AIR2
Access to INFRASTRUCTURES for Radiation protection Research

Special Issue 12
May 2020

Editorial

VERIDIC, a project selected during the second call for projects of CONCERT, is dedicated to the radioprotection of patients. Of course, in a medical context, people are, knowingly and deliberately, exposed for their own benefit. However, the reduction of global doses during diagnostic examinations or those to healthy tissues during therapies must be able to benefit from all the advances in science and new technologies. This subject is a priority for MELODI, EURADOS and EURAMED. The prerequisite for a dose reduction is to know how to calculate it precisely for each individual. This is the challenge that VERIDIC has set itself in order to reduce the doses to the skin in interventional cardiology, taking into account the variety of manufacturers and the numerous software used in hospitals.

Dr Laure Sabatier, CEA

The floor to...

VERIDIC — Validation and Estimation of Radiation skIn Dose in Interventional Cardiology

During interventional cardiology (IC) procedures, patients may be exposed to high doses to the skin resulting in tissue reactions. The growing number and complexity of IC procedures has further increased the need for patient-specific dose calculation.

To address this issue, online and offline software exist to estimate the maximum skin dose (MSD) to the patient from IC procedures. However, the capabilities and accuracy of such skin dose calculation (SDC) software to estimate MSD and 2D dose distributions markedly differ among vendors; but there is currently no acceptance testing and quality control (QC) protocols of such systems. In addition, the reporting of the MSD estimate is neither systematic nor harmonised among the software solutions.

The objective of the VERIDIC project was to contribute to the harmonisation and the validation of SDC software products in IC.

Firstly, the existing software solutions were reviewed according to their capacities and features and a complete list of parameters necessary to calculate MSD and 2D dose distribution was made. This served as a basis for recommendations for procedure parameter archiving and MSD recording.

Secondly, acceptance and quality control (QC) testing protocols for the accuracy of SDC software in interventional cardiology were developed. Measurements were performed following the protocols to benchmark four angiographic units from the main manufacturers and 10 SDC software solutions. In support of the measurements, a comprehensive calibration and uncertainty assessment of the field dosimeters used for software validation was performed.

Thirdly, technical and clinical parameters from high-dose procedure were collected from 8 European countries and 12 hospitals. The correlation between key parameters and patients' exposure was investigated in order to identify potentially high-dose procedures and formulate recommendations for dose reduction.

VERIDIC Coordinator
Ir. Jérémie Dabin, Research in Dosimetric Applications

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Photo: SCK CEN

CONCERT CORNER

VERIDIC Validation and Estimation of Radiation skIn Dose in Interventional Cardiology

Keywords:
Interventional Cardiology, Skin Dose, Patient, Dose Mapping, Radiation Protection

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Duration:
24 months (2018-2020)

Total project budget:
705 100 €

Project website:
https://www.researchgate.net/project/VERIDIC-Validation-and-Estimation-of-Radiation-skIn-Dose-in-Interventional-Cardiology

Open Access of produced data:
No, owing to protection of patient privacy.
All publications will be open-access.

Related to:
EURADOS
EURAMED

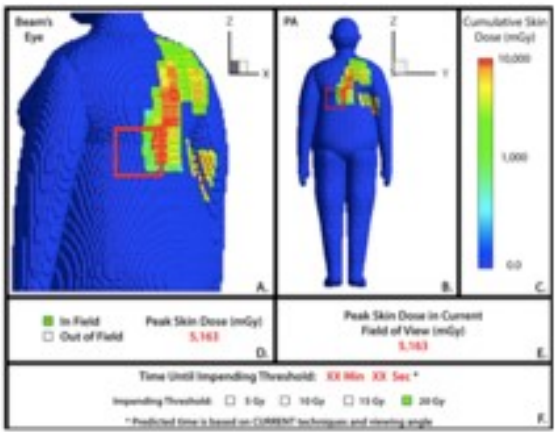
Contents:

EUROPEAN JOINT PROGRAMME FOR THE INTEGRATION OF RADIATION PROTECTION RESEARCH
CONCERT
HORIZON 2020

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287

Standards for digital dose reporting

In interventional cardiology (IC), patients may be exposed to high doses to the skin resulting in tissue reactions (e.g. skin burns) following single or multiple procedures. Assessing the maximum skin dose (MSD) to the patient together with the dose distribution during (or after) these procedures is, as recommended by the ICRP Committee 3, essential from patient radiation protection point of view.



