

**Patients' Safety ensured by accredited
Certification Programs:
The implementation of BS EN 15224:2016 -
European requirements for Quality Management
Systems in Healthcare**

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Cv-short

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- 2004 – 2012: General Director Health Units S.A - TQM Director of the Olympic Village Polyclinic (OVP)
- 2002 – 2005: Employed by the Greek Ministry of Health and Social Solidarity - PPP projects and projects within the 3rd European Support Framework. Senior management positions - Member of various ‘E- health’ projects’ Workgroups and Review Committees on behalf of Information Society S.A.
- 2000 – 2002 Scientific Partner of Faculties of Nursing Studies

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CEN (& CENELEC) Members

1 European Standard...
... replaces **33** different
national standards
in Europe



CEN CENELEC



<http://www.cen.eu/cen/Members/Pages/default.aspx>

European Standards for Healthcare Services

EN/TC 362	<u>CEN/TR 15592:2007</u> (WI=00362001) Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance improvement	Published
CEN/TC 362	<u>EN 15224:2016</u> (WI=00362005) Quality management systems - EN ISO 9001:2015 for healthcare	Published
CEN/TC 403	<u>EN 16372:2014</u> (WI=00403001) Aesthetic surgery services	Published
CEN/TC 403	<u>FprEN 16844</u> (WI=00403002) Aesthetic medicine services - Non-surgical medical treatments	Approved

CEN Technical Committees on healthcare

Committee	Subject	Standard reference
CEN/TC 394	Healthcare provision by chiropractors	<u>EN 16224:2012</u>
CEN/TC 403	Aesthetic surgery services	prEN 16372
CEN/TC 414	Osteopathic healthcare provision	EN 16686
CEN/TC 424	Early care services for babies born with cleft lip and/or palate	CEN/TR 16824
CEN/TC 427	Services of medical doctors with additional qualification in homeopathy	prEN 00427001

Sept 28 Brussels

Shaw Healthcare standards

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Context and reasons behind the proposals

- Increasing mobility of patients
 - Patients look for better financial deals
 - Cheap flights make them mobile
- Increase patient safety
 - Build trust and confidence of patients
- Improved service quality
 - Minimum requirements, benchmark & best practices
- Mobility of health professionals
 - Mutual recognition of qualifications
- Level playing field at European level
 - Complement legislation where it exists, or provide reference document where it does not



Healthcare in crisis-hit Greece under threat



By Katerina Voussoura

A new round of cuts in debt-hit Greece's troubled health sector could cause irreversible damage to the country's already struggling public healthcare, insiders warn.

Under its EU-IMF deal, which is keeping its economy afloat with bailout loans, Greece has pledged to redeploy 25,000 civil servants and axe 4,000 state jobs by the end of the year.

As part of this process, eight hospitals in Athens and Thessaloniki are currently being downsized and turned into health centers, with 1,618 of their staff

transferred elsewhere.

Public healthcare is free in Greece but the system has been mismanaged for decades, leading to chronic corruption and overspending on drugs and hospital supplies that is only gradually coming to light.

After the economic crisis erupted, authorities sought to get a better control over health spending.

Financial crisis crippling Greek healthcare



JUNE 14, 2012, 4:26 PM | Greece's bureaucratic healthcare system has always been inefficient. But, as Clarissa Ward reports, austerity measures introduced in the wake of the financial crisis have cut public health spending by 25 percent - bringing the system to its knees.

Malaria and HIV Spike as Greece Cuts Healthcare Spending

The nasty downside of austerity.

MICHAEL SCATURRO | MAY 15 2013, 9:00 AM ET



A pharmacist arranges drugs in a pharmacy in Athens on March 1, 2012. (John Kolesidis/Reuters)

ANCET

Search for: All Fields



Doctors Launch Awareness Campaign on Collapsing Greek Health System

By Philip Chrysopoulos - Apr 19, 2016

A group of Belgian doctors and the Greek branch of Doctors of the World have launched an awareness campaign on the [Greek health system](#) that is on the verge of collapse.

The “Emergency Greece” campaign has called the medical situation in Greece “apocalyptic,” blaming the European Union austerity policies, according to a EurActiv France report.

