INTRODUCTION TO THE USE OF FRAM ON THE EFFECTIVENESS ASSESSMENT OF A RADIOPHARMACEUTICAL DISPATCHES PROCESS

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ABSTRACT

This article aims to make an introduction to the use of Functional Resonance Analysis Method (FRAM) on the effectiveness assessment of a specific radiopharmaceutical dispatching process. The main purpose was to provide a didactic view of the method application to further in-depth analysis. The investigation also provided a relevant body of knowledge of radiopharmaceuticals dispatches processes. This work uses the term 'effectiveness assessment' instead of 'risk assessment' due to the broader meaning the former provide.

The radiopharmaceutical dispatching process is the final task of a dynamic system designed to attend several medical facilities. It is comprised by functions involving mostly human activities, such as checking and packaging the product and measuring the radiopharmaceutical nuclear activity. Although the dispatch process has well-known steps for its completion, the human factor is the fundamental mechanism of work and control, being susceptible of irregular and instable performance. As a socio-technical system, the risk assessment provided by FRAM may be of importance for safety and quality improvements, even more if considered the nuclear nature of the product, which makes risk assessment critical and mandatory.

A system is safe if it is resistant and resilient to perturbations. Identification and assessment of possible risks is, therefore, an essential prerequisite for system safety. Although this seems obvious, most risk assessments are conducted under relative ignorance of the full behavior of the system. Such condition has lead to an approach to assess the risks of intractable systems (i.e., systems that are incompletely described or underspecified), namely Resilience Engineering. Into this area, the Functional Resonance Analysis Method has been developed in order to provide concepts, terminology and a set of methods capable of dealing with such systems.

The study was conducted following the Functional Resonance Analysis Method. At first, the functions of the radiopharmaceutical dispatches process were identified and described as required for everyday performance to succeed, than for every function the essentials aspects for the function to be carried out were described. After that, some scenarios or instantiations of the model were analyzed in order to propose ways to monitor and dampen performance variability.

1. INTRODUCTION

Radiopharmaceutical is a preparation containing a radioactive substance that is used in the diagnosis and treatment of cancer and in pain management of bone metastases. The production and transportation of radiopharmaceuticals are relevant processes for the society in general, and for the patients using it, in particular. Delays on the radiopharmaceuticals delivery may represent lost of material, time, and unnecessary trouble for the clinic, the physician, and mostly, for patients, reducing the process effectiveness. In addition, the manipulation, use and transportation of radioactive materials represent potential risks for the workers, and for society as a whole, augmenting the threats over system effectiveness.

The complete process - from production to delivery to the costumer - involves acquiring raw material, irradiation, chemistry processing, and dispatching the radiopharmaceuticals. This study focuses on the dispatch process to the nuclear clinics. This part of the process was chosen because it is responsible for setting the stage for the whole delivery process, being the interface with customers.

The main purpose of this study is to model a radiopharmaceutical dispatch process using the Functional Resonance Analysis Method (FRAM) in order to provide a didactic view of the process and how its performance variations can affect the effectiveness of system. Although FRAM has been conceived focusing on safety issues, this study proposes it can be useful for assessing the effectiveness of a system, since both are concerned with the system ability to succeed under varying conditions. This study considers effectiveness as the ability of the system of delivering what it was planned for, under varying conditions.

FRAM defines a system in terms of how it operates rather than in terms of its architecture and components. The aim of FRAM method is to represent the system's dynamics by modeling the non-linear interactions that are part of the system [1]. FRAM uses a non-linear model based on the assumption that accidents result from unexpected combinations (resonance) of normal performance variability. According to this view, undesirable results are prevented by monitoring and damping variability among system functions [2].

FRAM is didactic since it compels modelers to think globally by trying to understand the system connections and its boundaries; and to think locally, by compelling to understand the inputs and outputs of each task of the system. Moreover, FRAM provide a way of understanding how performance variations may propagate within these tasks. In order to assess the effectiveness of a system, the main query is whether its functions (or tasks) are producing an acceptable outcome under existing conditions and how all the functions may interact to produce an unintended or unwanted outcome.

