Standards on Medical Devices

Laboratorio di Tecnologie Biomediche A.A. 2017/2018

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What is a standard? (1/2)

European Directive 98/34/CE 1998 :

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0034&from=en

'**standard**', a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

- **international standard**: a standard adopted by an international standardisation organisation and made available to the public,
- **European standard**: a standard adopted by a European standardisation body and made available to the public,
- **national standard**: a standard adopted by a national standardisation body and made available to the public;

What is a standard? (2/2)

Principal characteristics of Standards:

- are **volunteers**;
- are based on the **consensus** and on the **transparency**;
- are re-examined every **5 years**;
- are made by **standardization bodies.**

Some standards have regulatory effect

- Harmonised standards in EU
- Recommended standards in USA

Where do standards come from?

There are particular institutions, national and international, all non-profit, which constantly develop and update this regulatory activity.

- **UNI** – Ente Nazionale Italiano di Unificazione
- **CEN** – Comité Européen de Normalisation
- **ISO** – International Organization of Standardization
- **IEC** – International Electrotechnical Commission
- **CENLEC** – Comité Européen de Normalisation Électrotechnique
- **CEI** – Comitato Elettrotecnico Italiano

Who are ISO and IEC?

- The **International Organization for Standardization** (ISO) is a worldwide federation of national standards bodies.
- The **International Electrotechnical Commission** (IEC) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

The official purpose for the issuance of ISO/IEC Standards is to facilitate world trade through standardization

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

ISO International Organization for Standardization

Standardization bodies (1/2)

ISO

- ISO

CEN

- EN

UNI

- UNI
- UNI EN
- UNI ISO
- UNI EN ISO

Standardization bodies (2/2)

IEC → CENLEC → CEI

- IEC
- CENLEC
- CEI
  - CEI CENLEC
  - CEI IEC
  - CEI CENLEC IEC

Standards and Medical Devices (1/2)

- **Device lifecycle is regulated by:**
  - ISO 13485 for Quality System
  - ISO 14971 for Risk Management
  - ISO 14155 and various guidelines for Clinical Investigations
- **Each product category is than regulated by technical norms**
  - For electro medical devices IEC 60601-1
  - For sterile device ISO 11137 et al
  - For devices in contact with the body ISO 10993
  - Multiple harmonised and not harmonised norms for technical regulation of product-specific features

Standards and Medical Devices (2/2)

IEC standards have numbers in the range 60000–79999

The IEC cooperates closely with the International Organization for Standardization (ISO)

Other standards developed in cooperation between IEC and ISO are assigned numbers in the 80000 series

IEC 60601 example (1/4)

IEC 60601 Medical Electrical Equipment

IEC 60601-x-xx

- The IEC 60601-1-xx series of **collateral** standards for MEDICAL DEVICE ELECTRICAL EQUIPEMENT
- The IEC 60601-2-xx series od **particular** standards for particular types of MEDICAL ELECTRICAL EQUIPMENT
- The IEC 60601-3-xx series of **performance** standards for particular types of MEDICAL ELECTRICAL EQUIPEMNT

IEC 60601 example (2/4)

