ISTITUTO CLINICO
HUMANITAS
Istituto di Ricovero e Cura
a Carattere Scientifico

We manage our sterilization errors: do you?

WFHSS
WORLD FORUM FOR HOSPITAL STERILE SUPPLY

G.O.R.N.A.
GREEK OPERATING NURSES ASSOCIATION

10th World Congress of Sterilization
7 – 10 October, Crete, Greece

Paolo TURRI, Chiara OGGIONI

Aim of the Lecture

- **Analyze the improvement gained in the sterilization process through the new traceability management system**

- **Identify process errors through an incident reporting system finalized to a continuous quality improvement**

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- Our Hospital: IRCCS Istituto Clinico Humanitas
- Sterilization process and traceability system
- Risk management and sterilization process errors
  - ✓ Activity data
  - ✓ Incident reporting system
  - ✓ Error analysis
- Corrective actions and Conclusions

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Our Hospital: IRCCS Istituto Clinico Humanitas

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Milano, Italy

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Our Hospital: IRCCS Istituto Clinico Humanitas

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21 Wards
747 Beds

72 Day Hospital Beds

Emergency Department

6 Operating Theatres

25 Operating Rooms

24 Intensive Care Beds

5 Angiography Rooms

10 Physiotherapy Boxes

140 Outpatient Clinic Rooms

University Research Center

IRCCS Gastroenterology

IRCCS
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Our Hospital: overall activity data (2008)

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Inpatient NHS		**42.187**
Surgery	**28.262**	
Admission NHS	**24.890**	
Admission DH		**14.765**
Admission ED		**7.218**
Admission Rehab	**2.531**	
Outpatient		**1.061.957**
Inpatient Insurance		**3.533**
Admission Insurance		**1.909**
Admission DH Insurance	**1.624**	

Impact factor 2008	**938**
Impact factor overall	**3.958**

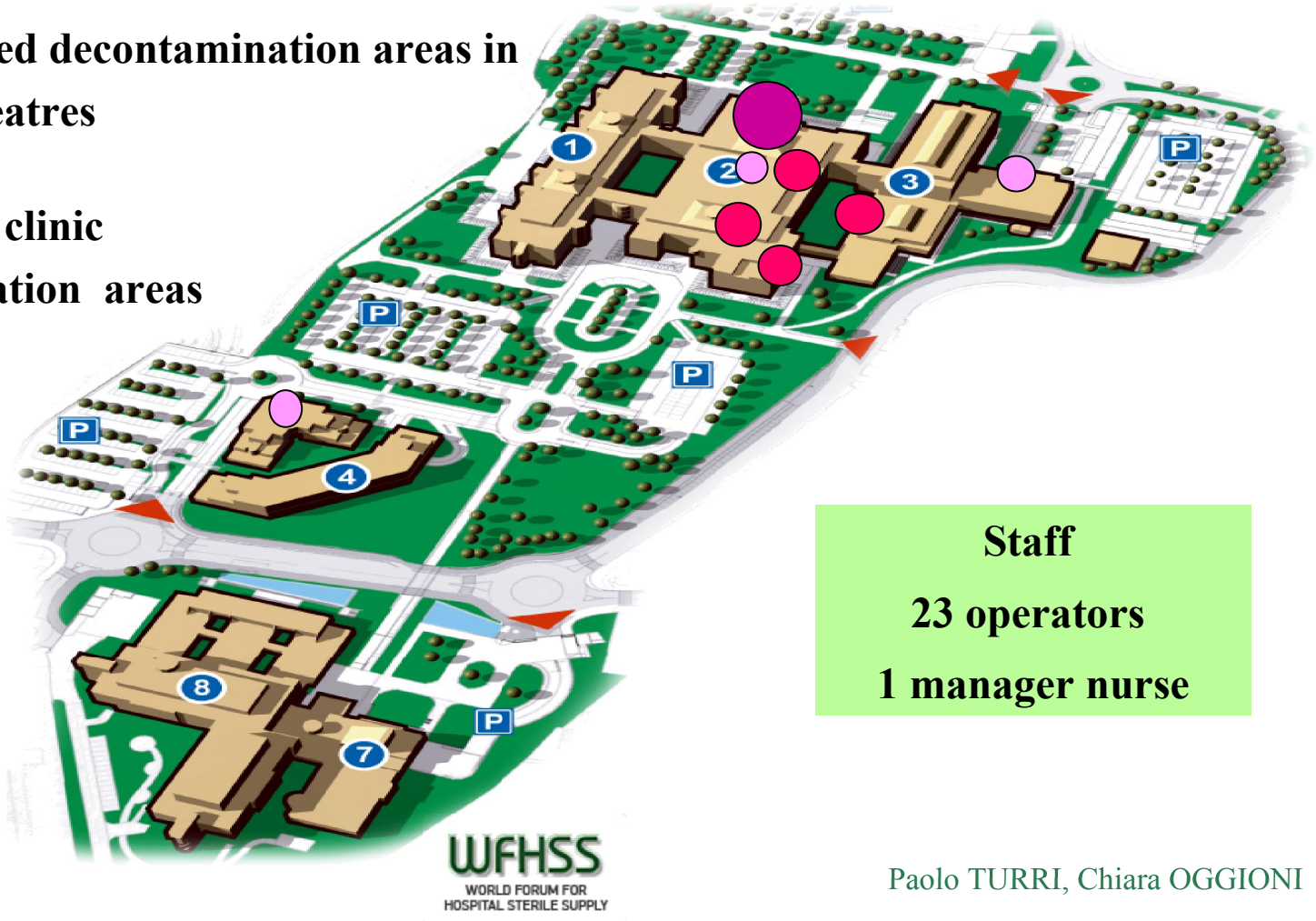
Medical	**449**	
Nurses, personal support	**936**	
Customer Service	**161**	
Staff		**157**
Research Area		**89**
Other		**78**
Total		**1.870**
University Students	***410***	

