

Address :3611, Hagun-ri, Yangchon-eup, Gimpo-si, Gyeonggi-do , South Korea (10048) Company Id No : 110111-243147 Tax & VAT Id No : 105-86-35114 Tel : (+82)2-6351-9001~5 / Fax : (+82)2-6351-9007 Home page : www.icrqa.com

Hot Issue

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- 2. Expanded standards for KOLAS Medical device field
- **3. IEC / EN 62368-1 KOLAS Audit**
- 4. Application of safety verification testing agency
- 5. HKMC EMC Technology council meeting
- 6. Wonju medical high school visiting ICR
- 7. ISO 19011:2018 Revision
- 8. OFFSHORE KOREA 2018
- 9. CSA Group Field Evaluation Seminar
- **10. CSA Group Cybersecurity Seminar**



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RRA Completion (Electromagnetic Test Headquarters)

On September 17, 2018 at the **RRA 5G mobile communication** Additional Designated.

	지 정	병 서	
	Certificate of	Designation	2
지정번호(Design	ation No.) : KR0165	5	
기관명(Name of	<i>CAB)</i> : 주식회사 이	아씨알 (ICF	Co., Ltd.)
주소(Address):	경기도 김포시 양축	흔읍 황금3로	7번길 112
(112, Hwanggeum	3-ro 7beon-gil. Y	hen-eup, Gim	po-si, Gyeonggi-do, Kore
시험분야(Scope o	f Designation : 무선 미국 MB		성, 전자파강도, 베트남 MRA(Vietnam MRA
시험항목(Items o	of Test : 별지 광	z (sze Altac	hment)
	법」제58조의5의 규정 성평가 시험업무를 하는		025:2005에 의하여 방송 9학니다
This Laboratory	is accredited and	designated in	a accordance with the nal Standard ISO/IEC
	2018. 9	. 17.	
	국립전파	연구 원	N
	National Radio R Ministry of Scie	esearch Ager	cy St
			100 million (100 m

ICR Co., Ltd. has developed a For all electrical / electronic products in the industrial sector **KC test certification / registration** is provided. Thank you for your interest.

Expanded standards for KOLAS Medical device field



In order to provide safer and more accurate testing and certification services to our customers,

ICR conducted field assessments to standards change and update for KOLAS medical devices field.

In addition, the latest standards will be applied to standards recognized **as CBTL by IECEE.**

We promise to provide you with a better level of testing in the future.

Expanded standards for KOLAS Medical device field



KOLAS	CBTL
IEC 60601-2-2:2017	IEC 60601-2-4:2010+A1:2018
IEC 60601-2-4:2010+A1:2018	
IEC 60601-2-28:2017	IEC 80601-2-30:2018
IEC 80601-2-30:2018	IEC 80601-2-49:2018
IEC 60601-2-43:2010+A1:2017	IEC 60601-2- 54:2009+A1:2015+A2:2018
IEC 80601-2-49:2018	ISO 80601-2-61:2017
IEC 60601-2- 54:2009+A1:2015+A2:2018	IEC 60601-2-63:2012+A1:2017
IEC 80601-2-59:2017	
ISO 80601-2-61:2017	IEC 60601-2-65:2012+A1:2017
IEC 60601-2-63:2012+A1:2017	
IEC 60601-2-65:2012+A1:2017	

IEC / EN 62368-1 KOLAS Audit



KOLAS is a Korean stabiliser and KOLAS recognition system Supports industrial activities through recognition system that can be used in various fields in domestic industry.

In large part, the company operates a system of accreditation by Calibration institutions, testing agencies, testing agencies, reference materials production agencies, medical testing institutions, and proficiency testing management institutions.

For 3 days from September 17 to 19, KOLAS was extended/renewed. This time, the Electrical & Electronics testing team has **extended the IEC / EN 62368-1 standard**, completed the audit without any problems and will serve.

Application of safety verification testing agency



We have completed the application of the safety verification testing agency on September 4 and will

be available as early as this year.

안전확인시험기관 지정신청서 접수번호 접수일 처리기간 60일 기관명 사업자등록번호 주식회사 아이씨알 (ICR) 105-86-35114 대표자 전자우편 신청인 김 덕 용 icrqa@icrqa.com 주소 저화번호/팩스번호 경기도 김포시 양촌읍 황금3로7번길 112 02-6351-9001/02-6351-9007 7. 전기기기 : 허. 교류전원을 사용하는 공기청정기, 조. 음식물처리기 9. 오디오·비디오 응용기기 : 가. 텔레비전수상기 신청범위 10. 정보·통신·사무기기 : 가. 모니터, 차. 디지털TV, 타. 노트북컴퓨터 ※ 자세한 내용은 [별지1] 참조 「전기용품 및 생활용품 안전관리법」 제14조제2항 및 같은 법 시행규칙 제23조제1항에 따라 안전확인시험 기관의 지정을 위와 같이 신청합니다 2018 4 9 신청인 김덕 (서명 또는 인) 국가기술표준원장 귀하

