How Long After Compliance Do You Benefit From Regulation? An Empirical Study on Diagnostic Imaging Equipment Requirements*

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***Abstract* — Few economic sectors are more regulated than healthcare. While excessive healthcare regulation is a bad thing, regulation compliance brings with it the benefits of market entry, product quality and availability, as well as access to tax rebates and credit benefits. In this paper, we investigate some connections between regulatory compliance and normative technical requirements. We present a multi-company exploratory case study on the variability of mean times-to-benefit after compliance. We focus here on the diagnostic imaging equipment segment and the normative context in Brazil. We show that, in what regards current tax benefit regulations, time-to-benefit depends on the normative technical requirements that different categories of diagnostic imaging equipment comply with. This suggests that product-engineering practices should be concerned not only with analyzing and ensuring compliance, but also with regulation diversity and dynamics.**

***Keywords* — Diagnostic Imaging Equipment, Healthcare, Public Policy, Legal Requirements, Translational Engineering.**

I. Introduction

The quality and strength of the healthcare sector in a country have been used as measures of its development level and capability to face social and economic challenges (cf. UNDP Millennium Development Goals). However, few economic sectors are more regulated than healthcare. While excessive healthcare regulation is a bad thing — since it may create market access barriers, increase time-to-market and compliance may be costly — compliance brings with it public welfare and corporate advantages — such as the assurance of market entry, product quality and availability, as well as access to tax rebates and credit benefits. The existence of local standards and the local availability of funding are recognized as important competitiveness factors in the healthcare (equipment) industry [1].

Health surveillance agencies implement healthcare regulation through economic, social or administrative measures [2]. Economic measures are implemented through standards, market entry conditions and access restrictions. Public health and well-being actions enforce social measures. Administrative measures are enforced using legal, tax and financial instruments. Regulatory texts and other types of documents, such as standards and contracts, often refer to technical requirements, such as system and software requirements. This affects the whole industry operation.

Due to their social and economic importance, it is worthwhile investigating the connections between regulatory compliance and technical requirements found in regulations. In particular, one may wonder if mean times-to-benefit after compliance depends upon posed technical requirements. We argue here that such concerns contribute to improving the engineering of healthcare policies, processes and products. We present a multi-company exploratory case study focused on the benefits of healthcare equipment compliance with health surveillance, credit and tax benefit regulations. We put together the applicable norms and different data sources to develop an empirical study of mean time-to-benefit variability. We investigate whether or not time-to-benefit measures depend on the normative technical requirements that different healthcare equipment categories comply with.

This paper presents an empirical study on diagnostic imaging equipment companies established in Brazil. It covers ultrasound and magnetic resonance imaging equipment; scintigraphy and densitometry equipment; gamma-ray and positron emission tomography equipment; audiometers; X-rays and computerized tomography equipment; manographs and angiographs. Most international suppliers, as well as local companies, have factories in Brazil. The local regulation is similar to that existing elsewhere and the internal market has considerable size (our dataset reports, in the decade ending in 2017, sales of 1.725 locally produced equipment, worth more than US$566 million). These reasons lead us to believe that our conclusions are of general interest and may be valid regarding other segments and regions.

We organize the paper as follows: Section 2 addresses related work; Section 3 describes the diagnostic imaging equipment segment in Brazil; Section 4 presents our dataset and research methodology; Section 5 contains our data analyses and research findings; Section 6 discusses some validity threats. We conclude the paper with a discussion of our results and suggestions for further research.

II. Related Work

Compliance with requirements is a recurrent theme in the literature of the healthcare equipment sector. The scope and the adopted investigation methods are, however, distinctive characteristics of our work.

A case of failure, due to requirements engineering problems while developing a user interface for a healthcare device, is reported in [3]. The authors elicited and analyzed goal, domain, product and design-level requirements, but recognized the root cause of problems in their failure to establish effective communication channels with customers. One may wonder that compliance assurance in relation to regulatory and legal documents, not addressed in the reported work, could have prevented some of the identified problems.

An empirically validated quality model to ensure user satisfaction with medical devices is reported in [4]. The model underlies an appraisal and measurement methodology that adopts user acceptance information early in systems

* The assumptions, views and opinions in this paper are solely those of the author and do not necessarily reflect the official policy, strategy or position of any Brazilian government entity.

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development. Although concerns with regulations and compliance were present, as well as empirical methods were used, the model is not connected to normative requirements.