Our Hospital: sterilization process

1 CSSD

4 decentralized decontamination areas in operating theatres

3 outpatient clinic decontamination areas



Staff

23 operators

1 manager nurse

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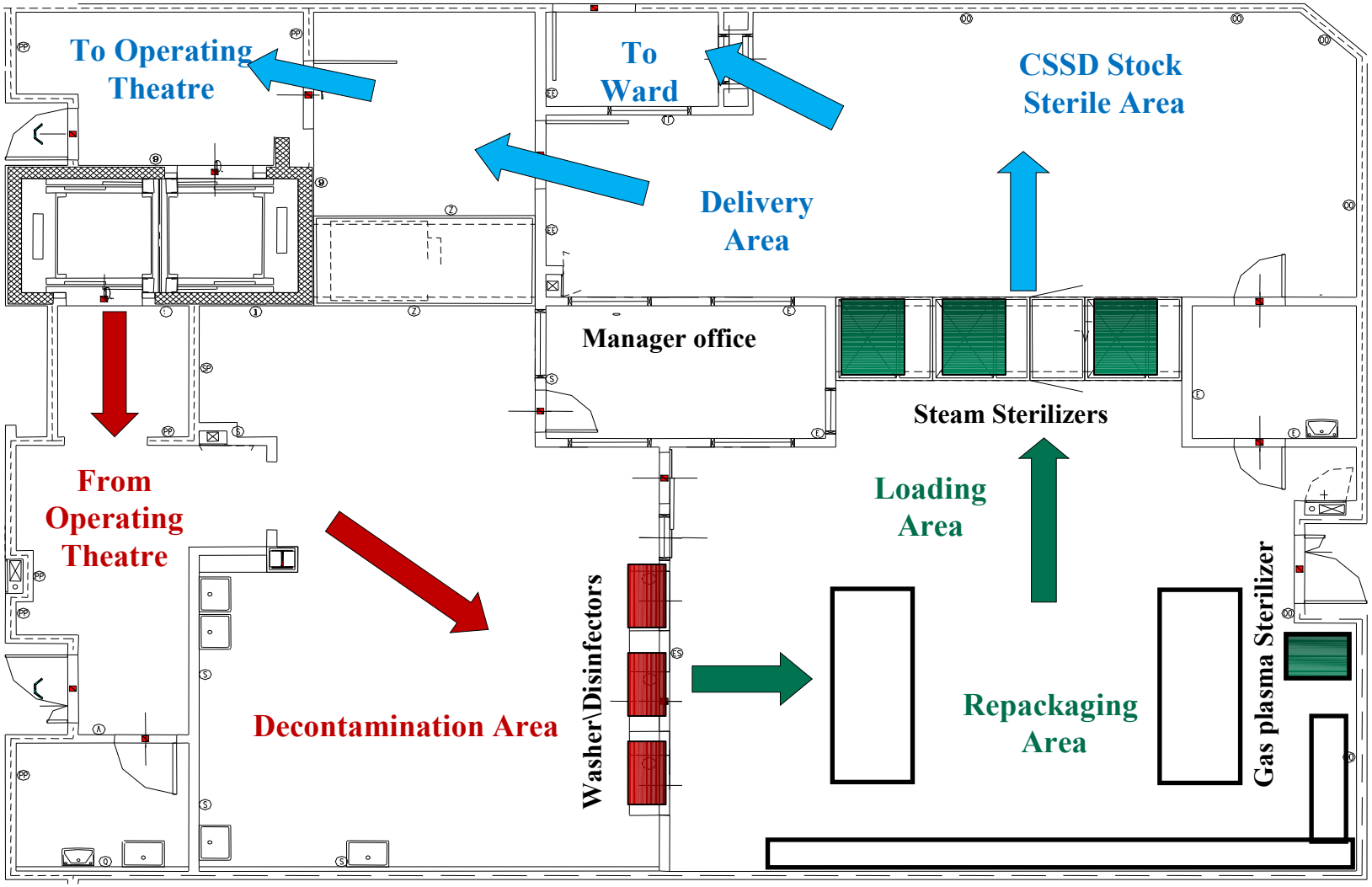
Sterilization process: CSSD