Example of dose mapping - Unversity of Florida

The VERIDIC project focused on the harmonization of RDSR and on the validation of SDC software products, which will optimise radiation protection of patients. Among the overall project objectives, the Work Package 1 (WP1) dealt with the SDC harmonization issue in the view of proposing a possible standardisation of the digital dose reporting. Two different sub-tasks were carried out: (i) The review of existing software and (ii) the harmonization of dose reporting and tracking.

In the first subtask (i), 19 software tools claiming SDC capacities were identified in the literature and reviewed according to their SDC algorithms and their capabilities. Special attention was dedicated to their main features and limitations of interest for the clinical user. In the second subtask (ii), RDSRs from recent systems of the four main manufacturers (Philips, Siemens, GE and Canon) were compared with a view to identifying the availability and the completeness of the data necessary for the calculation. The ability of two dose management systems to extract RDSR data was also investigated by comparing their output with the original RDSR.

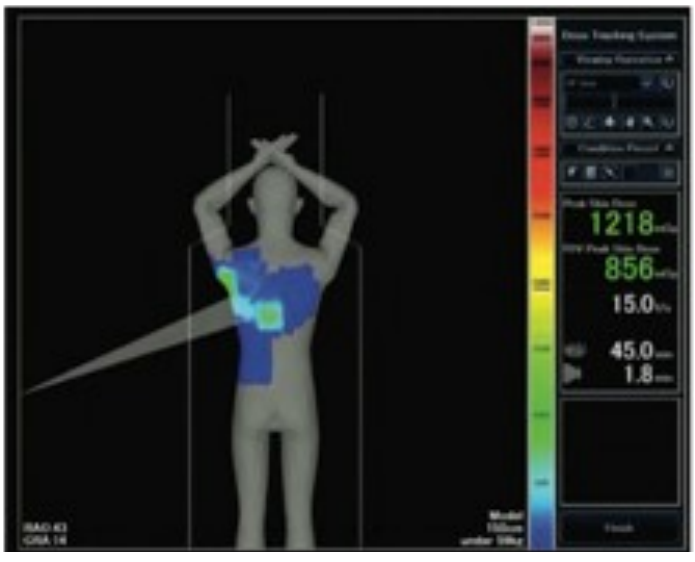
Although most SDC software tools use a comparable approach to estimate the skin dose, considerable differences in the implementation exist. While the accuracy of the 10 SDC products which were experimentally validated with measurements on phantoms, was acceptable (within ±25%); the agreement was poor for the two products which were also validated on patients (within ±43% and ±76%, respectively). In addition, no software has been validated on angiographic units from all manufacturers, though several software developers claimed vendor-independent transportability.

Photo: CAATS

F. Malchair & C. Maccia

Strong heterogeneities in examination related technical parameters encoded in RDSR by the manufacturers were found, especially important for all dose calculation related data; even more heterogeneities were pointed out when considering the DICOM fields exports through two dose management software products. This highlighted the need for harmonizing both RDSRs and their exports in order to be able to calculate MSD from these data in an easy and straightforward way.

Essential parameters for MSD calculation and dose mapping were listed and should be included in both RDSRs and exports. A public DICOM field to store MSD was suggested, as well as the use of the existing field to store final dose maps.