The authors of [5] describe the USA Food and Drug Administration (FDA) studies in partnership with researchers to develop software review methods for medical devices. They describe the adoption of device usage models, with the support of formal methods and static analysis techniques to improve software review. The paper presents a case study on improvements in the forensic analysis of software failures of infusion pumps. It aims to strengthen product registration and provide more rigor to the regulatory process, rather than analyzing the consequences of regulation.

An initiative to improve the requirements management processes of diagnostic imaging equipment is described in [6]. The paper reports empirically validated improvements in processes based on continuous information flows. The authors also study the influence of these improvements in time-to-market metrics, but present no product category breakdown, nor any analysis of regulatory compliance.

III. The Brazilian Healthcare Ecosystem

The healthcare sector in Brazil operates as a Unified Healthcare System (SUS) aiming to provide universal and decentralized health assistance to the population, through a network of public, private and philanthropic institutions.

1. The Production & Operational Context

Some healthcare equipment companies manufacture their products in Brazil relying on established chains of component suppliers and service providers, while others import their products directly or indirectly. Companies that locally design and manufacture products often rely on services provided by research, development and innovation (R,D&I) institutions, which may be connected or not to local hospitals and clinics.

The Ministry of Health orchestrates the activities and procedures under SUS, relying on local clinics, hospitals and service providers. The Brazilian Health Surveillance Agency (ANVISA) regulates and enforces measures on the production, marketing and usage of healthcare products.

2. The Normative Context

Public policies regarding the Brazilian healthcare sector are anchored in health surveillance measures under ANVISA regulation (c.f. Section 3.2.A), in credit and fiscal benefits implemented by other agencies (c.f. 3.2.B and C). Diverse regulatory documents implement such policies: laws, decrees and interim measures; govern agency ordinances, resolutions and adjustments; public agreements and contacts. Technical requirements are often made explicit in these documents.

We attribute a unique acronym to each norm and refer to norm parts using specific indexing patterns, which are regulated by Decree 4.176/2002. We define norm part identifiers by prefixing norm acronyms to part indexes. For example, (DUS 1.I) denotes Item I of Article 1 of MCTI/MDIC Ordinance 256/2013, while (SSP 25.§1) denotes Paragraph 1 of Article 25 of Law 6.360/1976.

A. Health and Environment Protection Regulation

The Brazilian regulation of health surveillance is similar to that implemented by the USA FDA and that enforced by the European Community (cf. CE marking).

Law 6.360/1976 (SSP) establishes health protection and surveillance measures covering medicines and correlated products (including medical devices). For instance, item X of Article 3 defines the meaning of a product registry:

(SSP 3.X) Registry: Registration, in the proper book, after the concessionary order of the Ministry of Health organ head, under the order number, of the products referred to in (SSP), with their names, manufacturer, provenance and purpose;

This law poses requirements on registry processes and the production, sales and delivery of healthcare products. Some of these requirements are:

(SSP 12) None of the products covered by (SSP), including imported products, may be industrialized, exposed for sale or delivered to consumption before registered;
(SSP 12.§1) The registration referred to in (SSP 12) shall be valid for five years and may be revalidated for equal and successive periods, maintaining the registration number;
(SSP 12.§4) The acts relating to the registration and revalidation of registration shall only take effect from the date of its publication in the Official Press onwards;

SSP also poses some requirements on companies that deal with healthcare products:

(SSP 50) The operation of companies covered by (SSP) will depend on the Ministry of Health authorization in view of the indication of industrial activity, products nature and species, insurance of technical, scientific and operational capacity;
(SSP 53) Companies carrying out activities provided for in (SSP) are obliged to maintain technically qualified personnel;

To provide further regulation for SSP, Decree 79.094/1977 was issued, but later substituted by Decree 8.077/2013 (SPR). One of its most relevant requirements is:

(SPR 2) The exercise of activities related to products referred to in (SSP) will depend on the authorization of ANVISA and the licensing of establishments by the competent health agencies of the States, Federal District or Municipalities;

ANVISA Resolution 185/2001 (REG) establishes procedures for the creation, change, revalidation and cancelation of registries. It classifies equipment according to their inherent operational risk. Invasive equipment or those that may severely affect the environment belong to the extreme risk class. Diagnostic imaging equipment have an intermediate risk classification. While the lowest risk products only have their data stored in ANVISA databases, other products must be effectively registered:

(REG 4) The manufacturer or importer shall, in a visible place on the equipment surface, present the following labeling information in an indelible manner: a) identification of the manufacturer (name or brand); b) identification of the equipment (name and model); c) serial number; d) equipment registration number with ANVISA;
(REG A1.2.1) Medical products covered by (REG) are classified according to the risk they pose to the health consumer, patient, operator or third parties in Classes I- IV;

B. Credit Incentive Regulation

Many institutions provide credit in Brazil aiming to foster the local development. The healthcare service and equipment industry sectors are often among their targets.