- **Multidisciplinary Process analysis in 2006**

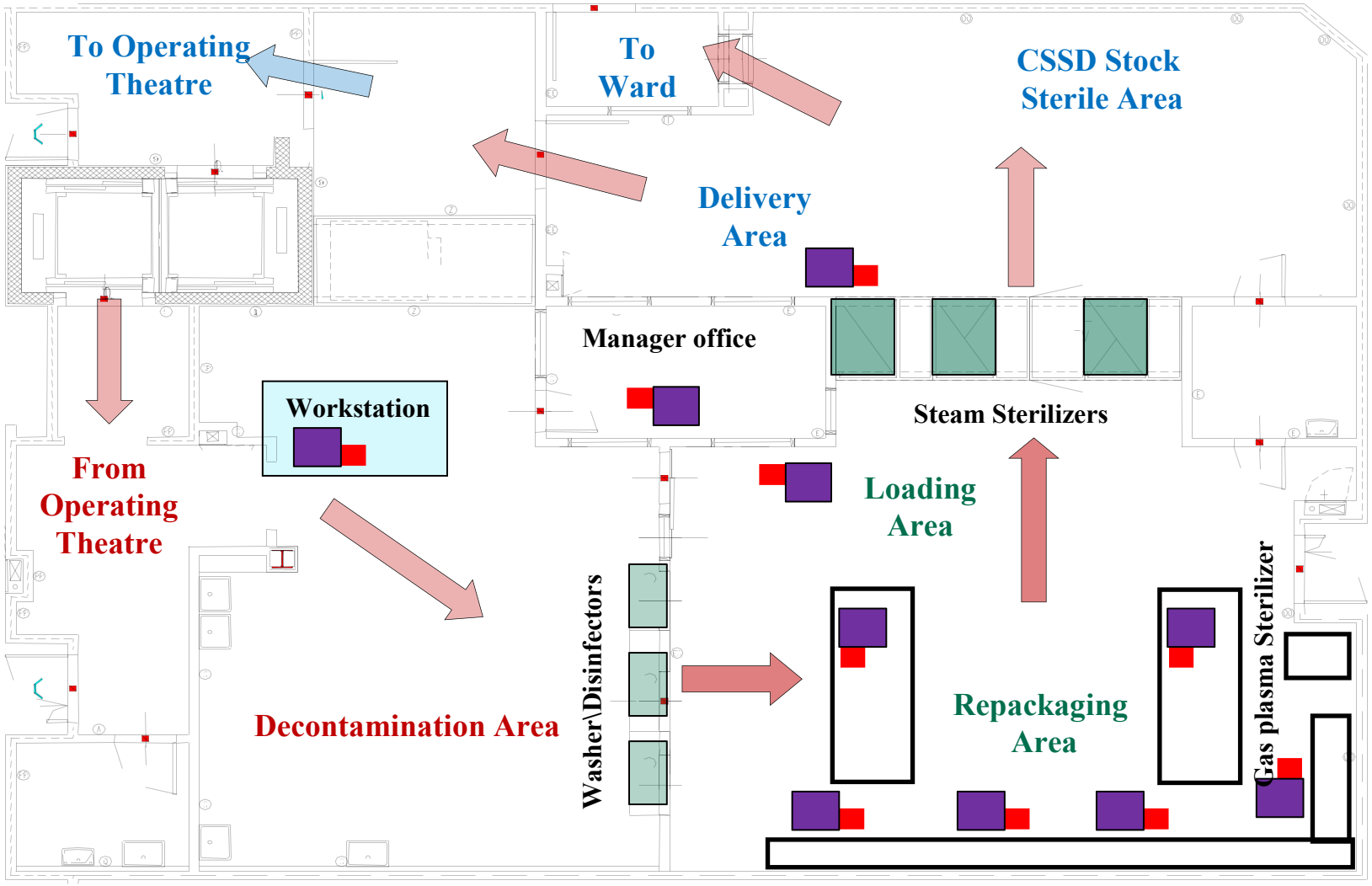
Needs

- **Improve Safety**
- **Standardize the activities**
- **Management and Control**
- **Centralization and Process Improvement**
- **Training of the Staff**
- **Cost Control**
- **Implement Traceability**

Milestones for changing

- From 1996 to 2006: manual traceability
- A senior-nurse dedicated to develop the project
- Installing traceability workstations in key points
- Data base loading with all figures
- Sept. 2006: software for traceability and management, instacount®PLUS (BBraun Aesculap, Tuttlingen, Germany)
- Overall 165 training hours to staff