Collateral Standards

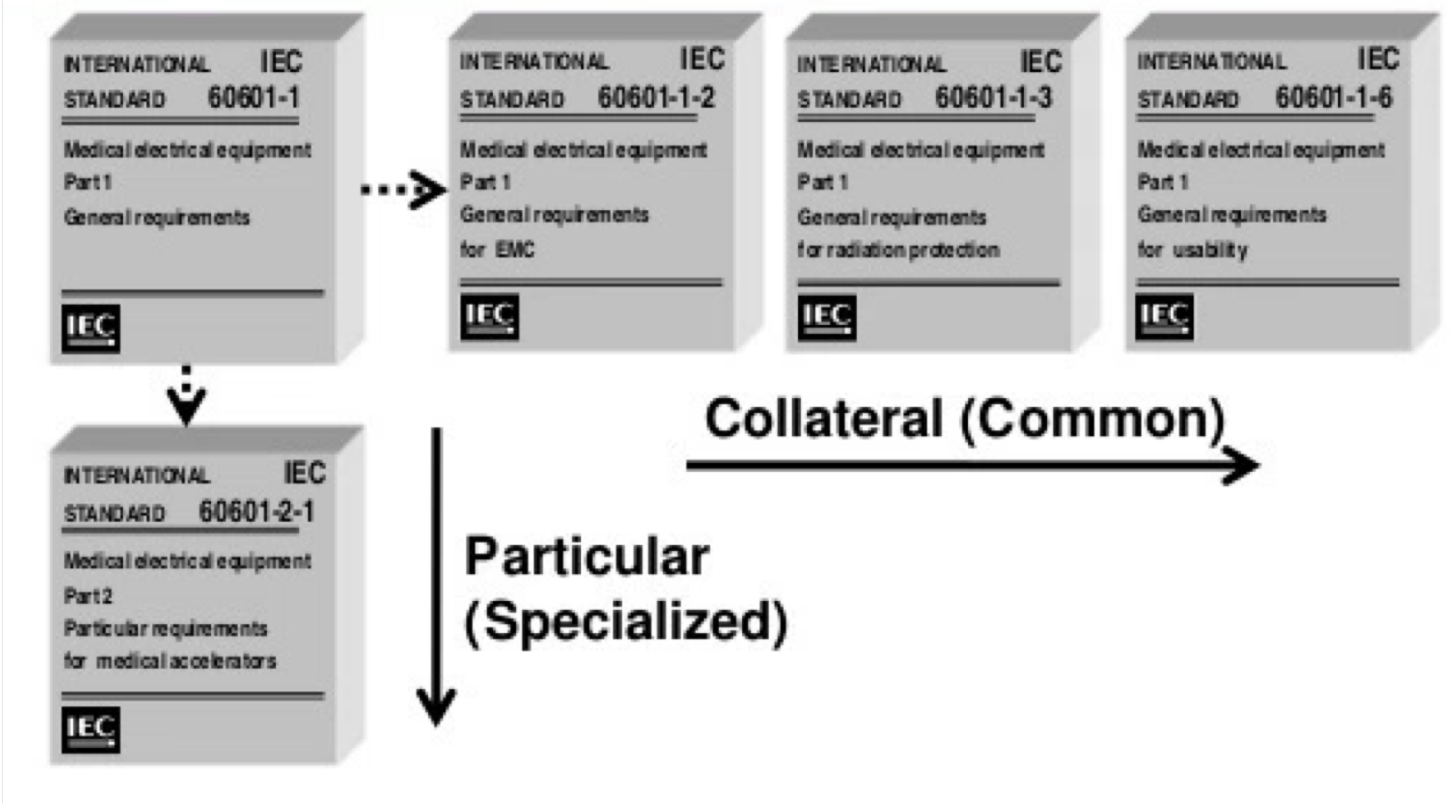
- IEC 60601-1-2, Medical electrical equipment – *Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests*
- IEC 60601-1-3, Medical electrical equipment – *Part 1-3: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*
- IEC 60601-1-6, Medical electrical equipment – *Part 1-6: General requirements for safety - Collateral standard: Usability*

IEC 60601 example (3/4)

Particular Standards

- IEC 60601-2-1 Medical electrical equipment - *Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
- IEC 60601-2-2, Medical electrical equipment - *Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
- IEC 60601-2-4, Medical electrical equipment - *Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

IEC 60601 example (4/4)



EN - How to download a standard? (1/5)