The case of the Brazilian Development Bank (BNDES), a state-owned company under private law, is paradigmatic: its primary source of funding has been the Brazilian Workers Assistance Fund (FAT), which only allows the application of supplied resources in financing projects and products with high degree of local content or which comply with local value-addition basic production process (PPBs).

To ensure credit eligibility, BNDES staff members perform accreditation activities: the process of officially recognizing a company as having the manufacturer status. BNDES accreditation involves: (i) verifying if a company and its products fulfill the corresponding obligations; (ii) classifying products as machines, equipment, systems or components; (iii) provided the fulfillment of i. and ii., granting access to specific BNDES credit lines.

Resolution 2.819/2015 passed by the Board of Directors of BNDES (CFI) formally regulated the accreditation process until 2018. Typical company obligations were:

(CFI 4) Take entire responsibility for problems related to product quality, warranty, price, technical assistance, delivery times and customer assistance;
(CFI 5) Ensure no violation of intellectual property rights arising from accreditation requests or accredited products, assuming entire responsibility for such problems;
(CFI 16) Sell with BNDES support only products complying with descriptions provided in the accreditation process;

Typical accredited company obligations were:

(CFI 23.VI) Mention, in sales invoices, the serial numbers of the products sold with BNDES financial support, corresponding exactly to the identification numbers presented on those products;
(CFI 23.VII) Mention in sale invoices the accreditation number of the products sold with BNDES financial support;

There were specific obligations concerning products subject to accreditation. For instance, they must be completely functional (CFI 5.1) and new (CFI 5.2). Distinct accreditation criteria could be chosen in a request: the attainment of local content indexes or the performance of local value addition steps in manufacturing processes.

In attempts of accreditation due to indexes attainment, the obligations included:

(CFI 17) For the accreditation of a product based on its local content, the product must attain simultaneously minimal value and weight indexes;
(CFI 10) The local content value index is calculated according to the formula $I_v = (1 - X/Y)*100$, where X is the foreign content cost and Y is the sales price;
(CFI 11) The local content weight index is calculated according to the formula $I_w = (1 - X_w/Y_w)*100$, where X_w is the imported content weight and Y_w is the total weight;

In attempts of accreditation due to PPB fulfillment, the obligations were:

(CFI 18) Only information technology products in the scope of Law 8.248/1993 qualify for accreditation due to the fulfillment of PPBs;
(**CFI 18.I)** The fulfillment of PPBs is evaluated based on habilitation documents jointly issued by the Ministry of Science, Technology and Innovation (MCTI) and the Ministry of Development, Industry and Commerce (MDIC), as well as on other documents requested by BNDES;

An example of a funding instrument that requires beforehand product accreditation is BNDES Finame (long-term credit for product acquisition, taking the product as collateral). We focus on this instrument in this paper and provide details on PPBs in the sequel.

C. Tax Benefit Regulation

In Brazil, tax incentives are considered complementary to credit benefits in public policy formulation. The healthcare equipment sector is no exception, since it is covered by the tax incentives granted to the Information and Communication Technology (ICT) industry, Law 8.248/1993 (ITL). It ensures rebates of manufacturing taxes over ICT goods in exchange for the application of a percentile of corporate revenues in R,D&I activities in partnership with universities and research centers, so long as production steps comply with some PPB.

Law 10.176/2001 (ICC) implemented a revision in ITL. ICC changed the required amount of investment in R,D&I activities so that it became regionally dependent, altered the tax rebates obtained by companies and defined in a precise way the categories of products eligible to obtain tax benefits.

Decree 5.906/2006 (ICR) provided additional regulation to ICC. ICR gave formal definitions for ICT components, products, software and services, with an extensive list of product categories eligible for tax benefits. It also provided definitions of what it means to establish a PPB and how a company can request a tax rebate habilitation.