Traceability system: CSSD

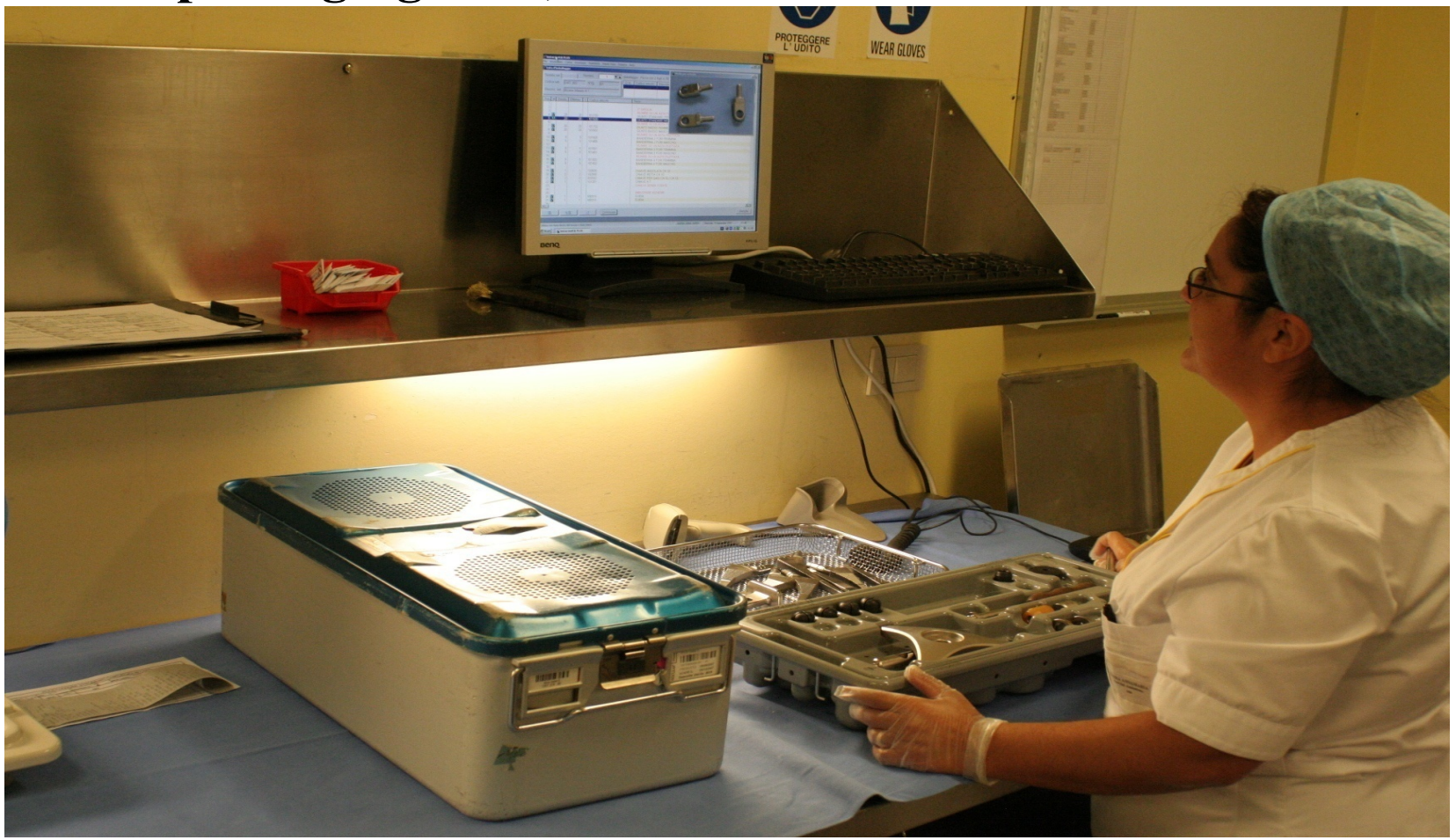


Traceability software manages the process

- **Process is checked and recorded in real time**
- **Staff is supported by the software**
- **Repackaging-list are easily updated**
- **Surgical kits are correctly directed**
- **Costs are properly allocated**
- **Report of traceability, including use of equipment and surgical instruments, are available**

Repackaging area, before

Repackaging area, after



Repackaging area, before

SET ILIZAROV					
ALVEARE A1 B1 C1					
DESCRIZIONE		**MISURA**	**CODICE**	**n° pezzi**	**NOTE**
		n° fori			
GIUNTO PER CERNIERA	***F** /standard*	1	101700	20	imbustare
GIUNTO PER CERNIERA	***M** /standard*	1	101600	20	20M + 20F
GIUNTO PER CERNIERA	***F** /prof basso*	1	101702	20	imbustare
GIUNTO PER CERNIERA	***M** /prof basso*	1	101602	20	20M + 20F
BANDIERINA A FILETTO FEMMINA		2	101500	10	imbustare
BANDIERINA A FILETTO MASCHIO		2	101400	10	10 M+10F
BANDIERINA A FILETTO FEMMINA		3	101501	10	imbustare
BANDIERINA A FILETTO MASCHIO		3	101401	10	10 M+10F
BANDIERINA A FILETTO FEMMINA		4	101502	10	imbustare
BANDIERINA A FILETTO MASCHIO		4	101402	10	10 M+10F
STRUMENTI					
CHIAVE ANGOLATA		CH10	103000	1	
CHIAVE RETTA		CH10	102900	2	
CHIAVE PER DADI		CH10/CH13	202002	2	

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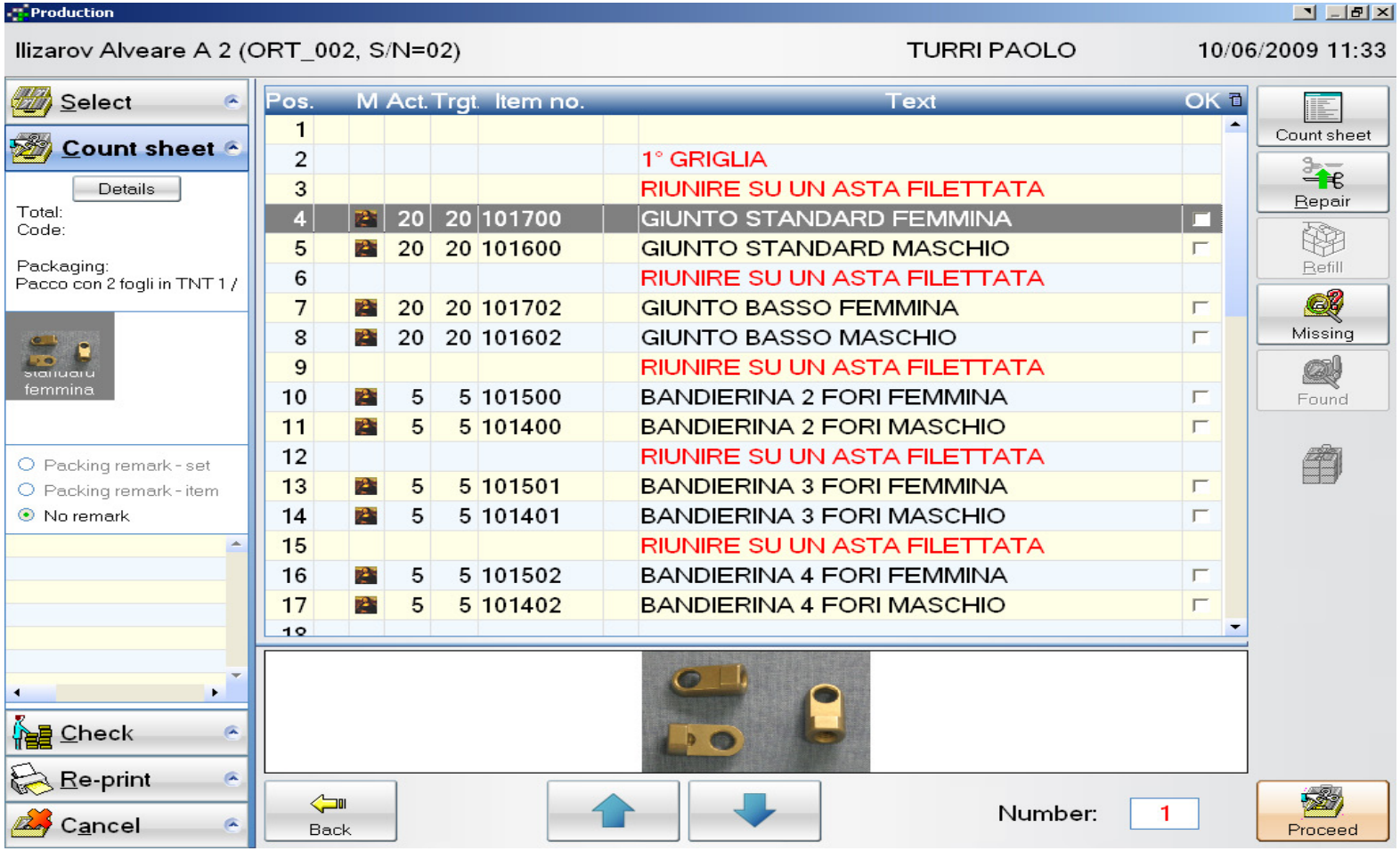
Repackaging area, after