After presenting the method step by step, two instantiations were done in order to demonstrate the modeling method, and to assess the effectiveness of a radiopharmaceutical dispatch process. Next, some issues were discussed, followed by conclusions.

2. THE FRAM METHOD

Before start the modeling process, it is necessary to identify whether the analysis is of an event investigation, that is concerned about something that has happened; or to a risk assessment, that looks at something that may happen in the future [3]. The reason for this is to set the method for its purpose, since there are some small differences for each application.

The method is comprised of four steps:

1. Identify the functions or operational units of the system being analyzed
2. Characterize the potential and expected variability of each function
3. To look at specific instantiations of the model and proceed with the aggregation of variabilities in order to find out disturbances in the system performance that may lead to unwanted results.

4. Propose solutions for dampen performance variabilities

2.1 First Step - Identifying Functions

The first step consists in breaking down the system into elementary operational units. These units are the functions needed for work to succeed. Each function can be characterized by six attributes: Input, Output, Precondition, Resources, Control and Time. These attributes serve as connectors between functions, since the functions are potentially coupled if they have common descriptions of the aspects:

Input (I): that which the function processes or transforms or that which starts the function
Output (O): is the result of the function, can be an entity or a state change
Resource (R): resource(s) required for the processing performed by the function
Time (T): time required for the processing performed by the operational unit
Control (C): control(s) and constraint(s) the operational unit (exceptions, procedures, methods, etc.)
Precondition (P): conditions that must be satisfied before a function can be carried out

An operational unit or function is represented by an hexagon, where each vertex represents an attribute, as shown in the Fig. 1.

(I) Input
(O) Output
(R) Resource
(T) Time
(C) Control
(P) Precondition
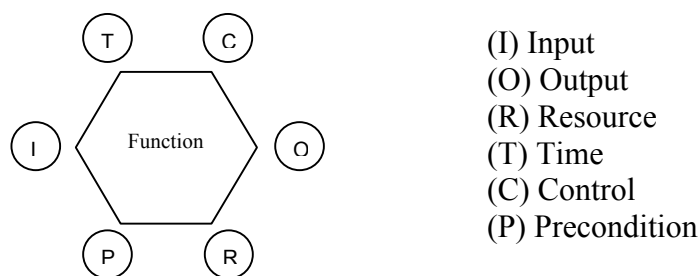
Figure 1: Hexagram representing an operational unit of FRAM

An operational unit is also and rather, represented by a frame, as shown in Fig. 2.

Name of the Function	
Description of the Function	
Aspects	
Input	
Output	
Precondition	
Resource	
Control	
Time	

Figure 2. A FRAM frame

2.2 Second Step - Determining the Potential Variability

The second step is about determining the potential variability of the functions described in the first step. In fact, the variability in question is the Output variability, since this outcome may be propagated thru the input of another function. There are three causes for the variability of the Output: internal, external or a result of influences from upstream functions.

In order to investigate performance variability of the functions, FRAM characterize operational units as technological, human or organizational and points to possible internal and external causes for the functions to vary [3].

For technological functions, the main source of internal performance variability can be the degradation of internal components; and for external performance variability, the main sources can be improper maintenance, over-speed, excessive stress, improper use and so on.

Human functions are inclined to be variable because people must adjust their performance to the working conditions [4]. For human functions, the sources of internal performance variability can be fatigue and stress, circadian rhythm, illness, temporary disabilities and so on; while for external performance variability, the main sources can be group pressures, implicit norms, expectations, demands, pressures, policies and so on.

For organizational functions, the sources of internal performance variability can result from effectiveness of communication, authority gradient, trust, organizational culture and so on. The sources of external variability can derive from customer demands or expectations, availability of resources, commercial pressure, weather and ambient conditions and so on.

In order to identify the potential performance variability some questions may be done: why this function may vary? Which are the sources or reasons for this function to vary? This query drives the manager or researcher to face the real working conditions and its influence over the quality of the outcomes. For instance, if a function is mainly 'human' and the worker is submitted to huge pressures for productivity, it is presumable that the function performance may vary.