Through the Emergency Greece initiative, the doctors launched an appeal for donations and a petition to convince the EU to spare the country’s medical sector from the severe budget cuts imposed on the country as part of its bailout deal.

[Home](#) / [Society](#) / [Social issues](#)

Poor healthcare quality in Greece due to spending cuts

28 January 2016 / 20:01:43 [GRReporter](#)

987 reads



723

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3175

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Subscribers

Current weather

Athens 11 °C

Thessaloniki 8 °C

Heraklion 16 °C

Sofia -1 °C

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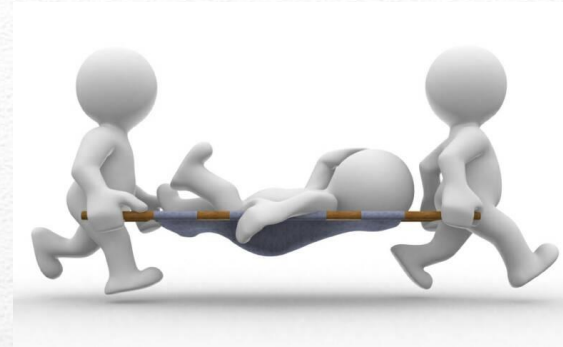
Translators: [Michaela Kichkova](#), [Georgi Pashov](#)

Astrologer: [Galina Ivanova](#)

Regines: [Danielle Lachana](#)

- It is estimated that **8-12% of patients admitted to hospital in the EU** suffer from **adverse events**, such as **healthcare-associated infections** (which account for approximately 25% of adverse events); **medication-related errors; surgical errors; medical device failures; errors in diagnosis**; and failure to act on the results of test (WHO, 2014)
- On any given day one in 18 patients in European hospitals have at least one healthcare associated infection
- Every year an estimated **4.1 million patients acquire a healthcare associated infection in the EU, and at least 37,000 die as a result**. Furthermore it is estimated that **20-30% of healthcare-associated infections** can be prevented by intensive hygiene and control programme
- Evidence on medical errors shows that **50% to 70.2%** of such harm can be prevented through comprehensive systematic approaches to patient safety.
- Statistics show that strategies to reduce the rate of adverse events in the **European Union** alone would lead to the prevention of more **than 750 000 harm-inflicting medical errors** per year, leading in turn to over
 - **3.2 million fewer days of hospitalization,**
 - **260 000 fewer incidents of permanent disability, and**
 - **95 000 fewer deaths per year.**

(WHO, 2014) / Euro barometer 2014



Infections associated with health care services affect an estimated 1 in 20 hospital patients on annual average (estimated at 4.1 million patients worldwide):

urinary tract infections (27%),
lower respiratory tract infections (24%),
surgical site infections (17%) and
bloodstream infections (10.5%)

MRSA is isolated in about 5% of all infections associated with health care. The United Kingdom National Audit Office estimates the cost of such infections at £1 billion per year.

Medical errors are NOT systematically recorded and referred in Greece (OECD tables do not provide Greece figures).

Sporadical research findings:

❖ *Leonet et al, 2012*: Study of 56 legal records

➤ 1/2 of medical errors might cause death

➤ Estimation of 6.000 deaths/year

➤ 37% cause severe disability

❖ *Liaropoulos, 2012*: 40 patients out of 200 operated patients had a miss/failure in treatment, 7,5% threatened patient safety

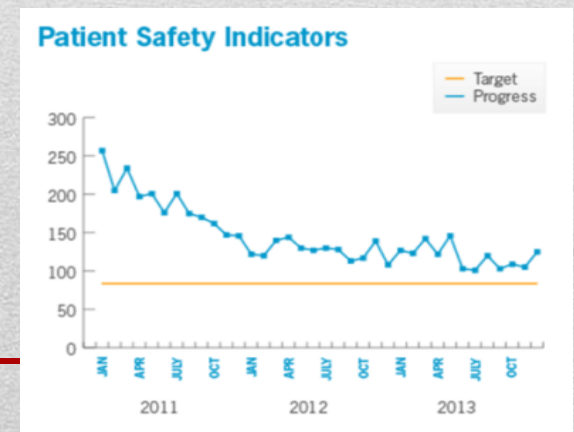
❖ Lack of standardized recording and safety management systems in the Greek hospitals