According to ICR, joint ministerial ordinances published in the Official Press establish PPBs for ICT products. Each ordinance specifies production steps and obligations that companies must fulfill to enjoy tax rebates. PPB establishment ordinances are goal-oriented [7], since they demand public consultations to inquire manufacturers about the feasibility of production steps and R,D&I investments in the country. To obtain a tax rebate habilitation due to a PPB fulfillment, each company must submit a proposal to the responsible ministries, leading to the publication of a PPB habilitation ordinance in case of approval. From that date onwards, the company can enjoy tax rebate benefits. Technical staff members of BNDES take PPB ordinances into account while performing product accreditation.

The Joint MCTI/MDIC Ministry Ordinance 101/1993 established a generic PPB (GPP), applicable to the production of any ICT product. We list below the technical requirements established by GPP relevant to our work:

(GPP 1) For the purposes listed in (ITL 4), the ICT products manufactured in the country have local added value if they satisfy all the following production process steps:
- **(GPP 1.I)** Assembly/welding of all electronic components on printed circuit boards (PCBs);
- **(GPP 1.II)** Assembly of electrical/mechanical parts totally disaggregated at component level;
- **(GPP 1.III)** Integration of PCBs, electrical and mechanical parts to form the final product, assembled in accordance with (GPP 1.I) and (GPP 1.II);

Instead of obtaining tax rebate habilitation due to compliance with the steps and obligations established in (GPP), it is possible to seek compliance with PPBs established in other ordinances, which are particular to a product model or generic by addressing a product category. Regarding the PPBs applicable to digital diagnostic imaging equipment, the respective ordinances are listed in Table I.

TABLE I. PPB ORDINANCES, THEIR NUMBERS AND PUBLICATION DATES.

Mnm.	Name of Equipment Model/Category	#	Date
GPP	Any ICT Equipment	101	07/04/1993
CT	Computerized Tomography Equipment	24	09/02/2010
MRI	Magnetic Resonance Imaging Equipment	26	09/02/2010
DUS	Doppler Ultrasound Equipment	256	21/08/2013
FXR	Fixed Digital X-Ray Equipment	19	28/01/2014
MXR	Mobile Digital X-Ray Equipment	24	05/02/2014
PET-CT	Positron Emission Tomography Equipment	26	05/02/2014
NA	Other Not Covered by the PPB Legislation	–	–

The requirements posed by these ordinances vary substantially. While the ultrasound equipment ordinance requires the local production of transducers (DUS 1.I) and PCBs implementing signal detection, processing and output (DUS 1.II), the MRI PPB requires the local assembly of the magnet (MRI 1.I) and fueling of coolant (MRI 1.III). Both PPBs also require local software installation and configuration. PPBs steps of X-Ray based equipment require locally mounting connections with emission tubes and assembling detectors, as well as aligning them in relation to each other. There are also commonalities in the requirements posed by these ordinances, such as the compulsory acquisition of computers, printers and power generation, management and distribution systems manufactured according to the respective PPBs, in case the equipment is sold with these items, or higher than usual investments in R,D&I activities. In a way, such ordinances trade locally assembling and welding PCBs, which may be challenging to perform locally depending on their complexity, for the local production of critical sub-systems or additional investments in R,D&I. The commonalities and differences of the requirements in these ordinances are what we analyze in the sequel, in contrast to health surveillance, habilitation and accreditation compliance, as well as sales data.

IV. RESEARCH DATA & METHODOLOGY

1. *Norm Data Collection & Treatment*

The starting point of our study was the set of norms that capture public policies regarding the diagnostic imaging equipment segment in Brazil. First, we had to identify which were those norms (already outlined in Section 3), obtain their contents online (in textual format) and transform them into a tabular form with the aid of spreadsheets.

Afterwards, we carried out a norm transformation process preserving hierarchical structure and semantics. A transformation was applied to each document, eliminating irrelevant parts for our analyses, such as norm heading, type, number, date and purpose, keeping just the norm body. Structural elements used to ensure effective norm presentation were also eliminated in tabular representations, such as redundancies, unnecessary punctuation, as well as headings and titles of major norm parts.

We captured the structure of each norm through the unique identifiers that refer to norms and their parts. As a final step in treating documents, we transformed each norm to substitute cross-references by the respective identifiers.

2. *Compliance and Sales Data & Their Treatment*

The main subjects of our study were the manufacturers of diagnostic imaging equipment in Brazil. According to ANVISA, there were just 52 companies with some (imported or not) registered equipment at the end of 2017 [8]. We gathered a dataset containing all the 13 local manufacturers, among which only six had habilitation to enjoy production tax rebates at the end of 2017, according to MCTI [9].