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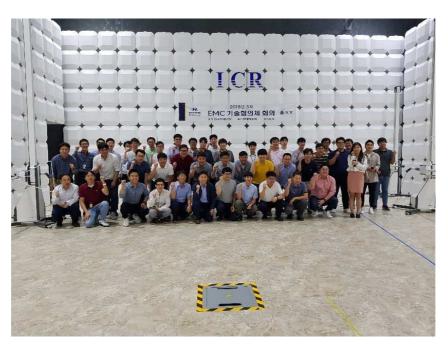
HKMC EMC Technology council meeting



HKMC 3rd 2018 EMC technology council meeting in ICR at 20th Sep 2018.



HKMC EMC Technology council meeting



Subject

- Wireless changing system and EMC considerations
- High voltage system and EMC considerations for commercial vehicles
- ICR lab tour
- EMC technology trend of ADAS
- HKMC test plan



From September 27th to 28th, we conducted an ICR tour at Wonju Medical Equipment Technology High school, which is a mecca for training medical professionals.

Wonju Medical Equipment Technology High school is the only Mister High School in Korea in the medical equipment field, and it is a school that boasts excellent education as well as fostering the medical device industry.



Through this tour, we have provided students with detailed explanations on medical device certification and the IEC 60601-1 standard, which is a common standard for medical devices, as well as providing lectures on system certification and product certification.



In this tour, the actual students were not only trained in specification theory, but also conducted electrical safety tests based on the common standard of IFC 60601-1. Through power input, leakage current, and ground continuity test, it was a good opportunity for students to realize the importance and methods of testing carried out in an actual laboratory.

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The ICR was also meaningful as I met students of Wonju Medical Equipment Technology High school, who are excellent human resources based on various curricula and expertise of medical equipment development.

By taking this opportunity in the future, we will become an ICR that will bring many experiences to future students.

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ISO 19011:2018 Revision



In July 2018, Guidelines for auditing management systems, **ISO 19011:2018** is revised and published.

Followings are the main changes.

- The importance of audit program is emphasized.
- Risk-based approach is adopted throughout the entire audit processes.
- Auditing guidance for the risk-based thinking, context of organization, etc., which are newly introduced by High Level Structure, is clearly explained.

ISO 19011:2018 Revision



ISO 19011:2018 Requirements

3. Terms and definitions

4. Principles of auditing

5. Managing an audit programme

- 5.1 General
- 5.2 Establishing audit programme objectives
- 5.3 Determining and evaluating audit programme risks and opportunities
 - 5.4 Establishing the audit programme
 - 5.5 Implementing audit programme
 - 5.6 Monitoring audit programme
 - 5.7 Reviewing and improving audit programme

6. Conducting an audit

- 6.1 General
- 6.2 Initiating audit
- 6.3 Preparing audit activities
- 6.4 Conducting audit activities
- 6.5 Preparing and distributing audit report
- 6.6 Completing audit
- 6.7 Conducting audit follow-up

7. Competence and evaluation of auditors

- 7.1 General
- 7.2 Determining auditor competence
- 7.3 Establishing auditor evaluating criteria
- 7.4 Selecting appropriate auditor evaluation method
- 7.5 Conducting auditor evaluation
- 7.6 Maintaining and improving auditor competence





ICR has been designated as ATEX, ISO 45001, Korean Register of Shipping (KR) approval testing institute.

ICR will participate in **OFFSHORE KOREA 2018** to provide various services and promote.

The exhibition will be held at **Busan**, **BEXCO's 1st exhibition hall** from **October 10** to **October 12**, **2018**.



전	선시회 사전등록 안내	
	사전등록을 하시면 전시장 입장시 별도의 등록절차 없이 편리하게 <mark>무료 입장</mark> 하실 수 있습니다.	
	전시회 홈페이지 접속 후 사전등록 신청 (등록마감일: 10월 8일까지)	
	www.okkorea.org 접속 😧 사전등록 🕑 신규등록	
	현장등록비 입장료 5,000원 비사전등록비 입장료 무료	
	▶ 무료참관 사전등록 바로가기 ▶▶	

If you **register in advance**, you will be **free** to enter the exhibition hall without a separate registration procedure.