The next step is to find out how performance variability may affect downstream functions. This is done thru the characterization of the Output from a function in terms of 'timing' and 'precision' with regard to a downstream function.

In terms of time, the output can be produced early, on time, or late for being used by the downstream function. In terms of precision, an aspect can be precise, acceptable or imprecise for being used by the downstream function. The quality of the function output is the result of 'precision vs. timing' combination.

A precise output, i.e. an output produced exactly as intended, will satisfy the downstream function need; and "will…not in itself increase the variability of downstream functions, but may…reduce it." [3]. An acceptable output requires some adjustment for being used by downstream function, and may increase its performance variability. An imprecise output requires major adjustments and possible disambiguation and extra verifications, leading to time and resources consuming and increasing its performance variability.

2.3 Third Step

The next step of the analysis is the aggregation of performance variability. The aim of the third step is to look at instantiations of the model to assess the couplings among functions in order to seek whether it will lead to unwanted or unexpected outcomes that may compromise the process effectiveness.

An instantiation describes the linkage or coupling that may exist for a given scenario. At this step, the analyst should take in account ordinary scenarios, where small variabilities may be expected; as well as extraordinary scenarios, with major performance variabilities. There is no rule to establish those scenarios; indeed an experienced group should be consulted in order to obtain relevant information about the process behavior.

After choosing an specific function (or a group of functions) to vary, the coupling and performance variations of the other functions arises from the model built in step 1 and from the potential variability inferred at step 2.

2.4 Fourth Step

The final step aims to find ways to cope with the possible outcomes of uncontrolled performance variability found by the preceding steps. The solutions could be removing the threat, adding some barrier or defense, making easy useful practices; and protecting the system.

3. RADIOPHARMACEUTICAL DISPATCH PROCESS MODELING

This study is concerned about demonstrating a way to evaluate possible situations that may affect the effectiveness of the radiopharmaceutical dispatching process. It means this is a kind of risk assessment, since it looks into possible future events that could cause unwanted outcomes. At this step, the functions of the model were identified and described. These functions portraits the model.

Radiopharmaceutical dispatch process is comprised of identifying the client, packaging the material, monitoring its radioactive activity, filling the proper forms, and sending it to the clients. The whole process requires following safety procedures and additional caution due to radioactivity. In addition, the process is constrained by the substance half-life and the exams schedule.

3.1. Dispatching Process: Identify and Describe the Functions

The first attempt to model the dispatching process was based on a radiopharmaceutical producer formal document. The main operational units are listed on Table 1.

Table 1. Radiopharmaceutical Dispatch Process Core Functions

Open "Radiopharmaceutical Dispatch Process Report"
Verify monitoring equipments

Prepare packages, and set apart dispatch forms
Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation (Emergency Envelope)
Monitor vehicle
Authorize vehicle departure

These functions were characterized with regard the six FRAM aspects, being Input and Output the only mandatory aspects to be defined for core functions. These functions are represented bellow (Table 2 to Table 8)

Table 2. Function: Open "Radiopharmaceutical Dispatch Process Report"

Function	Open "Radiopharmaceutical Dispatch Process Report"
Description	The dispatching coordinator starts the process by filling the proper form after verifying the radiopharmaceuticals production schedule.
Input	Radiopharmaceuticals production schedule
Output	Dispatch Process Form opened

Table 3. Function: Verify monitoring equipments

Function	Verify monitoring equipments
Description	Dispatching coordinator verifies the radiation monitors operation conditions.
Input	Dispatch Process Form opened
Output	Radiation monitors ready to use

Table 4. Function: Prepare packages, and set apart dispatch forms

Function	Prepare packages, and set apart dispatch forms
Description	Technician label a tag on the package and set apart the proper forms in accordance with the type of transportation (air or terrestrial)
Input	Orders relation available
Output	Empty Package ready to use Forms set apart
Resource	Package available
Time	Dispatch schedule accomplished

Table 5. Function: Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation (Emergency Envelope)

Function	Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation (Emergency Envelope)