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English

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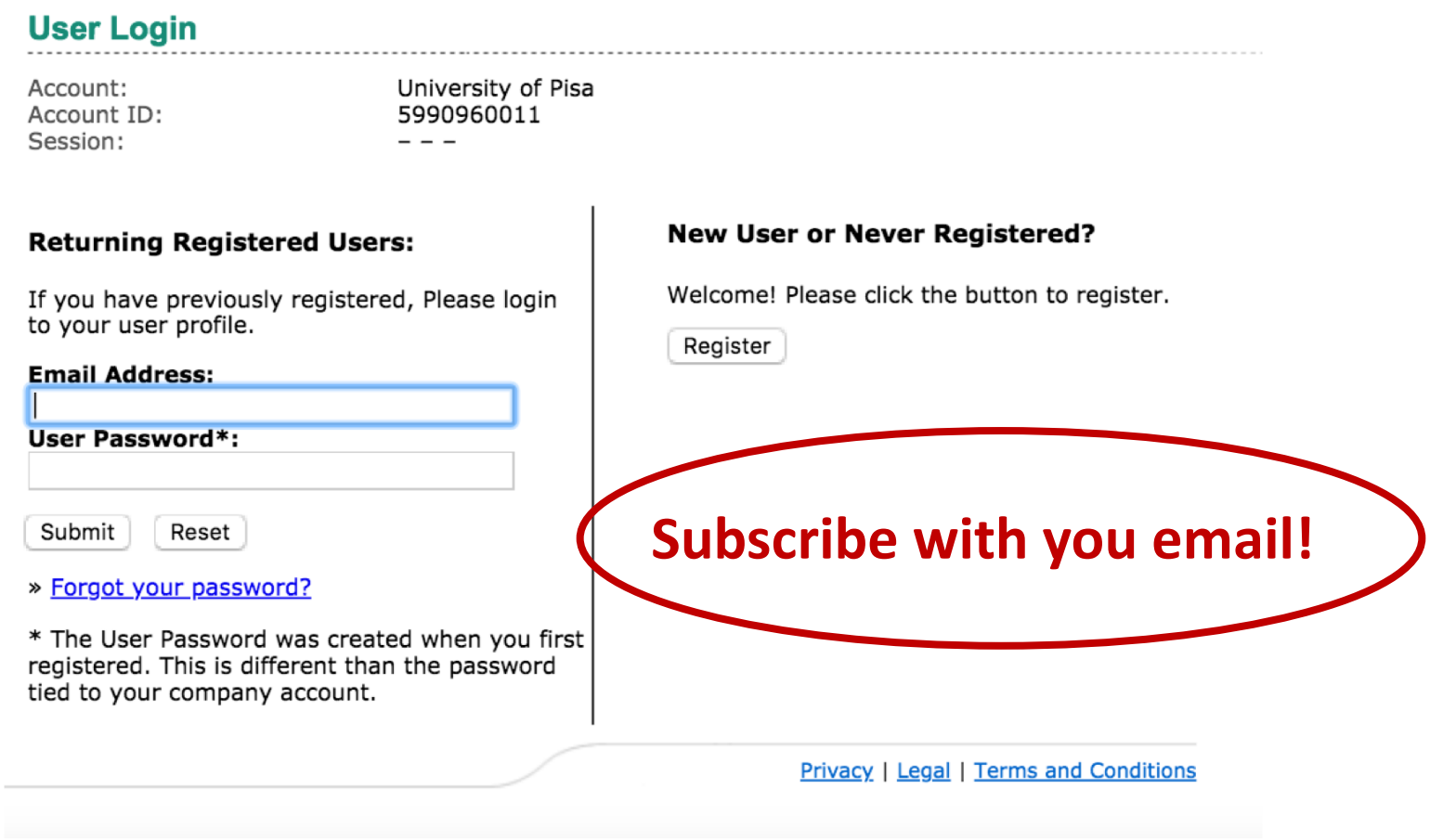