Pre-registration: https://www.okkorea.org





We introduce exhibitors with **OFFSHORE KOREA 2018**

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해양플랜트 기술 컨퍼런스(OK Conference 2018)

Plenary session

New Normal: Challenge and Response

일자 : 10월 10일(수) / 10:00~11:40 장소 : BEXCO 컨벤션홀 301호



모더레이터

정재훈 파트너 맥켄지 앤 컴퍼니 (한국 조선해양산업 관련 컨설팅 진행)



연사

닐 카바나 Neil Kavanagh

과학기술총괄 Chief Science & Technology Manager 우드사이드 Woodside Energy Ltd (호주 최대 에너지 다국적회사)

10월 10일(수)

세션1.FPSO	세션2. FLNG / FSRU
세션3. Fixed Platform	세션4. Drilling Unit
세션5. HSE	국가세션: 말레이시아

10월 11일(목)

세션6. Offshore Hydrodynamics 세션7. Offshore Equipment and Test Infrastructure 세션8. Digitalization 세션9. Offshore Production Technology 세션10. Standardization 국가세션: 중국

현장등록 JI 등록비 165,000원 (USD 165) / 사전등록 JI 등록비 110,000원 (USD 110)



바로가기 ▶▶

Ocean Plant Technology Conference (OK Conference 2018)





Busan, **BEXCO 1st exhibition hall** will be held.

Thank you for your interest and participation.



Product Safety Compliance in the North American Market An Introduction to CSA Group's North American Field Evaluation Service

Unique circumstances sometimes make it challenging, impractical, or even impossible for you to undergo the regular certification process. But demonstrating your electrical product's compliance to safety requirements through a field evaluation (FE) may be the solution. This one-time evaluation service is quick and efficient, and helps you get your products into North America when you need approval from local Authorities Having Jurisdiction (AHJ).

During this seminar, our technical experts at CSA Group will provide an in-depth overview of U.S. and Canadian regulations, including SPE 1000 and NFPA 791, to help ensure your products are accepted by state, provincial, and territorial authorities.



Agenda

Topic

General Overview of Model Code (Canada)

Construction Details (SPE-1000)

Testing and Marking (SPE-1000)

General Overview of NFPA-791 (USA)

How to Apply Field Evaluation (FE)

Q&A

Date: 2018. 10. 16 (TUE) 13:00~17:00 (Reception: 12:30~)
Venue: COEX Conference Room (South) 301A (513, Yeongdong-daero, Gangnamgu, Seoul)
Cost: Free Host: CSA Group's Korean Office

Register and Contact: Jessie Cho (CSA Group) (02-6371-6018, <u>Jessie.cho@csagroup.org</u>)





Navigating Regulatory Requirements for Medical Devices

Major advances in medical technologies over the last few decades have contributed to early diagnosis of diseases, more efficient delivery of treatment, and longer, healthier lives. Network-connected medical devices in particular are redefining 21st century healthcare. With many life-sustaining and life-supporting medical devices residing on hospital networks – and many more connected wirelessly – the risk for cyber-attack is high, and this could compromise a device's functionality, personal information, and patients' health and safety. Implementing cybersecurity measures for devices and the networks to which they connect is critical, and CSA Group's cybersecurity services can help.

Join CSA Group's Laura Élan, Senior Manager of Cybersecurity as she addresses including :

- Overview of Cybersecurity Regulatory Guidance with an Emphasis on US FDA Pre/Post Market Guidance
- Overview of Cybersecurity Frameworks and Standards to Support Medical Device Manufactures
- Essential Activities for Medical Device Companies to Address Product Cybersecurity
- Introduction to Security Risk Analysis for Medical Device and Software Manufactures





CSA Group Cybersecurity Seminar

Date: 2018. 10. 25 (THU) 13:30~18:00 (Reception: 13:00~) **Venue:** Conference B, SKY31 Convention, 31F,

Lotte World Tower (300 Olyimpic-ro, Songpa-gu, Seoul)

Cost: Free

Host: CSA Group's Korean Office

Speaker: Laura Élan, P.E., RAC,

Senior Manager of Cybersecurity, CSA Group

Laura Élan recently joined CSA Group's Innovation Team as Sr. Cyber security Manager to support several industry verticals including healthc are solutions. Prior to joining CSA Group, she served as the Cybersec urity Practice Lead for UL's Digital Health Service team, supporting me dical device software and solutions customers in meeting regulatory an d business imperatives for software and cybersecurity assurance. Laur a has more than 30 years of software and product development and co mpliance engineering experience, grounded in several decades of seni or leadership roles with R&D and manufacturing organizations, includi ng medical devices, and commercial and consumer electronics compa nies. Laura holds a BSEE from the University of Illinois, Urbana, and a n MSEE from the Illinois Institute of Technology, Chicago. She is curre ntly pursuing a graduate degree in computer science with a focus on c ybersecurity. She is a licensed Professional Engineer in the State of Illi nois and holds the RAC credential from the Regulatory Affairs Professi onals Society.

Register and Contact: Jessie Cho (CSA Group) (02-6371-6018, <u>Jessie.cho@csagroup.org</u>)



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ICRO-31/R20161125 본 문서는 법률 제 14088호 저작권법의 보호대상이며, ICR의 지적 자산으로 불법 편집 및 복사를 금합니다.

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