We organized our dataset using the Brazilian Corporate Tax Payer Registry (CNPJ) unique identification number. The dataset contains company name and CNPJ number, product portfolio, compliance and sales data: dates in which registry, tax benefit habilitation and credit accreditation, as well as sales, first happened for each product.

We gathered compliance and sales data from primary sources only. First, we run queries using business intelligence solutions of BNDES to obtain financed sales data. The studied companies themselves, when questioned, reported the existence of other sales. Next, we queried online databases to obtain registration [8], habilitation [9] and accreditation [10] data. Finally, we sent specific questions to companies in order to clear apparent inconsistencies in collected data, which were answered and treated.

We coined the following definitions to refer to the dates of PPB establishment, norm compliance and first sales:

- d_e: Establishment of PPB applied to an equipment production;
- d_h: Tax rebate habilitation to foster an equipment production;
- d_r: Health surveillance registry of an equipment;
- d_a: Credit accreditation of an equipment;
- d_{fs}: First Finame financed sale of the equipment;
- d_{os}: Other reported or observed sales of the equipment;
- $d_s = min\ (d_{fs}, d_{os})$: Date of first sale;

All the categories in Table I have representatives in our dataset, except PET-CT devices (not produced in Brazil). The dataset covers other equipment types, such as audiometers, manographs and angiographs, whose production processes either comply with the generic PPB or do not comply with PPBs at all (accredited due to local content indexes attainment). An outline of our dataset appears in Table II.

TABLE II. STATISTICAL OUTLINE OF OUR DATASET.

		Products							
	Companies	**NA**	**GPP**	**CT**	**MRI**	**DUS**	**FXR**	**MXR**	**PET-CT**	**TOTAL**
Registries	52	123	NA	52	44	134	40	34	12	439
In Dataset	13	32	7	21	18	15	2	1	0	96
Coverage	25%	26%	NA	40%	41%	11%	5%	3%	0%	22%
Habilitations	6	NA	13	41	27	20	7	2	0	110
In Dataset	6	NA	7	21	18	15	2	1	0	64
Coverage	100%	NA	54%	51%	67%	75%	29%	50%	NA	58%
In Dataset	13	32	7	21	18	15	2	1	0	96
Selected	9	9	6	17	14	14	2	1	0	63
Coverage	69%	28%	86%	81%	78%	93%	100%	100%	NA	66%

3. Data Adjustment, Filtering & Computation

We had to perform data adjustments to recognize under some companies habilitations issued to their subsidiaries, a common practice among foreign capital manufacturers in Brazil. We also recognized under some companies the registries, habilitations and accreditations granted initially to other entities, due to merger and acquisitions, as well as economic group reorganizations, happening over time.

We organized collected data in time series of registries, habilitations, accreditations and sales. Although some of these series begin in 1998 and end in 2017, we noticed great uncertainty at the beginning of this period due to regulatory transitions. Indeed, the currently adopted practices in Brazil arose only after passing (REG) in 2001, (ICR) in 2006 and BNDES changed CFI to adopt PPBs as an accreditation criterion in 2007. So, we applied a temporal filtering process to ignore any observation corresponding to sales before 2008 (that is, we analyzed only the ten-year sales from 2008 to 2017). The last three lines of Table II reflect this filter.

Considering the partial temporal ordering of registration, habilitation, accreditation and sale events, we used the aforementioned definitions to compute derived data, according to the following measure definitions:

$\Delta_{eh} = d_h - d_e > 0$: Time to comply with established PPB;
$\Delta_{rh} = d_h - d_r$: Time from registry to habilitation;
$\Delta_{ra} = d_a - d_r$: Time to comply with accreditation;
$\Delta_{ha} = d_a - d_h$: Time from habilitation to accreditation;
$\Delta_{ros} = d_{os} - d_r > 0$: Time from registry to other sales;
$\Delta_{afs} = d_{fs} - d_a > 0$: Time from accreditation to financed sales;
$\Delta_{rfs} = d_{fs} - d_r > 0$: Time from registry to first financed sale;
$\Delta_{rs} = min\ (\Delta_{rfs}, \Delta_{ros})$: Time from registry to first sale.

V. Data Analyses & Research Findings

We now show that some time-to-benefit measures depend on the requirements found in regulatory documents. In particular, we demonstrate significant differences in some measures depending on the distinct regulations that the categories of healthcare equipment comply with.