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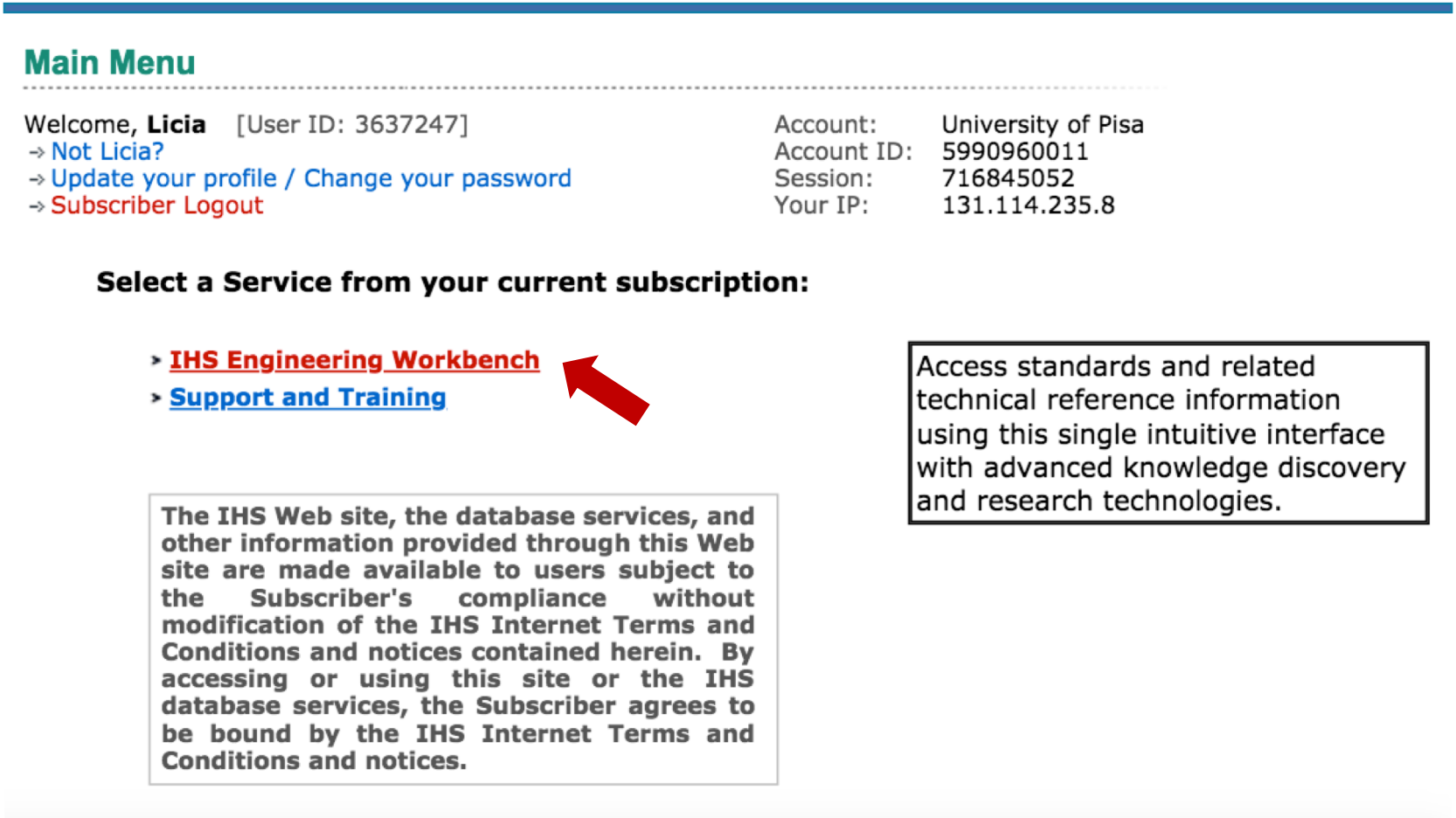

