



Editorial

Dear Reader,

At the end of 2016, we can look back on a very exciting year with far-reaching changes in many regards, and particularly in terms of privacy and data protection. Since the entry into force of the GDPR last spring, EuroPriSe has put a great deal of effort into preparing itself for the future regulatory framework, which will apply starting late May 2018. The tasks to be accomplished include EuroPriSe's accreditation as a certification body under the GDPR and the adaptation of our certification scheme to the new legal framework.

Very recently, we reached an important milestone on the road to being fully prepared for offering our certification services under the umbrella of the GDPR. In mid-December, we managed to complete an update of our certification criteria for products and services which focused on bringing them in accordance with the new legal requirements for the processing of personal data. It is worth noting that we incorporated the feedback of the members of our Advisory Board into the final version of the updated criteria document. This means that our certification criteria for products and services are now "GDPR-ready" and can be used for upcoming certification projects starting January 2017.

On behalf of EuroPriSe CA, Stefan Drost and I wish you a Merry Christmas and a Happy New Year!

Yours,

Sebastian Meissner

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GENERAL DATA PROTECTION REFORM

GDPR-adjusted certification criteria ready for use

The entry into force of the General Data Protection Regulation in spring 2016 marked a caesura in the development of EU data protection law, with a major impact on the entire privacy community and, not least, on EuroPriSe.

Right after the final version of the GDPR became known, EuroPriSe Certification Authority (CA) commenced work on an update of the certification criteria for IT products and IT-based services. The overall objective of this work was to incorporate the new legal provisions of the GDPR into the EuroPriSe criteria catalogue. It soon became apparent that this task did not require a revision of the tried and tested general structure of the certification criteria. That implies that the four basic sets to which the criteria are assigned could remain unchanged. Namely, these include:

1. overview on fundamental issues,
2. legitimacy of data processing,

3. technical-organisational measures,
4. and data subjects' rights.

There was, however, a clear need to make amendments to quite a few of the existing subsets of the criteria and to even add a new subset. This new subset gathers a multitude of general requirements relating to topics such as the maintenance of a record of processing activities, the designation of a data protection officer, the designation of a representative in the EU, the conduct of a data protection impact assessment and the notification of a personal data breach. The main modifications of existing subsets can be summarised as follows: In Set 1, it is now clearly distinguished between data protection by design and data protection by default. New requirements dealing with topics such as processing of sensitive data for archiving, research or statistical purposes or processing of genetic or biometric data were added to Subset 2.1 ("legal basis"). Additional amendments of Set 2 concern the introduction of a specific requirement dealing with processing of personal data relating to children and the addition of further general data protection principles such as integrity, confidentiality and accountability to the respective Subset 2.5. Finally, some new requirements approaching topics such as the right to data portability and processing that does not require identification now form part of Set 4 of the criteria catalogue.

In addition, EuroPriSe CA also took the opportunity to adjust the catalogue to the effect that it distinguishes even more clearly between the certification of IT products and IT-based services. More precisely, the

document now poses specific questions that are tailored to products, controller services (service provider = controller) and processor services (service provider = processor). One important reason for this is that there are quite some differences between products and processor services on the one hand and controller services on the other hand when it comes to the legal evaluation according to EuroPriSe. While it is clearly feasible to evaluate the legal compliance of a controller service once and for all, this is not possible for IT products and processor services, since it is the user of the product or service who finally determines the purposes of the processing and who, thus, qualifies as a controller in data protection terms. In the latter scenarios, the legal evaluation must focus on and is somewhat limited to topics such as privacy-friendly default settings and documentation.

In early December 2016, the EuroPriSe Advisory Board met for the third time to discuss GDPR-related topics. A full-fledged draft version of the updated criteria catalogue had been distributed to the members of the Advisory Board prior to the meeting. During the session, board members provided their feedback on the updated certification criteria; this was generally positive but contained some suggestions of how to further improve the readability and understandability of the overall criteria catalogue. Subsequent to the meeting, EuroPriSe CA produced a final version of the catalogue, thereby taking into account all of the recommendations that had been made by the members of the board. This final version has already been



published on the EuroPriSe website and can be used for new certification projects starting January 2017. Hereby, EuroPriSe provides its existing and future clients with the opportunity to prove from day 1 of the GDPR's applicability in late May 2018 that they comply with the new legislative framework.

► **Further information:**

<https://www.european-privacy-seal.eu/EPSe-en/Criteria>

EuroPriSe's GDPR-related activities on EU level in 2016

In summer 2016, EuroPriSe CA travelled to Brussels several times to discuss the new legal framework in general, as well as the GDPR's provisions regarding data protection certification mechanisms and data protection seals and marks. In particular, this was discussed with stakeholders such as the Article 29 Working Party (WP29) and the European Commission (EC).

At first, CA met with several members of the Commission's data protection unit at the beginning of July to exchange views on the new legal framework for certification mechanisms and seals (cf. Articles 42 f. GDPR). It was confirmed during the meeting that the European Commission had EuroPriSe in mind as a role model when drafting the respective legal provisions at the beginning of the legislative procedure regarding the General Data Protection Regulation. Furthermore, CA's dialogue partners stated that the Commission continues to support and encourages EuroPriSe's certification activities.