WHO Patient safety priorities



1. Look-alike, sound-alike medication.
2. Patient Identification
3. Communication during patient handovers
4. Peri-operative patient safety (Performance of correct procedure at correct body site)
5. Control of concentrated electrolyte solutions
6. Assuring medication accuracy at transitions of care
7. Avoiding catheter and tubing mis-connections
8. Single use of injection devices
9. Improved hand hygiene to prevent health care associated infection
10. Follow-up on critical test results
11. Patient falls
12. Health care-associated infections
13. Central lines
14. Pressure ulcers
15. Response to the deteriorating patient





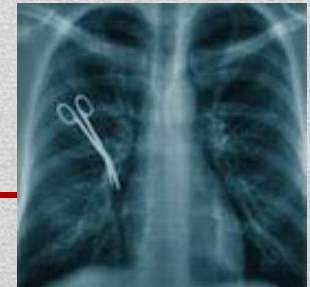
Main Areas of Patients' Risks



Adverse/ Critical events

❖ Adverse events do not have to be caused by the drug or therapy

- Events of wrong site surgery
- Inpatient suicides
- Operative/post op complications
- Events related to medication errors
- Deaths related to delay in treatment
- Patient falls
- Assault/rape/homicide
- Retained foreign objects
- Deaths of patients in restraints
- Prenatal death/injury
- Transfusion-related events
- Infection-related events
- Deaths following elopement
- Anesthesia-related events
- Fires
- ❖ Postoperative physiological and metabolic derangement
- ❖ Complications of anesthesia
- ❖ Deaths in low mortality cases
- ❖ Pressure ulcer
- ❖ Failure to rescue
- ❖ Foreign body left during procedure*
- ❖ Selected infections due to medical care*
- ❖ Postoperative hemorrhage or hematoma
- ❖ Postoperative hip fracture
- ❖ Postoperative respiratory failure
- ❖ Postoperative sepsis
- ❖ Postoperative wound dehiscence*
- ❖ Technical difficulty with procedure*
- ❖ Transfusion reaction*
- ❖ Birth trauma -injury to neonate
- ❖ Patient falls
- ❖ Allergy reaction to medication and others





DIN EN 15224: Main areas – Approach – Applied Methodologies

DIN EN 15224:

Quality Management for Healthcare

- Published in December 2012, updated in 2015 (NEW version BS/ EN 15224:2016)
 - It is the first, uniform European and industry-specific standard for healthcare.
 - The DIN EN 15224 is based on DIN EN ISO 9001.
 - ISO 9001 applies to all companies, and DIN EN 15224 represents an extension of the general parts of ISO 9001, such as organization and quality management.
 - DIN EN 15224 is specifically tailored to the needs of healthcare providers: hospitals, inpatient and outpatient care facilities, doctors' offices and also organizations in social care.
 - The focus is on risk management and health-related issues such as patient safety and the management of clinical risks in planning, execution and governance processes.
-

Quality Management System DIN EN 15224

11 principles of Quality in Healthcare- among them:

- ❖ Appropriate, correct care
- ❖ Availability
- ❖ Continuity of the care
- ❖ Effectiveness
- ❖ Efficiency
- ❖ Consistency
- ❖ Evidence-based, knowledge-based care
- ❖ Patient care, including the physical and psychological integrity of the care
- ❖ Integration of the patient
- ❖ Patient safety
- ❖ Timeliness and accessibility



HEALTHCARE SERVICES

Primary - Secondary - Tertiary Care

Hospitals- Clinics
(General- Specialized)