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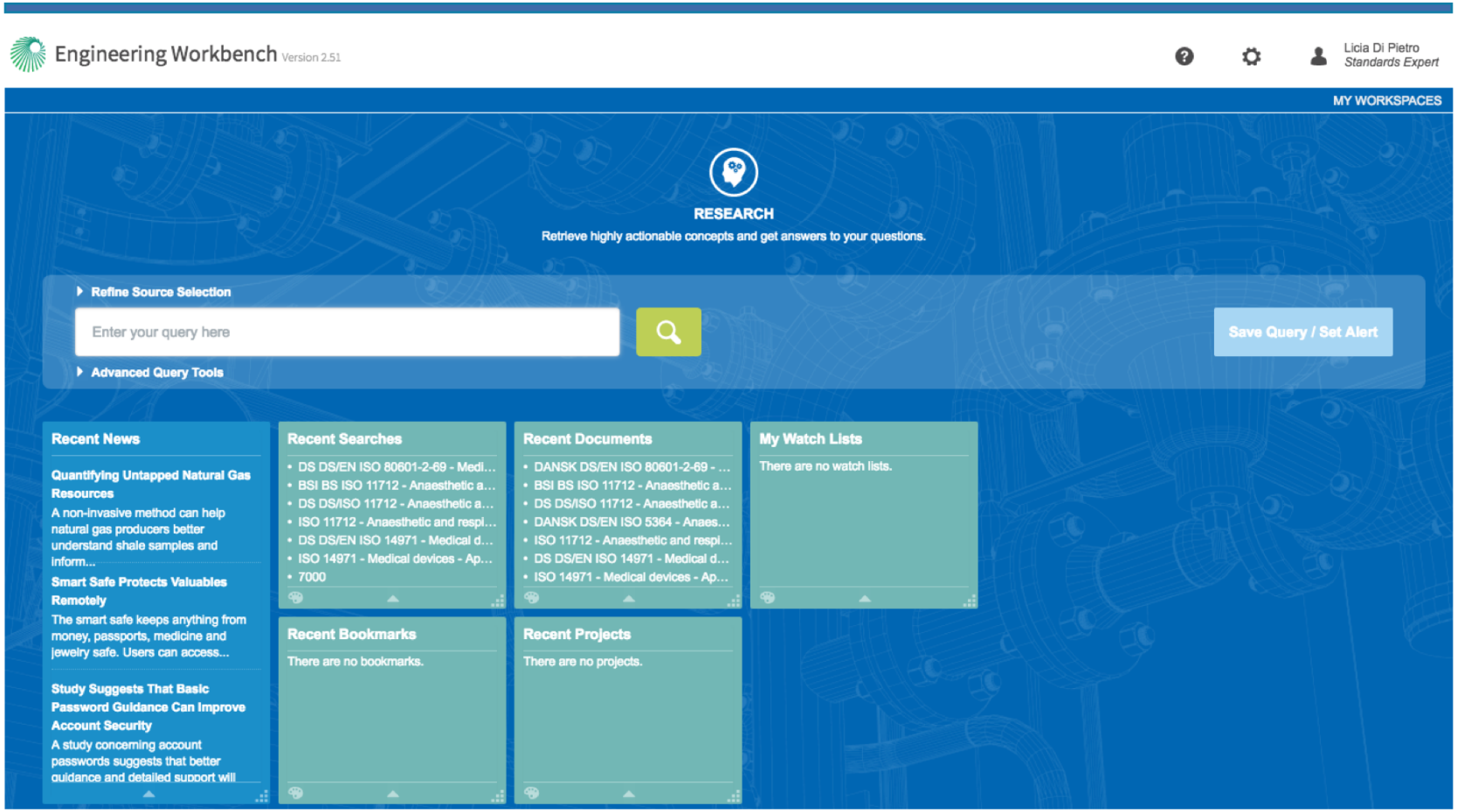

EN - How to download a standard? (5/5)

CEI - How to download a standard? (1/8)