Description	Dispatching technician puts each radiopharmaceutical inside one package and monitors it. Dispatching coordinator prints transportation documents and insert them into the "Emergency Envelope"
Input	Empty Package ready to use Forms set apart
Output	Filled package ready to go
Precondition	Monitor turned on 15 minutes before operation
Control	Transportation documents printed and put inside the "Emergency Envelope" Package monitoring approved
Time	Dispatch schedule accomplished

Table 6. Function: Monitor vehicle

Function	Monitor vehicle
Description	To be done by the radioprotection technician
Input	Filled packages fixed into the vehicle
Output	Vehicle monitored
Precondition	Monitor turned on 15 minutes before operation Emergency envelope ready to go
Time	Dispatch schedule accomplished

Table 7. Function: Authorize vehicle departure

Function	Authorize vehicle departure
Description	To be done by the radioprotection technician after checking driver signature
Input	Vehicle monitored
Output	Vehicle ready to go
Precondition	Vehicle monitoring approved
Control	"Emergency envelope approved" by driver
Time	Dispatch schedule accomplished

Table 8. Function: Deliver radiopharmaceuticals

Function	Deliver radiopharmaceuticals
Description	To be done by the transportation company
Input	Vehicle ready to go
Output	Radiopharmaceutical delivered
Time	Dispatch schedule accomplished

In order to complete the model a second interaction had to be done. This step was necessary because no aspects should occur for one function only. The functions inserted in the model are listed bellow – Table 9.

Table 9. Functions from second interaction

Have the orders of the day available
Approve filled packages monitoring results
Approve vehicle monitoring results
Print transportation documents and insert them into the "Emergency Envelope"
Arrange and fix filled packages into the vehicle
Approve filled packages stowage into the vehicle
Accomplish dispatch process schedule
Follow monitoring rules
Turn on monitor 15 minutes before any monitoring process
Deliver radiopharmaceuticals

3.2 Dispatching Process: The identification of Variability

The dispatching process is mainly conducted by human functions, and there is no machinery-based function. Despite the use of hardware, like computers, printers, monitors and vehicles, are necessary, the model can assume it as resources for the human functions. No technological function was defined in the model.

Human functions are willing to vary. As the dispatching process must attend radioactivity safety rules and exams scheduling, workers are subjected to pressure and stress situations, leading to potential performance variability.

Considering that human functions are prone to vary, it was considered how performance variability affects downstream functions. This was done thru the characterization of the Output from a function in terms of 'timing' and 'precision' as it may be used by the downstream function. Figure 3 summarizes possible characterizations.
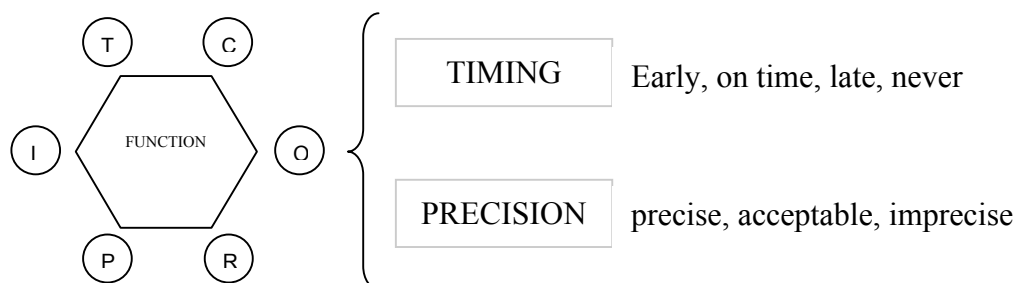
Figure 3. Characterization of the Output

3.3 - Dispatching Process: The aggregation of Variability

An instantiation represents a concrete instance of the model for given (actual or assumed) circumstances and set(s) of conditions, and the details provided by the instantiation makes it possible to be more precise about whether and how the potential variability can become actual variability [3].

The upstream-downstream couplings were examined in order to identify how performance or quality variation of a function could affect the performance or quality of the receptor function.

In order to make the aggregation of variability and present a way to assess the effectiveness of the process, two instantiations were chosen based on the importance of the functions for the process. The instantiations of the models should start by the core, or foreground, functions. But it may also include background functions in order to evaluate possible resonance over the expected results of the system. The selected functions were: (a) verify monitor equipments and (b) Prepare packages and set apart dispatch forms.