Example of dose mapping (DTS - Canon)

ID Card:

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D9.141 - Standards for digital dose reporting, available at https://concert-h2020.eu/en/Publications
Patient dosimetry for x rays used in medical imaging, J ICRU (2005), 5 (2):iv-vi, doi:10.1093/jicru/ndi018
Medical Electrical Equipment–Part 2-43: Particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Interventional Procedures, International Electrotechnical Commission, Geneva, 2010. IEC 60601-2-43. 2010

Commissioning and quality control protocols for skin dose calculation software

Acceptance and quality control (QC) testing protocols for the accuracy of skin dose calculation (SDC) software in interventional cardiology were developed. The acceptance protocol is composed of 13 fundamental irradiation set-ups and 3 clinical procedures, intended to represent more realistic conditions. The QC protocol is based upon the acceptance protocol and is made of 8 fundamental irradiation set-ups.

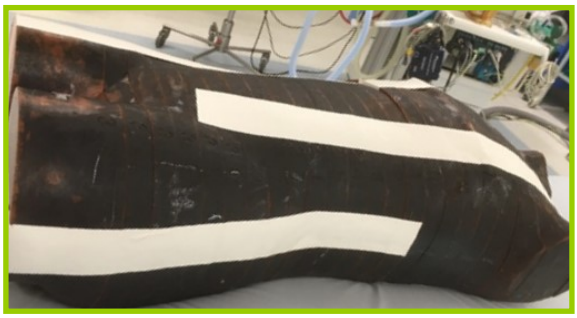


Photo: CAATS

Anthropomorphic phantom (type Rando-Alderson) used for the benchmarking of the skin dose calculation software solutions

Prior to measurements, solid-state dosimeters (multimeters), gafchromic films and thermoluminescent dosimeters were thoroughly calibrated using newly defined primary standards representative of beam qualities encountered in interventional cardiology (IC). The uncertainty associated with skin dose measurements was carefully assessed. Skin dose measurements were then performed following the acceptance protocol on four angiographic systems: a GE Innova IGS 540, a Philips Allura Xper, a Siemens Artis Zee biplane and a Canon Infinix CF-i biplane. Skin dose was then calculated with up to 10 SDC software solutions, depending on their compatibility with the angiography units: CareMonitor, Dose Tracking System, DOSE by Qaelum, DoseMap, em.dose, OpenSkin, Radiation Dose Monitor, DoseWatch Skin Dose Map (two versions) and SkinCare.

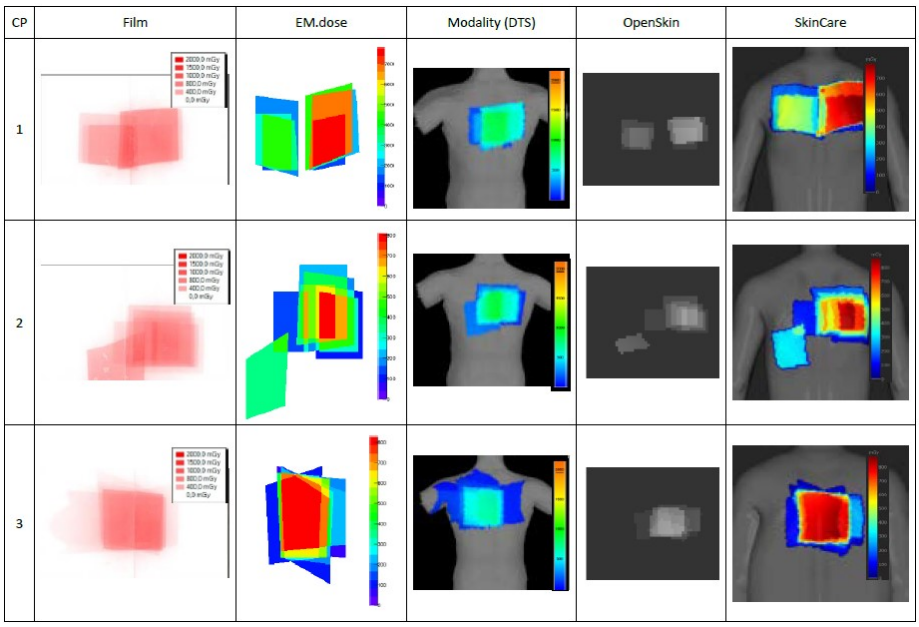
The maximum skin dose (MSDs) estimated by most SDC software products was within ±40% of the measurements during the basic beam projections and the clinical procedures. However, approximately half of the software products could not provide MSD estimates for lateral beam projections because a flat phantom was used. Among the remaining software products, accuracy of the MSD estimate for lateral projections was quite variable and could be very poor, with under/over-estimation greater than 60%. The dimensions, the shape and the relative position of the MSD region for most SDC software maps were acceptable. Some software products, however, could miss the MSD region when situated at the thin intersection of multiple fields.