Our time-to-benefit measures have two baselines: the publication date of a PPB establishment ordinance for a product category (d_e) and the product registry date with ANVISA (d_r). As terminal dates, we adopt those ensuring benefits to companies: the dates from which tax rebates can be enjoyed (d_h) and credit for sales can be obtained (d_a), as well as the market entry date (d_s, the lesser of d_{fs} and d_{os}).

The partial temporal order emerging from such events highlights the possible causal connections and statistical dependencies between their dates. Thus, we arranged our measures in a factorial design, by computing a matrix containing correlation indexes between each pair of measures. Since our definitions explain some correlations, we focus on measures not correlated by definition, deriving conclusions from the paths allowed by the implied order.

Despite any existing measure correlation, observations of measures from each respective population are statistically independent of one another, in the sense that each observation does not affect the probability of occurrence of another one of the same kind. This allows us to perform statistical analyses to investigate causal connections and dependencies between measure groups, as well as relationships with normative technical requirements.

We wondered whether distinctions in measure observations happened just by chance. Hypothesis testing is the standard technique to investigate this situation. Variance analysis and post hoc multiple comparison methods help in identifying distinctive groups of observations and spot where variance lies. However, our data were not normally distributed and were arranged in groups of different sizes. We applied non-parametric tests considering these circumstances.

We applied Kruskal-Wallis tests to determine differences between group means [11]. This test ranks all observations, combines them in groups and compares group average ranks. The null hypothesis is that all groups have the same mean (that is, the same average rank). The main hypothesis is that some groups have distinctive means. Since the test only works properly for groups with five or more observations, we put groups with up to four elements together.

We also performed post-hoc variance analyses to identify which groups were different from each other. These required the computation of *z* indexes based on the differences between the average ranks of each pair of groups, which were checked against the *z* statistics for significance. We adopted a significance level of 0.05 in our study.

1. Tax Rebate Time-To-Benefit

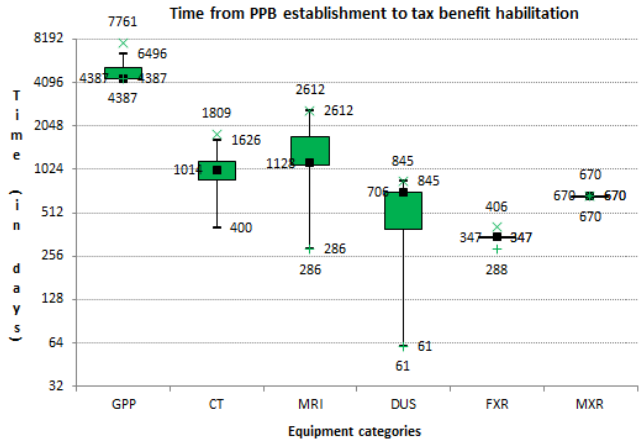
Recall that Δ_{eh} measures, since the establishment of a given PPB, the time spent by a company to provide the responsible ministries with convincing evidence of compliance with the production steps and R,D&I obligations posed by the respective ordinance. It is driven by the company effort to obtain attractive tax conditions for launching a new product (model) in the market, since the company can enjoy, once habilitation is granted, rebates in production taxes charged in each sale. Even before any sale, customers can perceive this benefit, when the tax rebate is treated as a deduction in pricing models. Since PPB ordinances applicable to diagnostic imaging equipment are diverse, this led us to the following research question:

(RQ 1) Does tax rebate time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to answer (RQ1) arranging the computed Δ_{eh} data in groups organized according to the PPB ordinance (as listed in Table I) adopted in each equipment production. We ended up with *54* observations distributed in five groups of different sizes. In order to apply the Kruskal-Wallis test, we computed, from group sizes and their average ranks, a statistics $H = 30.5974$ with four degrees of freedom, yielding a p-value of *0,000004*, which is smaller than the significance level adopted in our study. This allowed us to reject the null hypothesis and confirm that there was some group with a distinctive Δ_{eh} mean. Since we arranged Δ_{eh} groups according to PPB ordinances and each ordinance poses distinct normative technical requirements on diagnostic imaging equipment, this allowed us to answer (RQ1) positively.