Still in July, CA participated in the Article 29 Working Party's Fablab on the GDPR.

At the event, more than 90 participants representing data protection authorities, industry, civil society, academics and relevant associations discussed certain operational and practical issues regarding the GDPR. The Fablab's objective was to provide input to the working party, in order to develop best practices and guidelines with regards to the following topics:

- data protection officer,
- data portability,
- data protection impact assessment,
- and certification.

Prior to the event, EuroPriSe had been invited to moderate the workshop on certification, which dealt with the definition of criteria and mechanisms relating to certification and certification bodies. During the Fablab, CA had the opportunity to talk to, among others, Ms. Isabelle Falque-Pierrotin, chairman of the Article 29 Working Party and of the French data protection authority CNIL, and Mr. Giovanni Buttarelli, European Data Protection Supervisor. The results of the Fablab have been made publicly available in the meantime.

In December, the Article 29 Working Party announced that it will adopt guidelines with respect to certification in the course of 2017. When drafting these guidelines, the outcome of the workshop on certification during the Fablab will be taken into account. It has already been indicated to EuroPriSe that it may be invited to participate in one of the sessions, during which the responsible subgroup of the working party is going to

discuss the content of the future guidelines on certification.

Finally, EuroPriSe CA attended a workshop on the GDPR, hosted by the European Commission, which took place the day after the Fablab. A particular focus of this event was on codes of conduct and certification. The keynote speech for it was delivered by Ms. Vera Jourova, Commissioner for Justice, Consumers and Gender Equality. During the event, CA talked to Paul Nemitz, Director for Fundamental Rights and Union Citizenship in the European Commission's Directorate-General for Justice and Consumers, who reaffirmed that the Commission continues to support EuroPriSe.

► **Further information:**

http://ec.europa.eu/justice/data-protection/article-29/documentation/other-document/files/2016/20160930_fablab_results_of_discussions_en.pdf

http://ec.europa.eu/newsroom/document.cfm?doc_id=40853

<https://www.bna.com/eu-certificate-may-n73014446298/>



NEWS FROM EUROPRISE

Selection of Awarded Seals

European Privacy Seal for teamplay (Siemens Healthineers)

In October 2016, Siemens Healthineers were awarded the EuroPriSe seal for the teamplay cloud-based service for monitoring dose levels and imaging system efficiency.

Siemens Healthineers provide the cloud-based service teamplay that can be accessed via <https://teamplay.siemens.com> teamplay enables hospitals and other medical facilities to monitor the utilization efficiency of their medical imaging devices as well as radiation doses. This helps them to improve their image acquisition procedures and ensure that radiation doses are as low as reasonably possible to meet clinical needs. teamplay consists of web-based services and a software-only gateway (the "teamplay receiver") that acts as an intermediary between hospital systems and the web-based services.

In respect to the amount of patient data to be processed, Siemens Healthineers provide different options to the users of the service. If a user chooses the strictest of the preconfigured settings of the service ("privacy profiles"), then only anonymous data is processed by teamplay. When one of the two remaining privacy profiles is chosen, patient data is de-identified, but still constitutes personal data.



The responsibility for the lawful processing of patient data lies with the users of the service. Siemens Healthineers inform (prospective) users of the service about the fact that it is their responsibility to collect patients' consent and release from medical confidentiality prior to uploading patient data to teamplay if they choose a privacy profile which does not provide for anonymization of patient data.

The evaluation according to EuroPriSe was conducted by Dr. Irene Karper (legal expert) and Ralf von Rahden (technical expert). One particular focus of the evaluation was on the examination of the de-identification of patient data.

The result of the evaluation was that the teamplay receiver completely removes data types that could be used for (re-)identification of

patients or reliably replaces them with a pseudonym or a less precise value in accordance with the selected privacy profile.

► **Further information:**

<https://www.european-privacy-seal.eu/EPS-en/siemens-healthcare-teamplay>

Photo by Siemens AG



European Privacy Seal for Qentry (Brainlab)

In April 2016, Brainlab AG was awarded with the European Privacy Seal for its cloud-based service Qentry for the collaboration of medical professionals.

Munich-based enterprise Brainlab AG provides the cloud-based service Qentry that can be accessed via <https://www.qentry.com>. Qentry enables medical professionals to share medical images, to display medical images in a web-based viewer and to add comments such as medical opinions.

The responsibility for the lawful processing of patient data lies with the users of the service. They are advised by Brainlab that the legitimate use of Qentry requires the collection of patients' informed consent and release from medical confidentiality and that they are obliged to verify the identity of other users in a reliable way prior to sharing medical information with them.

The evaluation according to EuroPriSe was conducted by Johanna Laas (legal expert) and Dr. Michael Foth (technical expert). One particular focus of the evaluation was on the examination of the multi-layered encryption solution that is employed by Brainlab to ensure the confidentiality of patient data that is processed within Qentry.

The result of the technical evaluation was that this innovative solution approximates the level of a true end-to-end encryption to the greatest extent possible under the given circumstances.



► Further information:

<https://www.european-privacy-seal.eu/EPS-en/>

Photo by Brainlab AG



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Season's greetings and
best wishes for a Happy
New Year!