Photo: SCK CEN

Jérémie Dabin

SDC software solutions can produce acceptable results and may include fine technical details of the procedure as calculation input; however, the determination of the patient body contour and position remains challenging. This can dramatically degrade the software accuracy particularly for lateral projections and those that are not centred on the patient's back.

Photo: SCK CEN



Dose maps as measured with films on the back of a Rando-Alderson phantom for three clinical procedures using a Canon system and as calculated with SDC software (from D9.143)

D9.142 – Dosimeter calibration and measurement uncertainties in Interventional Cardiology, available at https://concert-h2020.eu/en/Publications

D9.143 - Acceptance and quality control protocols for skin dose calculating software solutions in interventional cardiology, available at https://www.concert-h2020.eu/en/Publications

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- French Alternative Energies and Atomic Energy Commission (CEA)
- University Hospital of Geneva (HUG)
- University Hospital of Lausanne (CHUV)
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- University Hospital Limerick (UHL)

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Exposure platforms:
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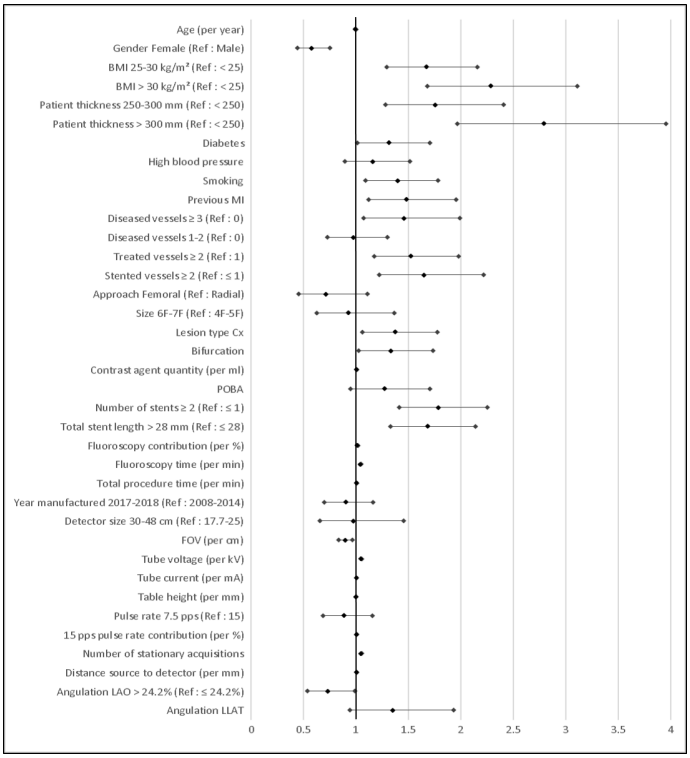
Special Issue 12
May 2020

Investigation of skin dose determinants and optimisation of medical practice

This WP aimed at identifying key clinical and technical parameters which affect patients' exposure in interventional cardiology (IC) and establishing predictive models of peak skin dose (PSD).