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  - ✓ **Error analysis**
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Activity data 2008

STEAM ST.	SITE	St.U.	RUN	TOTAL CYCLES	St.U.	AVERAGE CYCLES
RUBINO	CSSD	8	23 hours	1350	10800	5
SMERALDO	CSSD	8	23 hours	1544	12352	6
TOPAZIO	CSSD	8	23 hours	1441	11528	6
EOLO	BOD	1	14 hours	2106	2106	9
HERMES	BOD	1	14 hours	1801	1801	8
COLOMBO	BOE	4	14 hours	883	3532	4
S. MARIA	BOE	4	14 hours	769	3076	4
PINTA	BOE	4	14 hours	576	2304	4
NINA	BOE	2	14 hours	557	1114	3
LUNA	BOF	4	14 hours	1979	7916	9
ROSA	BOC	1	14 hours	1800	1800	7
MINNIE	BOA	1	24 hours	1023	1023	4
TOPOLINO	BOA	1	24 hours	773	773	3
		47		**16602**	**60125**	**72**
GAS PLASMA ST.					**St.U. TOT.**	**64285**
ZAFFIRO	BOE	1	14 hours	1240		
QUARZO	CSSD	1	23 hours	2920		
				4160		

Risk assessment

- **Sterilization process is critical and should be characterized by a Risk Management system**
- **Risk assessment in sterilization process should be based on a good incident reporting system to:**
  - ✓ **Learn from experience**
  - ✓ **Monitor errors and implement corrective actions**
  - ✓ **Monitor progress in the prevention of errors**

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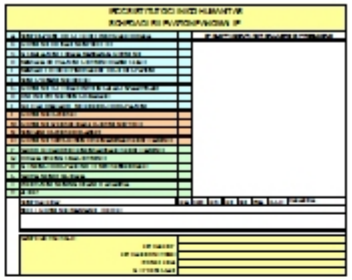
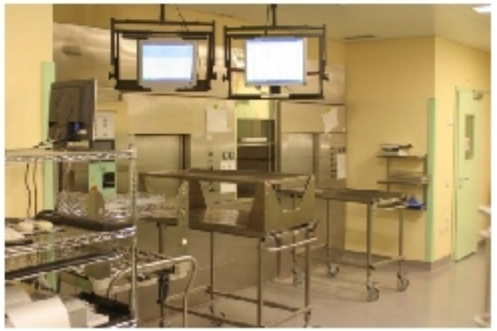
Incident reporting system

ERROR IDENTIFICATION

INCIDENT REPORTING CARD COMPILATION

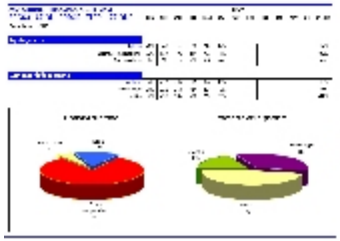


MAIL TO CSSD



COLLECT AND ANALYZE ERRORS DATA

ERRORS DATA REPORT



CORRECTIVE ACTIONS

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Incident reporting card

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SCHEDA DI RILEVAZIONE ANOMALIE

A	COMPOSIZIONE DEL SET O DEL IMBUSTATO ERRATA	
B	STRUMENTI DELICATI NON PROTETTI	
C	SEGNALAZIONE ERRATA MANCANZA STRUMENTI	
D	MANCATA RILEVAZIONE STRUMENTI DANNEGGIATI	
E	MANCA IL FILTRO O L'INDICATORE DI STERILIZZAZIONE	
F	CONFEZIONAMENTO ROTTO	
G	STRUMENTI / SET TRATTENUTI IN SALA SENZA AVVISARE	
H	STRUMENTO SPORCO	
I	STRUMENTI SPORCHI TRA GLI STRUMENTI PULITI	
L	CONTAINER SPORCHI DI SANGUE	
M	STRUMENTI CHIUSI O NON DECONTAMINATI CORRETTAMENTE	
N	CARRELLO DA RIPORTO NON CARICATO CORRETTAMENTE	
O	FINE INTERVENTO NON SEGNALATO	
P	SCELTA ERRATA DEL METODO DI STERILIZZAZIONE	
Q	ERRATA RICONSEGNA STRUMENTI	
R	SET NON STERILIZZATO NEL TEMPO CONCORDATO	
S	CARICA NON REGISTRATA	
T	PRODUZIONE NON INSERITA NELLA CARICA	
U	ALTRO:	