We also performed a post-hoc analysis to identify the pairwise differences in Δ_{eh} means between groups. The analysis showed statistically significant differences in Δ_{eh} means of diagnostic imaging equipment complying with (GPP) in relation to the groups determined by (CT), (MRI), (DUS) and (FXR | MRX), as well as for (DUS) equipment when compared to those complying with (CT) or (MRI). We illustrate this using the box-plot in Fig. 1.

Figure 1. Box-plot of tax rebate time-to-benefit measures.



The box-plot shows distinctions in Δ_{eh} means (the square box in each bar) and variability (presented through the height of each bar) between groups. It makes explicit the distortion caused by the fact that (GPP) was established long ago, nevertheless putting complying equipment in a distinctive group. In addition, the graph presents without much distinction the (CT) and (MRI) groups, which are put apart from the (DUS) group. Finally, the graph also reflects the reason for joining the (FXR) and (MXR) groups, due to their small number of observations.

When we treated the distorted (GPP) group, by adopting the 2008 version of the respective ordinance instead of its 1993 version, we reached the same conclusions. We also noticed that, in each product category, there were no significant differences in measures from one company to another. Consequently, we concluded that the significant distinctions in tax rebate time-to-benefit measures between groups (GPP), (CT | MRI) and (DUS) were due to different technical requirements in the ordinances giving rise to these groups. As an aside, we noticed that the lack of distinction between CT and MRI arose by the similarity of respective ordinance requirements, since products in these categories are structurally similar, as well as their assembly processes.

2. *Credit Time-To-Benefit*

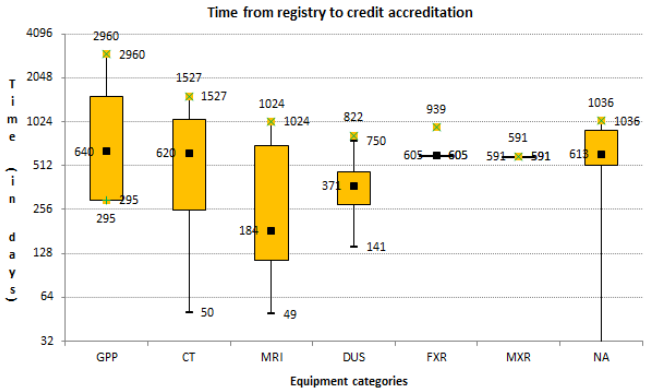
Recall that Δ_{ra} measures, since the registration of a healthcare equipment with ANVISA, the time spent by a manufacturer to provide BNDES with acceptable evidence of compliance with the requirements posed by a chosen PPB ordinance or local content indexes attainment. It is driven by the company effort to obtain attractive financing conditions for launching a new product in the market, since the company can enjoy, once accreditation is granted, credit for product sales. Even before any sale, customers can perceive this benefit, when commercial proposals make explicit the availability of financing conditions. Considering that PPB ordinances applicable to diagnostic imaging equipment are diverse and a company may even decide not to comply with any of them, this led us to the following research question:

(RQ 2) Does credit time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to answer (RQ2) arranging Δ_{ra} data in groups according to the PPB ordinances listed in Table I and the attainment of local content indexes (denoted by NA). We ended up with *55* observations in six groups. To apply the Kruskal-Wallis test, we computed a statistics $H = 6.2915$ with five degrees of freedom, yielding a p-value of *0.2788*, greater than our significance level. This did not allow us to reject the null hypothesis, nor to answer (RQ2) affirmatively, since there was no significant evidence to ascertain that credit time-to-benefit depends on normative technical requirements. We present the respective box-plot in Fig. 2.

Although this result may come as a surprise, sufficient justification came from the fact that BNDES accreditation is not tightly connected to product registries or tax rebate habilitations, procedures not mandatory for accreditation. Indeed, our box-plot shows that mean credit time-to-benefit is not sensibly different among groups and variability is substantially higher than in the tax rebate case: Δ_{ra} average is *565* days and standard deviation is *484* days.

Figure 2. Box-plot of credit time-to-benefit measures



3. *Market-Entry Time-To-Benefit*

Recall that Δ_{rs} measures, since the registration of an equipment with ANVISA, the time spent by a company to perform the first product sale. It is driven by the company effort to introduce the new product in the market. Considering that PPB ordinances applicable to diagnostic imaging equipment are diverse and a company may not comply with them while manufacturing and selling products, this led us to formulate the following research question:

(RQ 3) Does market entry time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to answer (RQ3) arranging the computed Δ_{rs} data in groups formed by the adopted PPB ordinances and the attainment of local content indexes. We ended up with 62 observations in six groups. We applied the Kruskal-Wallis test and computed a statistics $H = 9.1642$ with five degrees of freedom, yielding a p-value of *0.1027*, which is greater than our significance level. This did not allow us to reject the null hypothesis, preventing an affirmative answer to (RQ3). We omit the respective box-plot, which is similar to Fig. 2.

