality assessment systems and from regulatory inspections. There are clear differences in the purpose and focus of the evaluation, scope, and the methods employed as well as in the consequences of the results of the observations, their impact and use.

Clinical audits should be established and developed in a way which minimizes unnecessary overlap, or duplication of efforts, with the other quality assessment systems and regulatory inspections.

A special *national or regional advisory group*, or *steering committee*, of clinical experts, independent of the auditing organizations, may prove useful in the overall coordination and development of the clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organization, in order to ensure appropriate authority and financing.







The use of radiation for medical diagnostic examinations contributes over 95 % of the manmade radiation exposure and is only exceeded by natural background as a source of exposure (UNSCEAR, 2000). In the next few years, particularly with the rapidly increasing use of computed tomography (CT), the medical use of radiation may exceed natural background as a source of population exposure.

Accreditation. Accreditation is an external assessment of the competence of the organization to carry out defined tasks (e.g. patient examinations) in accordance with a given standard. Audits carried out for accreditation may in certain respects come closest to the objectives of clinical auditing, but they do not include all those items which are included in clinical audits and are focused on standard procedures where definite standards are available.

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Structure	The mission of the unit for RADIOLOGICAL practices Lines of authorities and radiation safety responsibilities Staffing levels, competence and continuous professional development of staff, in particular for radiation protection Adequacy and quality of premises and equipment
Process	Justification and referral practices, including referral criteria Availability and quality of examination and treatment guidelines (protocols, procedures) Optimization procedures Patient dose and image quality in diagnostic radiology and nuclear medicine procedures, and comparison of patient dose with nationally accepted reference levels Procedures for dose delivery to the patient in radiotherapy (beam calibrations, accuracy of dosimetry and treatment planning) Quality assurance and quality control programmes Emergency procedures for incidents in use of radiation Reliability of information transfer systems
Outcome	Methods for the follow-up of outcome of examinations and treatment (short term and long term)

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