ETICHETTA CONTAINER O NUMERO DI PRODUZIONE

Wrong composition errors

Hygiene errors

Running errors

COMPILATO DA:	BOA	BOD	BOC	BOE	BOF	PMA	CSSD	DATA/ORA
NOTE / STRUMENTO MANCANTE / ROTTO								

CAMPO AD USO CSSD	
OPERATORE:	
OPERATORI IN TURNO	
TURNO / ORA:	
SET PROCESSATI	

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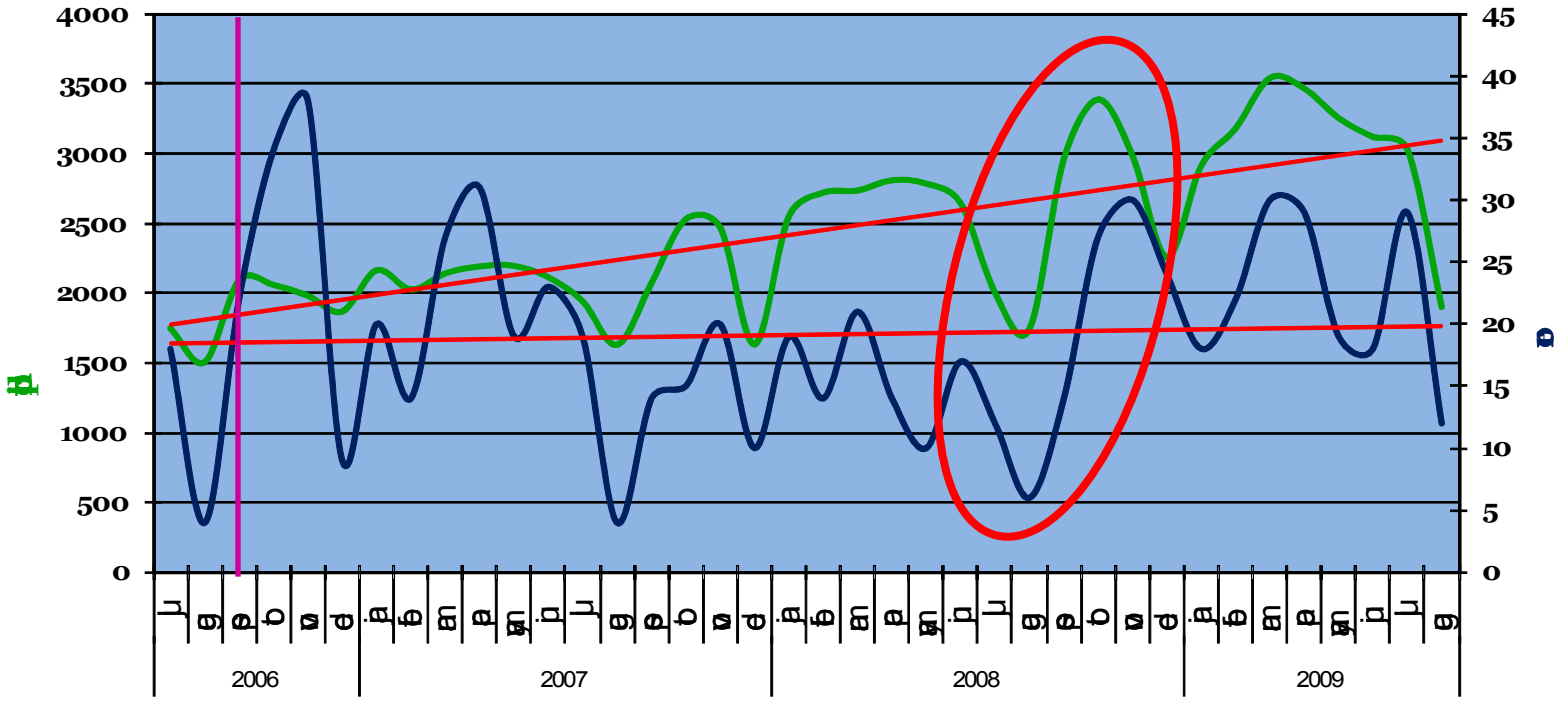
Error analysis

Relationship between error and production



	IRR	Std. Err.	z	P>z	inf (95%)	sup (95%)
production	1,00028	6,72E-05	4,1	0	1,00015	1,00041