Dental units

Day Care Units

IVF Units

Eye Clinics

Rehabilitation Centers- Inpatients/ Outpatients

Mental Health centers

Hospices- Seniors Houses

Pharmacies

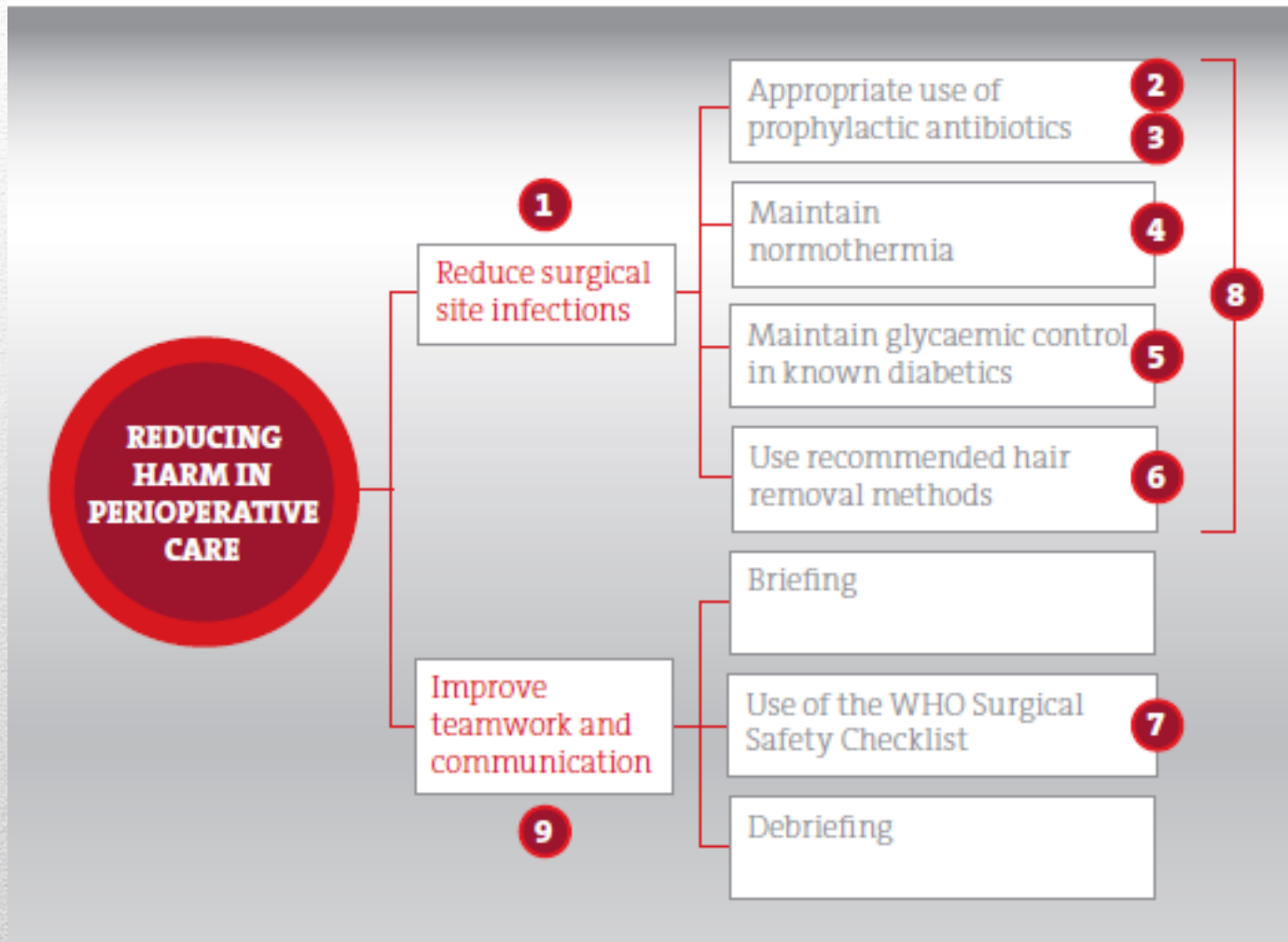
Alternative Medicine



Infection control, hygiene & prevention

- ❖ Infection control screening process and protocols for patients – isolation policy upon admission (cohorting patients)
 - Risk assessment/ risks' allocation upon admission
 - Action plan including preventive measures/interventions/monitoring and documentation procedures
 - ❖ Cleaning policies- Waste management procedures
 - ❖ Cultures program
 - ❖ Monitoring program
 - ❖ Occupational medicine and employees' health programs
-

Pre-operative and Peri-operative



Safety means...