WP3 analyzed prospectively collected patient data from 8 European countries and 12 hospitals performing PCI (Percutaneous Coronary Intervention), CTO (Chronic Total Occlusion Percutaneous Coronary Intervention) and TAVI procedures (Trans catheter Aortic Valve Implantation).



Forest plots univariate analysis results for PCI procedures and PSD. Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval.

Two surveys were developed containing 62 clinical complexity parameters and 31 technical parameters. Univariate regressions were performed to identify key parameters affecting PSD. Multiple linear regressions models were next used to examine independent associations between exposure data (PKA, $K_{a,r}$, PSD) and the significantly associated variables identified in the univariate analysis. A priori predictive models were then built using stepwise multiple linear regressions and considering clinical complexity parameters available before the procedure. A posteriori models were similarly developed using both clinical and technical parameters. A 4-fold cross validation was performed with 75% of the data used to generate and train the model estimation of PSD while the remaining data was used for validation.

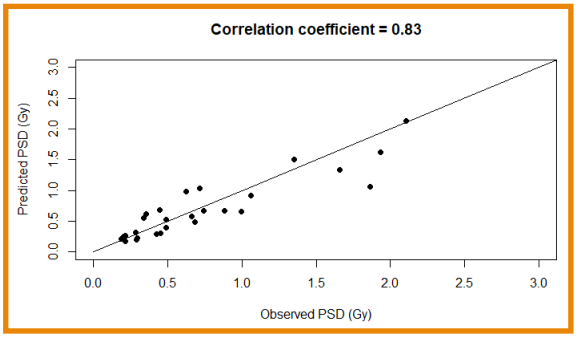
Patient exposure, clinical and technical parameters were collected for a total of 962 procedures including 534 PCI, 219 CTO and 209 TAVI. For PCI procedures, the three most prominent clinical parameters on PSD were BMI/patient thickness, number of stents and total stent length, while the technical parameters included fluoroscopy time, tube voltage and number of stationary acquisitions. Similarly, for CTO procedures these were total stent length, BMI/patient thickness and previous anterograde/retrograde technique that failed in the same session. As for technical parameters and CTO: number of stationary acquisitions, tube voltage and fluoroscopy time. For TAVI procedures these were sex, BMI and number of diseased vessels. Technical parameters for TAVI procedures were tube voltage, stationary acquisition (cine mode) and fluoroscopy time.

Photo: APHP

Joëlle Ann Feghali

Multivariate analysis from which a posteriori models were developed for PCI procedures, showed limited impact of clinical parameters on PSD which increased with fluoroscopy time, tube voltage, current and source to detector distance. For CTO procedures, age, BMI, sex, number of fluoro/cine acquisitions as well as sheath size were determinant factors increasing PSD. For TAVI procedures, sex, age, fluoroscopy time and stationary acquisition (cine mode) were most prominent in predicting PSD. The a priori models did not perform very well as the overall correlation coefficient was <0.6 for PCI, CTO and 0.58 for TAVI procedures. A posteriori models combining clinical and technical parameters showed better performance (correlation coefficient was 0.89 for PCI, 0.67 for CTO and 0.65 for TAVI) demonstrating that technical parameters are the most influential inputs on patient exposure.

Prior knowledge of the key factors influencing skin dose will help optimize patients' radiation protection in IC. A priori models can provide a rough estimate of PSD at the start of the procedure while a posteriori models would provide finer PSD values when proper calculation software are not available.



Correlation between predicted and observed PSD for a posteriori model in PCI procedures

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- Veneto Institute of Oncology (IOV -IRCCS)
- Greek Atomic Energy Commission (EEAE)
- University of Belgrade, Vinca Institute of Nuclear Sciences (VINCA)
- University Hospital Limerick (UHL)
- Ruđer Bošković Institute (RBI)

Infrastructures:
Hospitals: 251 Airforce General Hospital, Greece; Clinical Center of Serbia, Serbia; Euroclinic Hospital, Greece; Hôpital Européen Georges Pompidou, France; Hôpital Laribosière, France; University Hospital Centre Zagreb, Croatia; University Hospital Limerick, Ireland; University Hospital of Geneva, Switzerland; University Hospital of Padua, Italy; Ygeia Hospital, Greece