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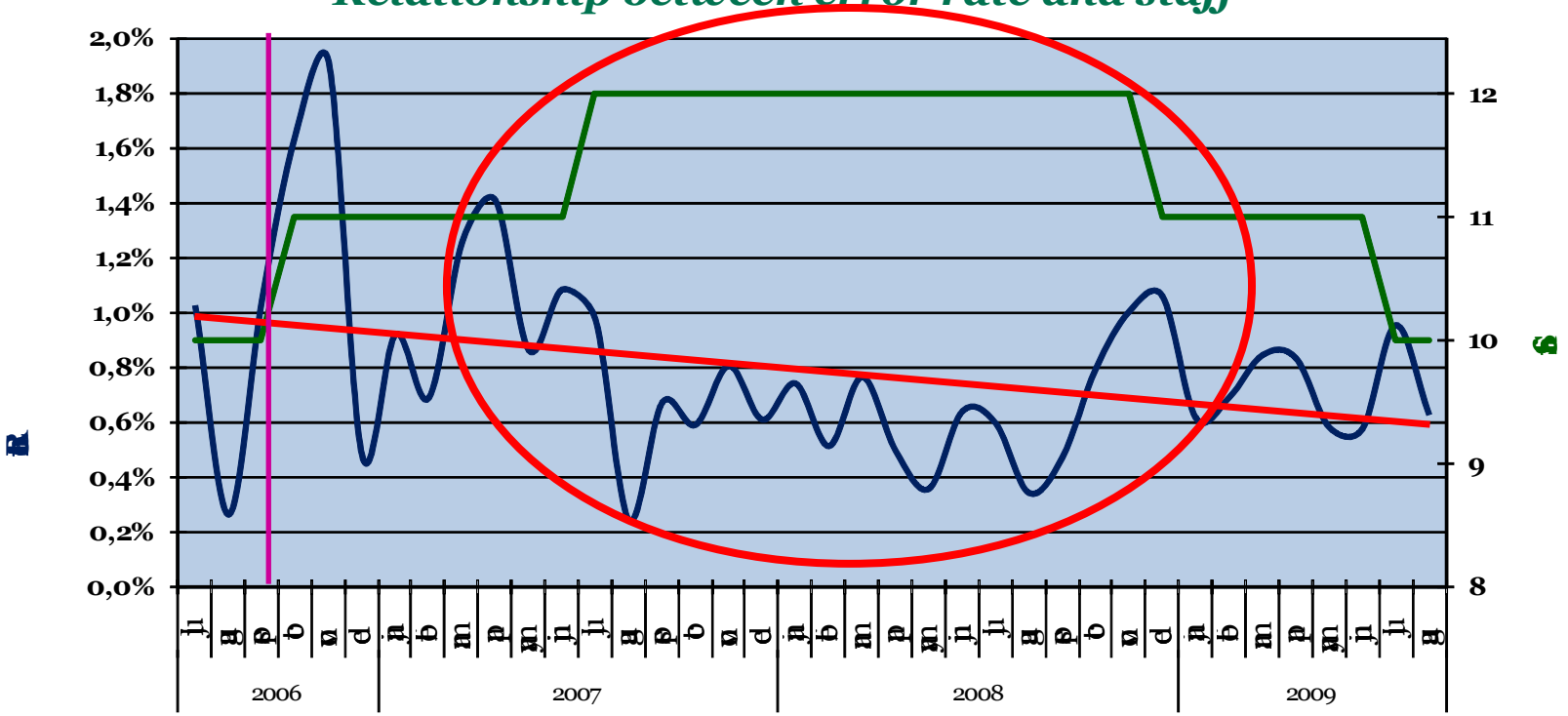
Error analysis

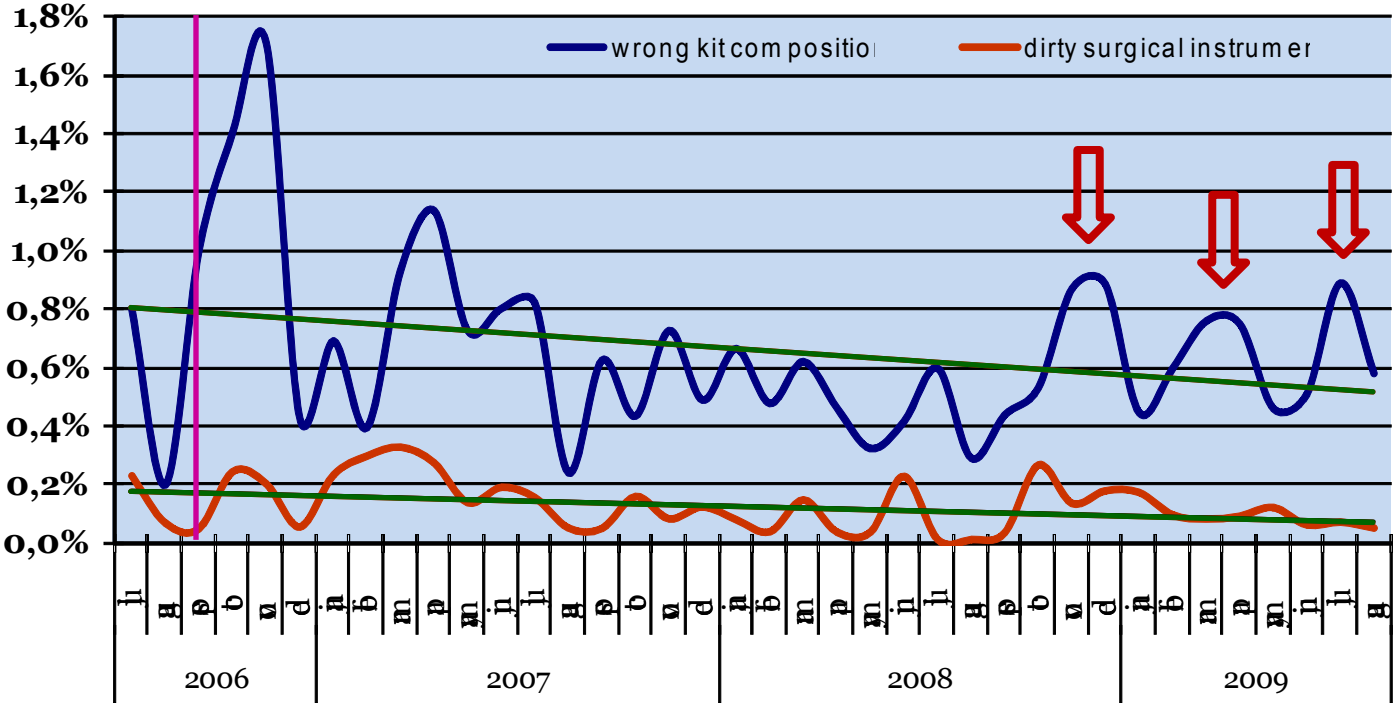
Relationship between error rate and staff