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English

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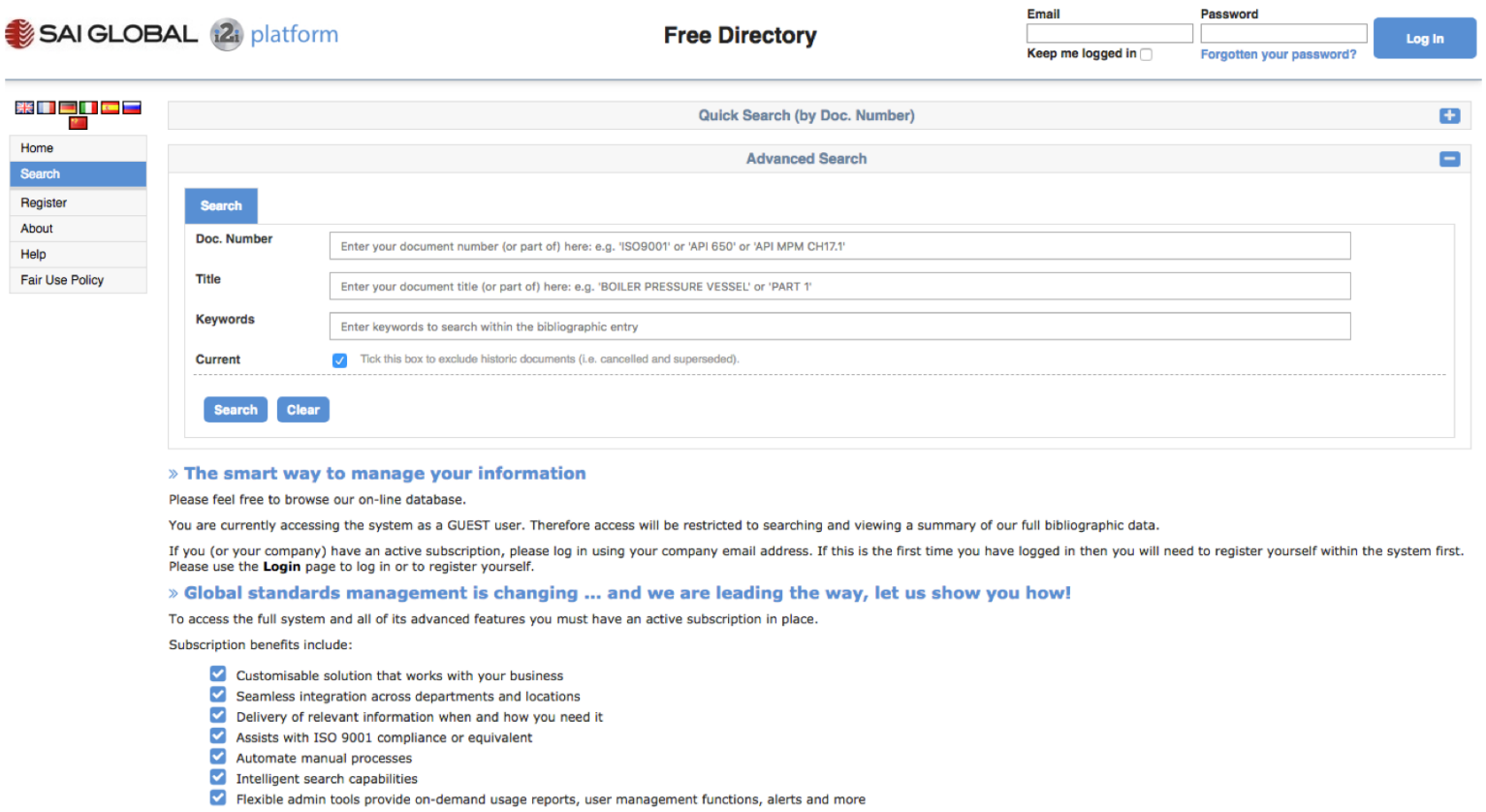

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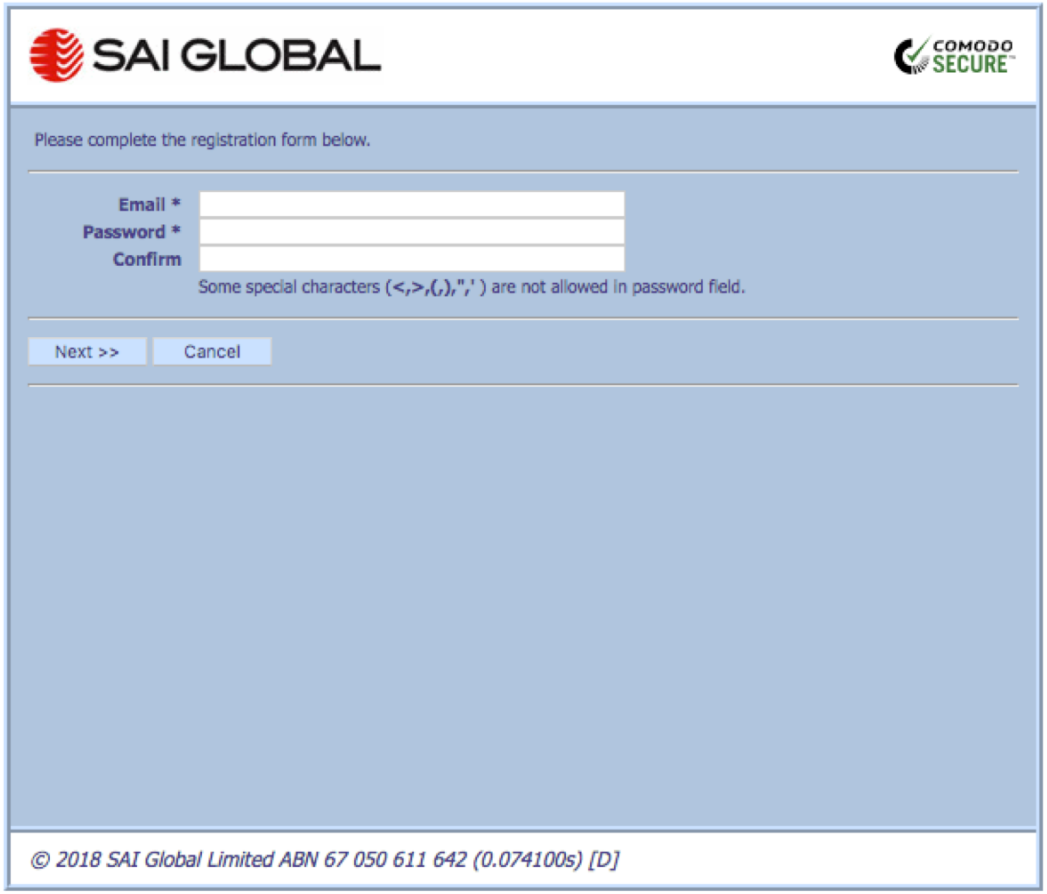