Databases: Multicentric database of high-dose procedures

Models and tools: Univariate, Multivariate and Predictive Models (stepwise multiple linear regressions), R statistical software

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D9.144 - Investigation of skin dose determinants and optimisation of medical practice, available at **https://concert-h2020.eu/en/Publications**

Results of the European VERIDIC project WP3. Part 1: Patient exposure and peak skin dose in interventional cardiology per clinical and technical complexity levels, Feghali et al (2020), in preparation

Results of the European VERIDIC project WP3. Part 2: Establishing a priori and a posteriori predictive models to assess patients' peak skin dose in interventional cardiology, Feghali et al (2020), in preparation

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Access to INFRASTRUCTURES

Issue	Exposure platforms	Databases, Sample banks, Cohorts	Analytical platforms, Models & Tools
Published to date:			
Oct 2015, #1	FIGARO	FREDERICA	RENEB
Nov 2015, #2	B3, Animal Contamination Facility	The Wismut Cohort and Biobank	The Hungarian Genomics Research Network
Dec 2015, #3	Pulex Cosmic Silence	STORE	METABOHUB
Feb 2016, #4	SNAKE	French Haemangioma Cohort and Biobank	Dose Estimate, CABAS, NETA
Mar 2016, #5	Radon exposure chamber	3-Generations exposure study	PROFI
Apr 2016, #6	Biological Irradiation Facility	Wildlife TransferDatabase	Radiobiology and immunology platform (CTU-FBME)
May2016, #7	CIRIL	Portuguese Tinea Capitis Cohort	LDRadStatsNet
Jun 2016, #8	Mixed alpha and X-ray exposure facility	Elfe Cohort	ERICA Tool
Jul 2016, #9	SCRS-GIG	RES^{3}T	CROM-8
Sep 2016, #10	Facility radionuclides availability, transfer and migration	INWORKS cohort	France Génomique
Oct 2016 #11	LIBIS gamma low dose rate facility ISS	JANUS	Transcriptomics platform SCKCEN
Nov 2016, #12	Microtron laboratory	EPI-CT Scan cohort	CATI
Dec 2016, #13	Nanoparticle Inhalation Facility	UEF Biobanking	The Analytical Platform of the PREPARE project
Feb 2017, #14	Infrastructure for retrospective radon & thoron dosimetry	Chernobyl Tissue Bank	HZDR Radioanalytical Laboratories
Special Issue 1	1st CONCERT Call: CONFIDENCE, LDLensRad, TERRITORIES	1st CONCERT Call: CONFIDENCE, LDLensRad, TERRITORIES	1st CONCERT Call: CONFIDENCE, LDLensRad, TERRITORIES
Mar 2017, #15	Alpha Particles Irradiator Calibration Laboratory at KIT		SYMBIOSE
Apr 2017, #16	Changing Dose rate (SU) Low dose rate (SU)		Advanced Technologies Network Center
May 2017, #17	Chernobyl Exclusion Zone	Chernobyl clean-up workers from Latvia	BfS whole and partial body Counting
Jun 2017, #18	MELAF	Belgian Soil Collection	INFRAFONTIER
Jul 2017, #19	MICADO'LAB	Estchern Cohort	ECORITME
Sep 2017, #20	DOS NDS		CERES
Oct 2017, #21	CALLAB Radon Calibration Laboratory		CORIF
Nov 2017, #22	Calibration and Dosimetry Laboratory (INTE-UPC)	German airline crew cohort	Centre for Omic Sciences (COS)
Dec 2017, #23	NMG	Techa River Cohort (TRC)	iGE3
Special Issue 2	MEDIRAD	MEDIRAD	MEDIRAD
Feb 2018, #24	UNIPI-AmBe	Greek interventional cardiologists cohort	SNAP

Future events:

CONCERT Short Courses

18-29 May 2020

Modelling radiation effects from initial physical events,
University of Pavia, Italy
Contact:
Andrea Ottolenghi

To verify for modifications due to the COVID-19 outbreak!