Dealing with All types of Hazards

- **CODE RED: Fire**
- **CODE PINK: Missing Infant or Child**
- **CODE BLUE: Medical Emergency/
Cardiac/Respiratory Arrest**
- **CODE BLACK: Severe Weather**
- **CODE YELLOW: External/Mass Casualty Disaster**
- **CODE ORANGE: Hazardous Exposure**

+ CODE WHITE (PURPLE in US): Disruptive person/ security incident

BS/DIN/SN EN 15224:2016

Clauses at a glance

- **4 Context of the organization**
 - 4.1 Understanding the organization and its context
 - 4.2 Understanding the needs and expectations of interested parties
 - 4.3 Determining the scope of the quality management system
 - 4.4 Quality management system and its processes
 - **5 Leadership**
 - 5.1 Leadership and commitment
 - 5.2 Policy
 - 5.3 Organizational roles, responsibilities and authorities
 - **6 Planning**
 - 6.1 Actions to address risks and opportunities
 - 6.2 Quality objectives and planning to achieve them
 - 6.3 Planning of changes
 - **7 Support**
 - 7.1 Resources
 - 7.2 Competence
 - 7.3 Awareness
 - 7.4 Communication
 - 7.5 Documented information
 - **8 Operation**
 - 8.1 Operational planning and control
 - 8.2 Requirements for products and services
 - 8.3 Design and development of products and services
 - 8.4 Control of externally provided healthcare processes, products and services
 - 8.5 Production and service provision
 - 8.6 Release of products and services
 - 8.7 Control of nonconforming outputs
 - **9 Performance evaluation**
 - 9.1 Monitoring, measurement, analysis and evaluation
 - 9.2 Internal audit
 - 9.3 Management review
 - **10 Improvement**
 - 10.1 General
 - 10.2 Nonconformity and corrective action
 - 10.3 Continual improvement
-

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Implementation Guideline EN 15224 by Swiss Approval

Certification Guideline	APPROVAL SWISS Objectively True	21-41-002
Basic Text		Rev.: 02.1 EN
Quality Management System	BS /DIN EN 15224 QUALITY MANAGEMENT SYSTEMS IN HEALTHCARE SERVICES CERTIFICATION GUIDELINE – STANDARD ANALYSIS- CHECKLIST	Date of Issue: July 2016 Page: 1 of 25