	IRR	Std. Err.	z	P>z	inf (95%)	sup (95%)
staff	0,78680	0,04819	-4	0	0,69780	0,88715

Error analysis

Error rate trend 2006 - 2009

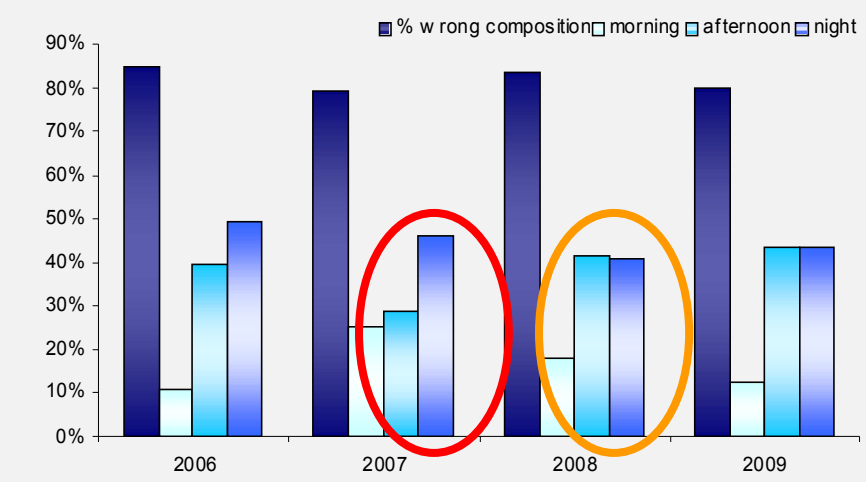


	IRR	Std. Err.	z	P>z	inf (95%)	sup (95%)
month	0,98468	0,003592	-4	0	0,97767	0,99175

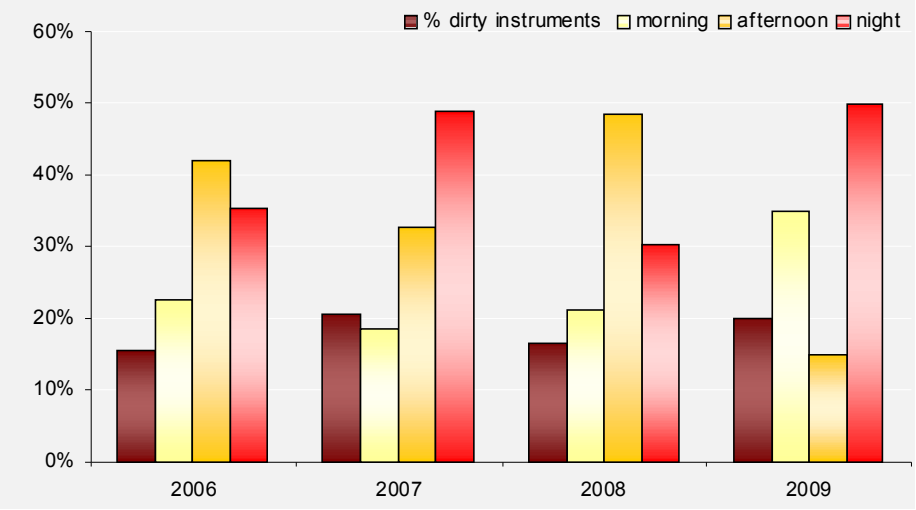
Activity data and Error analysis

Distribution of incidence error rate by Shift, 2006 - 2009

wrong composition



dirty instrument



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Corrective actions

- **Strengthening of night shift in CSSD**
- **Replacing washer-disinfector and introducing new detergent**
- **Addition of new pictures of surgical kits**
- **Addendum of further notes to surgical kit lists**
- **Standardization of sterilization process, through unification of procedures and training of the staff**

Conclusion

- **Traceability management system is a fundamental tool for a good risk assessment approach**
- **Increasing of surgical kit production leads to increasing of errors (1 additionally kit produces 0,002 more risk)**
- **Increasing sterilization staff whit 1 unit leads to decreasing of 22 % risk errors**
- **Incidence of error rate decreased during 36 months of the study by 2% per month**
- **Risk assessment in sterilization process management enables to control and reduce errors**

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Special thanks to all our collaborators: **all sterilization process staff**, our risk manager ing. **Chiara Signori**, our statitical support and quality manager, mr. **Francesco De Fazio**

Activity data 2006 - 2009

	STERILIZATION SERVICE			
year	2006	2007	2008	2009'
surgical kits	51.420	69.753	79.561	39.984
peel pouch	131.228	122.450	124.845	75.852
TOTAL	182.648	192.203	204.406	115.836
StU	na	47.634	48.474	24.739

na: not available data

' 1 st semester

Error analysis

Overall errors count 2006 - 2009

period	months	kit production	errors count
jul - dec 2006	6	11285	125
jan - jul 2007	6	12859	134
jul - dec 2007	6	12307	82
jan - jun 2008	6	16265	95
jul - dec 2008	6	15355	113
jan - jun 2009	6	19486	136
jul - aug 2009	2	4941	41

Error analysis

Relationship between error rate and staff

period	months	staff	error incidence rate	kit product. average
2006	12	10,25	0,86%	1939,6
2007	12	11,5	0,83%	2097,2
2008	12	11,92	0,64%	2635,0
2009	8	10,78	0,72%	2035,6