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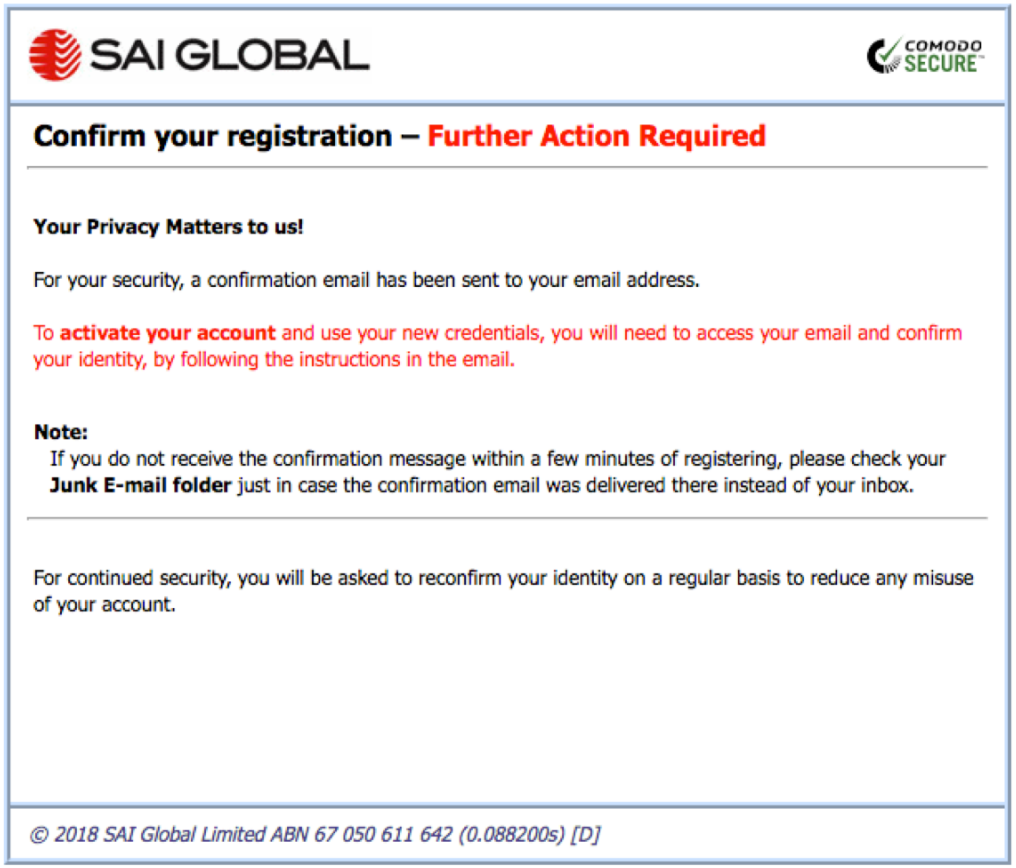