DIN EN 15224-

IMPLEMENTATION GUIDELINES AND BEST PRACTICE

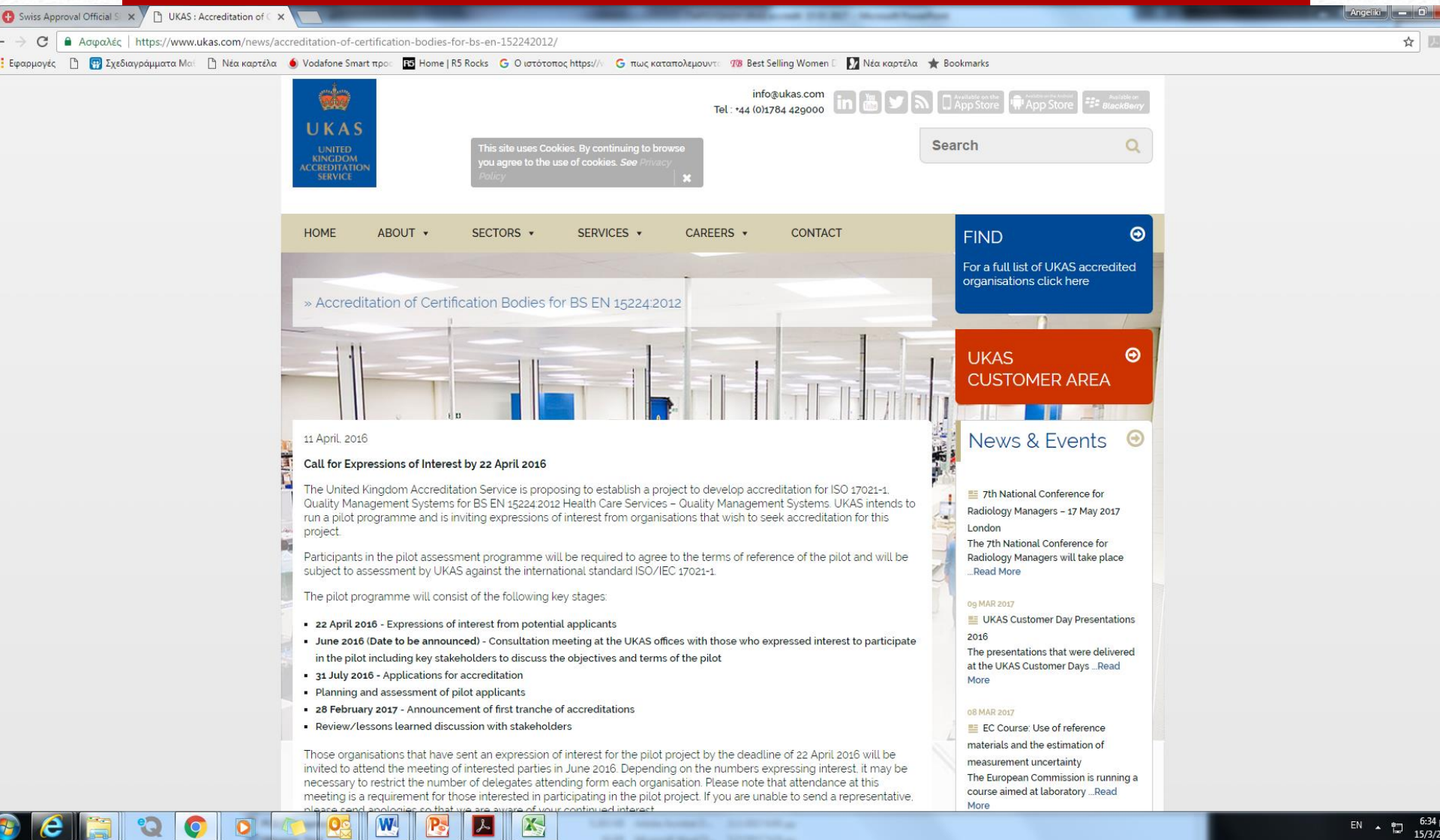
**SWISS APPROVAL INTERNATIONAL
HEALTHCARE SECTION**

Certification Guideline	APPROVAL SWISS Objectively True	21-41-002
Basic Text		Rev.: 02.1 EN
Quality Management System	BS /DIN EN 15224 QUALITY MANAGEMENT SYSTEMS IN HEALTHCARE SERVICES CERTIFICATION GUIDELINE – STANDARD ANALYSIS- CHECKLIST	Date of Issue: July 2016 Page: 2 of 25

QUALITY DIMENSIONS IN HEALTH SERVICES ACCORDING TO THE DIN EN 15224:2012

1. Appropriate care
2. Availability of the care service
3. Continuity of care
4. Effectiveness
5. Efficiency
6. Equitable service (Equality in provision of services)
7. Evidence/ knowledge - based care
8. Patient - centered care (integrating physical, psychological and social dimensions of the individual patient)
9. Informative care (by the patient's informed consensus and participation)
10. Patient's safety
11. Immediate Response- Service Accessibility

§	DIRECTIVE REQUIREMENT	DEFINITION	CONTROL POINTS
4.1	General requirements	This requirement of the standard describes the basic principles that the Health care Unit should have specified for the QMS's development and implementation based on the EN 15224 standard.	<ol style="list-style-type: none"> 1. Interaction diagram should be designed including all the processes (clinical and non-clinical) that affect the provision of healthcare services. 2. Quality objectives and prerequisites should be defined according to special quality characteristics of health services, defined by the standard 3. Determination of committees – supervisor bodies of the system 4. Determination of control methods (frequency, quality control methods, criteria, documentation and archives) for external partners like: cooperating specialists-medical doctors, external diagnostic laboratories, cleaning service



- October 2016: Office/ onsite assessments, Switzerland
- ~~November 2016: Office/ onsite assessments, Greece~~

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