Transformation Design – A New Method for Developing Medical Products

H. Waedt¹, M. Popa¹, and P. Manea²

¹ Technical University of Cluj-Napoca, Romania
² TEMCO, Cluj-Napoca, Romania

Abstract— „Transformation design” is the generic name of a new scientific method, appeared at the beginning of the 21st century [1], that is about to become a new independent scientific discipline [2]. The new method gains more importance in today’s conditions, when the effects of the world economic crisis are not completely eliminated.

Simplifying things, it can be said that transformation design is a process through which new, but obsolete, systems are brought to the requirements of the current quality standards [2].

Periodic mandatory consultations (chest X-ray) for certain occupational categories were made in Romania until the EU pre-accession phase (2004 – 2006). For this were used the Micro-Radio-Photography systems (MRF), which were based on the Roentgen rays scanning principle. These systems weren’t compliant with new regulations in force and, due to the specific legal and economic situation of Romania, extremely strict conditions were imposed to be satisfied until the accession, respectively till January 2007. Thus, the Romanian government had to regulate and plan the decommissioning of all MRF systems. In this situation were 21 MRF systems, new versions, which were installed just a few years earlier and recently put into operation in various clinics in Romania. These 21 MRF systems were technically new, but their principle of operation, Roentgen ray chest scanning, was no longer compliant with valid legal regulations in July 2006. The article describes the finding of a technical solution to solve the situation of the 21 MRF systems removed from service. This is possible by means of transformation design, which offers the possibility to transform these systems, whose principle of operation is contrary to legal norms in force, into X-ray systems with a new operating principle, compliant to these rules.

Keywords— transformation design, Roentgen standard, interdisciplinary process, standards, extended SID.

II. TRANSFORMATION DESIGN

Transformation design is an interdisciplinary scientific method that has as purpose the alteration of existing systems (socio-political or technical) in order to keep them updated in the accordance to the social or legal changes that take place in the medium that they are used. The arguments for which the transformation design method proves to be the only realistic solution to achieve the objectives set forth in this article, in comparison with other known methods, are as follows:

The Standard Design method [3, 4] is applicable for systems or products, already on the market, at which are necessary modifications, either for the creation of new versions or for the elimination of any reliability risks, identified due to users’ complaints [5].

The designing of a new system version is an extremely laborious and complex task, which does not change the basic product, which remains on the market. The new version of the system is usually intended for a new category of beneficiaries, without changing the principle of operation.

Standard engineering method [6] is applicable when a product on the market is replaced by a new one. The replacement process unfolds over time and involves a start phase and a finishing one. This means that, till the end of the process of replacement, on the market will exist, at the same time, both new and old products.

It is obvious that none of the methods described above is applicable for a system that is still on the market, although it is out of order, due to the principle of operation that is not meeting yet the new requirements for approval, and should be therefore transformed into a system based on an approved principle of operation.

Thus, compared to those above, transformation design is the only method that offers concrete ways to perform and finish a process of such complexity with manageable costs.

III. THE IMPORTANCE OF TRANSFORMATION DESIGN

Transformation design broadly defines an interdisciplinary process oriented toward meeting the human needs. Through transformation design is also aimed the achievement of lasting changes in individual behaviour, in form and functioning.
Transformation Design is presented as a phased, iterative process, applied to big and complex problems and many times without being limited only at the social aspects of these. In the application of this method problems are analyzed, chronologically and unitary, in interdependency, the components being grouped according to new criteria. The practice of transformation design method involves the analysis of the problems in a holistic way and to a lesser extent reductive, as single elements, in order to understand both the interdependence and mutual influence [8]. Transformation design involves, among others, applying techniques and methods of conception and design, already established, in new non-traditional areas, which leads to unprecedented solution and results. Transformation design, as emerging field, uses classic design disciplines such as:

- Service design
- User centred design
- Conception design
- Informational design
- Industrial design
- Graphic design
- Systems design
- Interactive design

Although much has been written and extensively discussed in recent years in scientific circles about the economic value and the necessity of introducing transformation design [2], the implementation of these innovative ideas took place barely in 2004, when “The Design Council”, the strategic body for design in Great Britain, decided the forming of the RED group, which self-defined as objectives not only the development of new solutions and concepts (think-tank), but also an "active" action mode (do-tank) in order to "transform" the public services [7]. This action was a response to the request of the Prime Minister Tony Blair to create "redesigned" public services, "transformed", centred on the needs of the user (patient, passenger, victim of a crime, etc.) [13].

IV. TRANSFORMATION DESIGN PROCESS

Because of the novelty, the stages and processes embedded in transformation design are still not covered by rules or standards. Based on the gathered experience from the projects where transformation design was already applied and on published scientific papers on this topic [15], the following methodology (order) for process flow was crystallized, methodology presented in the present paper for the application of this method in industrial projects:

- End user’s (beneficiary) point of view analysis.
- Market and product scope analysis for the out of use product and for the transformed product. For medical products the analysis will address both the international health sector and the national health sector, as a destination and use domain of these.
- Analysis of political influence and legal regulations for the application domain of the "transformation" process. The analysis will cover both the legal base and medical aspects related to the use of two systems – the one out of use and the "transformed" one.
- The analysis of the economic situation will focus initially on MRF systems with international research on the areas of use and also on justification of use up till the stopping of use.
- Basic “know-how” resources. The analysis will have as objective the basic operating principles for both systems out of operation and for the "transformed" system Development phase, the basic concept.
- Transformation design: Basic concept development phase.
- Transformation design: The design-development phase of the product and the improvement of its quality. The main activities of this phase will be:
  - Specifying of the usage conditions of the system. The design (development) of the product in Engineering.
  - Checking product safety
  - Simulation in meeting the imposed requirements and risk analysis.
- EU Directives and Regulations requirements for product design-development domain.
- EU requirements concerning the approval of transformed medical products.

In conclusion, the processes set out above will be the structure and the approaching way in carrying out the activities for the conversion of those 21 MRF systems through the application of the transformation design method from this paper.

V. ANALYSIS OF MARKET SITUATION

In accordance with the terms from the point above, in this paragraph, the world wide prevalence of different types of X-ray systems will be analyzed in order to make a ranking in descending order, starting with the most used, and to identify the development trends of this economic sector in the future. This analysis is an important criterion for evaluating the economic gain from the usage of MRF systems converted (transformed) in standard X-ray systems, in the terms of discontinuing the regular preventive radiological