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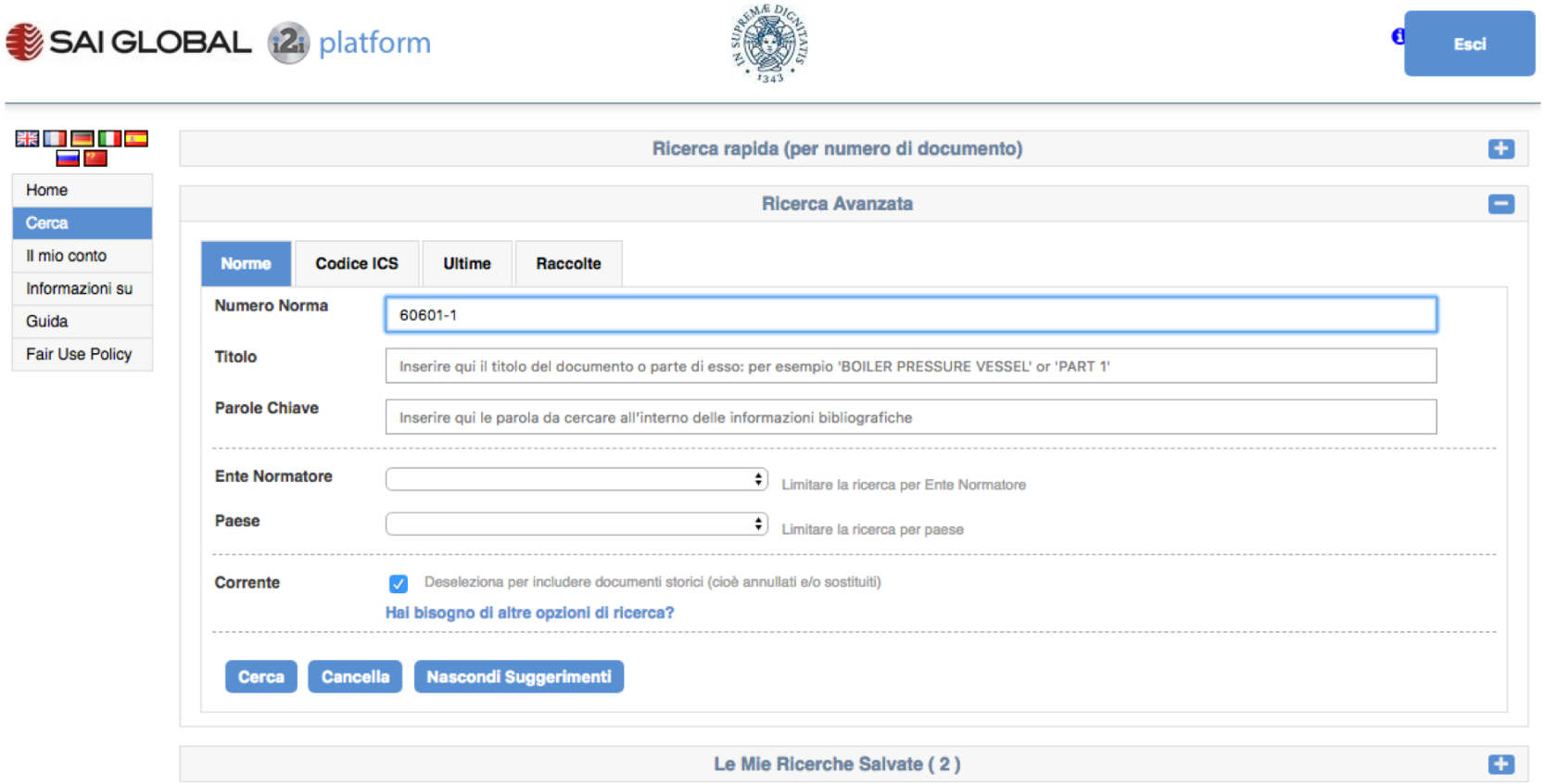

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