3.4 Instantiations of the model

The first instantiation is a scenario where one malfunctioning monitor is approved to operate without noticing. Considering this instantiation, the first downstream function is <Turn on monitor 15 minutes before any monitoring process>, which receives the Output from function <Verify monitoring equipments> as Input. The Input to the former function should be <monitors ready to use>, but if one malfunctioning monitor were designed to the downstream operational unit, its performance variability may increase (Table 10).

Table 10. Possible effects on 'Turn on monitor' function

Upstream function	Output➜Input	Downstream function	Time	Precision	Effects on downstream function
Verify monitoring equipments	Monitor not ready to use	Turn on monitor 15 minutes before any monitoring process	On time	Imprecise	Loss of time, loss of accuracy, misunderstandings [Variability ↑]

Considering variability was not dampened, i.e. nobody noticed the monitor were broken, the poor quality outcome would be spread thru the next downstream function (Table 11). Downstream function, <Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation>, needs the monitor ready to use 15 minutes before operation. This function already states a protection, i.e., the monitor must be turned on 15 minutes before operation allowing time to fix mistakes. In addition, this function also has a 'Control' unity, which states that monitoring must be approved. Such condition would make possible the working team notice the problem when performing the downstream function. In this case, another monitor should be ready for replacement in order to dampen the performance variability (Table 11.a).

Table 11. Possible effects on 'Pack radiopharmaceutical' function

Upstream function	Output→ Precondition	Downstream function	Time	Precision	Effects on downstream function
Turn on monitor 15 minutes before any monitoring process	Monitor turned on 15 minutes before operation, but malfunctioning	Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation	Early or On time	Imprecise	Possible damping [Variability ↓] (a)
			Late	Imprecise	Loss of time, Loss of accuracy, Misunderstandings [Variability ↑↑] (b)

If the output were produced later than expected, i.e., the monitor were turned on belated, and were malfunctioning (Table 11.b), probably there would be no time available to dampen the performance variability. The consequence would be a delay to monitor packages, leading to an increased performance variability of downstream functions. Even this situation would be better then not noticing monitor malfunctioning at all, since the former may not compromise the measures that should be done.

If the problem had not been perceived, and a defective monitor had been used for monitoring, the consequence would be the propagation of variability to downstream functions (Table 12). In such situation, it would be expected the packages had being fixed into the vehicle with wrong measurements done and therefore reduced accuracy.

Table 12. Possible effects on 'Arrange and fix' function (on time/imprecise input)

Upstream function	Output→ Input	Downstream function	Time	Precision	Effects on downstream function
Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation	Filled package ready to go on time, but wrong measures have been done due to malfunctioning monitor	Arrange and fix filled packages into the vehicle	On time	Imprecise	Loss of accuracy [Variability ↑]

On the other hand, for downstream function < Arrange and fix filled packages>, receiving a precise, but late Input, would lead to loss of time and also increased performance variability (Table 13). Time available to arrange and fix packages into the vehicle would be reduced, forcing the driver to do his job faster than usual. The Output would be precise if the unwanted performance variability found in monitor were corrected, i.e., if monitor had been replaced, allowing reliable measurements after radiopharmaceutical had been packaged. This situation would be preferable than a 'on time, but imprecise' output, which could lead to loss of measurements accuracy and potential unsafely situations for workers (Table 12).

Table 13. Possible effects on 'Arrange and fix' function (late-precise input)

Upstream function	Output→ Input	Downstream function	Time	Precision	Effects on downstream function
Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation	Filled package ready to go, but belated due to the necessity to replace monitor	Arrange and fix filled packages into the vehicle	Late (Due to time necessary for correction)	Precise (Malfunctioning had been corrected in the previous operational unit)	Loss of time [Variability↑]

Another situation would be replacing the monitor in previous operational unit without loosing significant time to process scheduling (Table 14). It would happen if the working team replaced the monitor at the beginning of the function <Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation>, since the function <turning on monitor 15 minutes before operation> is a Precondition to the former, and in principle should be checked properly before its start. This situation would lead to a performance variability damping.