See also on CONCERT website

Editorial Committee: Maria Panagiotopoulou, Jean-Michel Dolo, Laure Sabatier

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Access to INFRASTRUCTURES

Issue	Exposure platforms	Databases, Sample banks, Cohorts	Analytical platforms, Models & Tools
Published to date:			
Special Issue 3	2nd CONCERT Call: LEU-TRACK, PODIUM, SEPARATE, VERIDIC, ENGAGE, SHAMISEN-SINGS	2nd CONCERT Call: LEU-TRACK, PODIUM, SEPARATE, VERIDIC, ENGAGE, SHAMISEN-SINGS	2nd CONCERT Call: LEU-TRACK, PODIUM, SEPARATE, VERIDIC, ENGAGE, SHAMISEN-SINGS
Mar 2018, #25	IRRAD	MARiS	BIANCA
Apr 2018, #26	Forest observatory site in Yamakiya	BBM	OEDIPE
May 2018, #27	Belgian NORM Observatory Site	The German Thorotrast Cohort Study	VIB Proteomics Core
Jun 2018, #28	CERF	Mayak PA worker cohort	Geant4-DNA
Jul 2018, #29	TIFPA	RHRTR	D-DAT
Sep 2018, #30	HIT	The TRACY cohort	COOLER
Oct 2018, #31	PTB Microbeam	The BRIDE platform	BRENDA
Nov 2018, #32	AGOR Facility at KVI-CART LNK		MARS beamline at SOLEIL
Dec 2018, #33	PARISII	The ISIBELa cohort	CIEMAT WBC
Feb 2019, #34	The MIRCOM microbeam	The ISE cohort	EFFTRAN
Special Issue 4	NSRL	LSAH & LSDA	GeneLab
Mar 2019, #35	IRSE Experimental Farm	The MWF database	DSA Environmental Laboratory
Apr 2019, #36	PG stack at Barreiro, Portugal	CONSTANCES	The MCDA Tool
May 2019, #37	LERF	IMMO-LDRT01 cohort	Radiochemical and Radioactive Analysis Laboratory (INTE-UPC)
Jun 2019, #38	FAIR	The BACCARAT study	CIEMAT *In Vitro* Internal Dosimetry Laboratories
Jul 2019, #39	AMBIC	LSS	LRM
Sep 2019, #40	FRM II	REQUITE	TU Dublin Analytical Platform
Special Issue 5	CONFIDENCE	CONFIDENCE	CONFIDENCE
Special Issue 6	PODIUM	PODIUM	PODIUM
Special Issue 7	LDLensRad	LDLensRad	LDLensRad
Special Issue 8	ENGAGE	ENGAGE	ENGAGE
Special Issue 9	LEU-TRACK	LEU-TRACK	LEU-TRACK
Special Issue 10	CIEMAT External Dosimetry Service and Retrospective Luminescence Dosimetry Lab, AIFIRA Microbeam, The Calliope Facility, ZATU	The 'hematopoietic system' database for Mayak nuclear workers chronically exposed to ionizing radiation	
Special Issue 11	TERRITORIES	TERRITORIES	TERRITORIES
Special Issue 12	VERIDIC	VERIDIC	VERIDIC

Future events:

Other Events

1st ISORED scientific and organisation meeting, Sitges, Spain:
Postponed until spring 2021 because of the COVID-19 pandemic. The new dates will be communicated soon.

ERPW2020: European Radiation Protection Week 2020, Estoril, Portugal:
Postponed to 2021. More information to be announced soon.

To verify for modifications due to the COVID-19 outbreak!

Editorial Committee: Maria Panagiotopoulou, Jean-Michel Dolo, Laure Sabatier