Again, this should not come as a surprise, given that, although performing similar functions, diagnostic imaging equipment are not required to comply with the technical requirements established in PPB ordinances when introduced in the market. In this case, Δ_{rs} average is *734* days and standard deviation is *536*.

VI. Threats to Validity

The main threats to the validity of our work are internal ones, related to data collection, adjustment and computation.

External validity was not among our concerns, since the studied context is particular to the Brazilian economy.

Concerning data collection, although we adopted multiple and sometimes divergent sources, they were compiled by government institutions for official purposes. We cleared all inconsistencies by querying the studied companies. Thus, we are confident in the quality of data used in our study.

Raw data was adjusted/filtered and derived data computed. Adjustments were necessary due to the changing structure of studied economic groups. In the studied context, such changes involve legal aspects only, but not operational ones, not affecting our analyses. Likewise, a temporal filter had to be applied due to transient instabilities in legislation to eliminate their effect in analyses. Finally, derived data was computed to make relationships between events explicit. We believe that such adjustments, filters and computations mitigate potential threats that could have risen otherwise.

We collected a dataset covering *25%* of the companies and *22%* of the products registered with ANVISA (corresponding to *100%* of the companies and *92%* of the products with local production), but data collection followed a sequential procedure, not random sampling. The lack of randomness could harm the possibility of generalizing our findings obtained from statistical hypothesis testing, which is based on the randomness assumption.

Nevertheless, we have demonstrated that tax rebate time-to-benefit measures depend on the technical requirements found in regulatory documents applicable to the diagnostic imaging equipment segment in Brazil. We found no evidence that the same holds regarding credit and market entry time-to-benefit measures. We reached these conclusions from test samples covering *57%*, *44%* and *22%* of the respective populations. Higher population coverages could hardly be obtained, due to the unavailability of additional data sources. We also performed alternative analyzes using descriptive statistics and charts that confirmed our conclusions. Due to the lack of randomness in data collection, it is a subject for future research to determine whether this holds regarding other types of healthcare equipment and regions.

VII. Discussion & Concluding Remarks

We showed here that, in what regards tax benefit regulations, time-to-benefit clearly depends on the technical requirements found in regulations that diagnostic imaging equipment comply with in Brazil. Although our study context is local and covers just a specific market segment, we believe that our conclusions are of general interest and may be valid regarding other healthcare equipment segments and regions.

From the public policy perspective, this study is important because it suggests improvements in regulatory processes and norms. For instance, it is suggestive of a new PPB ordinance containing the commonalities in the treatment of all diagnostic imaging equipment categories. This can, in relation to other ordinances, balance in a different way production steps and R,D&I obligations in relation to benefits granted to companies, thereby yielding alternative time-to-benefit choices. This path has been pursued in Brazil regarding the telecommunications and industrial automation segments, but not for diagnostic imaging equipment. In addition, the collection and analysis of empirical data in the way reported here contributes to cost-effectiveness and broader accessibility goals in healthcare [12].

From the corporate perspective, it is important to study times-to-benefit and their variability for economic reasons. Companies seek to stay ahead of their competitors by ensuring customer satisfaction and compliance with regulations, bearing in mind their revenues and costs respectively. As we have demonstrated, such financial indicators sometimes depend upon compliance with technical requirements in norms. Although a particular analysis of the influence of enhanced requirement engineering processes in time-to-market appears in [6], we have extended this analysis to many times-to-benefit metrics, covering normative requirements and manufacturing processes. Thus, diagnostic imaging equipment companies should be compelled to consider times-to-benefit while managing process and product variability, in order to achieve economic goals [13].

The main lesson learned in our study is that current industrial practices should be concerned not only with analyzing and ensuring compliance, but also with regulation diversity and dynamics, since this contributes to improving healthcare policies, processes and products. The research reported herein is, in fact, part of a broader agenda, which seeks to assess and demonstrate the contributions to ICT businesses of normatively treating technical requirements. The additional illustration of these contributions in practice, with the proposed transportation of this study to other segments and regions, are clear candidates for future work.

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