Table 14. Possible effects on 'Arrange and fix' function (on time-precise input)

Upstream function	Output→ Input	Downstream function	Time	Precision	Effects on downstream function
Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation	Filled package ready to go, replacement had been done in time to attend scheduling	Arrange and fix filled packages into the vehicle	On time	Precise (Malfunctioning had been corrected in the previous operational unit)	Damping [Variability↓]

Once the radiopharmaceuticals were packaged, monitored, arranged and fixed into the vehicle, there would be no chance to redone measurements, unless the same equipment were used to monitor vehicle and a new operational evaluation were done, enabling a corrective action. If the non-conformity were not corrected, the performance variability would be spread thru the process leading to delays or loss of accuracy.

The second instantiation is a scenario where an order must be delivered by plane. This situation requires the technician set specific forms apart in order to ship the radiopharmaceutical via airplane. For some reason, the responsible worker exchanges the order forms, picking the ground transportation forms instead of air transportation forms (Table 15).

Table 15. Possible effects on 'Pack radiopharmaceuticals' function

Upstream function	Output→ Input	Downstream function	Time	Precision	Effects on downstream function
Prepare packages, and set apart dispatch forms	Empty Package ready to use, **Wrong** forms set apart	Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation	On time	Imprecise (Wrong forms had been set apart)	Misunderstandings, loss of accuracy, delays [Variability↑]

Downstream function < Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation> would receive an imprecise Input, increasing its performance variability. It means the quality of the downstream function Input was not adequate to the effectiveness of process and delays or loss of accuracy would be expected.

The sooner the mistake were noticed, the lesser the negative impact for the process. If a worker realized while completing the dispatch documentation that forms had been exchanged, there would be an opportunity to correct the mistake without loosing significant time. Obviously, not noticing the mistake would spread the performance variability thru downstream functions.

Downstream functions are: <Pack radiopharmaceuticals, monitor filled packages, and finish dispatch documentation>; <Arrange and fix filled packages into the vehicle>; <Approve filled packages stowage into the vehicle>; <Monitor vehicle>; <Approve vehicle monitoring results>, <Authorize vehicle departure>, <Deliver radiopharmaceuticals>. The best opportunity to dampen performance variability due to forms exchange would be at vehicle departure authorization, since this is the moment the driver should approve documentation. If the wrong forms go beyond this point, the error would only be noticed at the boarding gate, leading no time to correct the mistake.

4. DISCUSSION

FRAM Method is a tool to enhance risk assessment comprehension. Focus on performance variability rather than human error help may managers to achieve a global understanding of safety in complex systems. Identifying and characterizing FRAM functions are the most significant step of the method, and participation of the working team is crucial for its fidelity to reality.

Despite the functions <verify monitors> and <set apart dispatch forms> could be seen as ordinaries, this study showed how simple tasks could be combined in situations which could lead to major undesirable consequences. The functional resonance could be even worse of both situations occurred at the same day.

Despite its potential, the FRAM method for risk assessment is time consuming and need an experienced team to model and simulate the process. Modeling can also bring more understanding of the whole process and may stimulate the working team to pay attention on the connections and its consequences.

5. CONCLUSIONS

This study aimed to demonstrate some potential use of the FRAM method as a risk assessment tool thru its application on a Radiopharmaceutical Dispatch process. The steps to perform a risk assessment using the method had been present. At first, core functions were defined using the tool then, in order to complete the model, background functions have been added. Potential variability of process was suggested and two instantiations of the model have been presented.

The first instantiation was a situation where one malfunctioning monitor had been put to operate. The main conclusion was the necessity of settling a double check on monitor operational condition before demanded. The second instantiation was a situation in which dispatching forms had been changed. Error proven forms, for example, with different colors, would be used to avoid mistakes.

Considering future studies, more instantiations could be done in order to assess potential risks of a radiopharmaceutical dispatch process. In addition, despite the focus of FRAM on variability rather than probability, it may be possible to quantify the model using Fuzzy Sets, which, like FRAM, use language as a tool to characterize system attributes.

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