

A Hybrid Model to Evaluate Human Error Probability (HEP) in a Pharmaceutical Plant

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Abstract: The aim of the present research is to propose a hybrid model to evaluate Human Error Probability (HEP) called Logit Human Reliability (LHR). The new approach is based on logit normal distribution, Nuclear Action Reliability Assessment (NARA), and Performance Shaping Factors (PSFs) relationship. The present paper analyzed some shortcomings related to literature approaches, especially the limitations of the working time. We estimated PSFs after 8 hours (work standard) during emergency conditions. Therefore, the correlation between the advantages of these three methodologies allows proposing a HEP analysis during accident scenario and emergencies. The proposed approach considers internal and external factors that affect the operator’s ability. LHR has been applied in a pharmaceutical accident scenario, considering 24 hours of working time (more than 8 working hours).

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1. INTRODUCTION

The complexity of technological evolution has increased the risks related to the management of industrial machines [1]. Lately, after many accident situations, the emergency management in production systems has assumed an important role [2]. According to Sheridan and Ferrell [3], the emergency management evaluates two fundamental parameters: system reliability and human reliability. In particular, it is necessary to monitor the safety of critical infrastructures [4] because their failure could generate serious consequences on the surrounding environment and drastic emergency [5]. It is necessary to study human behavior during emergency conditions. An operator wrong choice could worsen emergency conditions. It is necessary to identify all factors that affect the operator's behavior [6]. Definitely, the emergencies are complex and dynamic; therefore, operators must recognize, prevent, and solve problems that can generate accidents [7]. It is important to analyze and manage external and internal factors relating to human [8]. The risk management studies all factors to limit emergency conditions and to reduce the consequences of human errors [9]. HRA is a systemic approach, which evaluates HEP during the working time, analyzing external and internal factors, which could influence workers' performance [10]. The “external” factors depend on the work environment. The “internal” factors are related to the individual's characteristics [11]. The paper analyses the most important HRA approaches. LHR method starts from the NARA model proposed by Kirwan et al. [12], the SPAR-H model proposed by Gertman et al. [13] and the Performance Shaping Factors (PSFs) dependence proposed by Boring [14]. The “external” factors depend on work environment; they modify the working conditions and thus leading to errors. The “internal” factors are related to the individual's characteristics, and individual psychophysical conditions of the operator

However, NARA and SPAR-H models do not analyze the dependencies between the external environmental

factors. Using PSFs it is possible to value the influence of many external environmental factors coming from the analysis of 82 real case studies.

The aim of this study is to propose a hybrid model, called Logit Human Reliability (LHR) for evaluating human error probability in the industrial plants during an emergency condition.

The proposed approach combines three methods of HRA: the NARA methodology, Logit Normal Distribution, and Boring's PSFs dependency. The fusion among these three methodologies allows to develop a reliable simulator for human error probability analysis during the emergency conditions.

The human (internal) and environmental (external) factors that influence the operator's ability are both evaluated in the proposed approach. The Boring's PSFs dependency considers the external factors, while the NARA methods consider the internal factors. The Logit Normal Distribution can be evaluated through basic HEP that will be corrected by PSFs. The proposed method uses Logit function because it represents the “wear-out” condition of the human operator. Using Logit distribution, HEP increase vs. time can be calculated.

LHR model is validated in a pharmaceutical plant. In particular, the operator's behavior in a control room is analyzed. The paper is organized as follows: Section 2 analyses the state of the art of HRA (human reliability analysis). In Section 3, the methodological research approach is presented. In Section 4, the case study is analyzed, while in Section 5, the results are presented and discussed. Finally, in Section 6, the conclusions and future developments are described.

2. LITERATURE REVIEW

Human Reliability Analysis (HRA) analyses the human reliability, in a similar way to the analysis of system reliability [15]. According to Swain and Guttman [16], HRA methodologies have motivated many activities in

research and development [17]. HRA influences the maintenance system [18]. The availability of a production system depends on the performance and connections of the machines and operators [19-20]. In general, the causes that lead to an accident are three: system failures, natural events, and human errors [21]. Several authors analyzed human behavior in emergency conditions. For example, Jung et al. [22] analyze the performance of the operator in a pharmaceutical plant. Houshyar and Imel [23] developed a simulation model of human behavior in a nuclear plant. Literature analysis divides HRA methodology in three different generations:

a) First generation (1970 - 1990) focus on the skills and rules of human factors without considering social interest, management factors and communication errors. Some first generation approaches are:

- Systematic Human Action Reliability (SHARP): it considers the integration of man and machines [24] and it calculates HEP in seven steps [25,26].
- The Empirical Technique to Estimate the Operator's Error (TESEO): considering five factors, it calculates the HEP of operator [27-28].
- Accident Sequence Evaluation Program (ASEP): it has been applied to nuclear plants. ASEP uses the correlation between time and reliability to obtain HEP [29,30].
- Human Cognitive Reliability Correlation (HCR): it used SLIM factors to estimate HEP. SLIM Equations have been revised to evaluate PSFs effect on human reliability [31].
- Technique for Human Error Rate Prediction (THERP): it analyzes some PSFs but not their effects on HEP [32].
- Success Likelihood Index Method (SLIM): It has been used in nuclear plants, but it can be easily applied to other plants. [33-34].
- Human error assessment and reduction technique (HEART): it has been developed in the early 1990's [35] in the United Kingdom nuclear plants. Identifying "generic tasks" (GTTs), the analyst can determinate the HEP basic [36].

b) Second generation methodologies (1990-2005), which integrate internal and external factors affecting human reliability. In second-generation models, the factors that determine PSFs are derived by focusing on the environmental impact on the cognitive level. Some methodologies below to the second generation are:

- Cognitive Reliability and Error Analysis Method (CREAM): it is based on the Contextual Control Model (COCOM) [37]. Konstandinidou et al. [38] used this approach to construction a fuzzy model for HRA. The approach is developed to determine the HEP with PSFs values.
- A Technique for Human Event Analysis (ATHEANA): it was designed to be a full scope HRA method including the capability for performing predictive task analysis and retrospective event analysis. [39].
- Standardized Plant Analysis Risk - Human RA (SPAR-H): it was a revised version of ASP approach. Rasmussen et al. [40] applied this approach to estimate

HRA to the pharmaceutical industry. SPAR-H is based on eight PSFs.

c) In the last ten years, the shortcomings of the second-generation HRA have been overcome by third-generation methods:

- Nuclear Action Reliability Assessment (NARA): it is an upgrade of the HEART method to (a) have better fit to nuclear context, (b) consider errors of commission, (c) have substantial data support, (d) consider long time scale scenarios, and (e) have better guidance on usage [41-42].

Boring [14] proposes a dependence model between the PSFs. Rauschert et al. [43] using GIS a geographic interface to manage emergencies. The research takes into account the external environment and its characteristics. Even Schafer, Ganoe and Carroll [44] manage the planning of emergency management through geographical software. Currión Silva and Van de Walle [45] developed a simulation tool to manage the coordination during an emergency. Levi et al. [46] describe the experience with developing and implementing the use of simulation software as a drilling technique used by Israeli hospitals. Cowan and Cloutier [47] describe a required, role-intensive leadership simulation in emergency and disaster medicine management for fourth-year medical students. Christie and Levary [48], which use the simulation model, "what-if" analyses to predict the consequences of conceivable scenarios.

The present study starts from several shortcomings of literature HRA models. The proposed model, called Logit Human Reliability (LHR), overcomes the limitations of the most conventional HRA methodologies, merging the advantages of NARA, PSFs, and SPAR-H models.

Furthermore, the present research analyzed three limitations related to the NARA model: 1) HEP is limited to the first 8 hours of work; 2) no dependency between the relationships of PSFs; 3) the failure rate is constant.

3. LOGIT HUMAN RELIABILITY (LHR)

In this section, the proposed LHR model is described. The new approach combines three methods of HRA: the NARA methodology, Logit Normal Distribution, and Boring's PSFs dependency. The human (internal) and environmental (external) factors that influence the operator's ability are both evaluated in the new approach.

We estimated HEP after 8 hours (work standard) during emergency conditions. The model will be applied during a simulated emergency in a pharmaceutical plant, considering 24 hours of working time. LHR method is structured in the following steps:

Step 1: Preliminary Analysis.

An identification of the activities to be simulated. It lists all activities performed by the decision makers while working in nominal conditions and during an emergency. HEP will be associated with each of these activities, where HEP represents the unreliability of the operator. For example, Di Pasquale et al. [49] and Gertman, and Blackman [50] simulated the HEP with the Weibull function, while Chiodo et al. [51] uses a random function to evaluate human performance. Usually, Logit Normal

function is selected during “wear out” phase of components. This phase can be compared to the stress phase of an operator during an accident scenario. Starting from the above analysis, we have selected Logit distribution to link HEP and operating time. The human unreliability has been evaluated by the Logit function of failure probability (Eq.1).

$$g(t) = 1 - \frac{e^{\left(\frac{t-\mu}{\sigma}\right)}}{1+e^{\left(\frac{t-\mu}{\sigma}\right)}} \quad (1)$$

Where μ is the average value and σ is the standard deviation.

Step 2: Identification of Internal Factors

In this phase, we defined Generic Tasks (GTTs), that represent the internal factors of the operators. Each GTT follows the Logit function. Using Logit distribution, HEP will be calculated. The HEP increase vs. time. Table 2 describes the NARA GTTs, while k is the human unreliability value to the 8th hour of working time, λ is the constant value of failure rate, μ is the Mean Time to Failure and σ is the standard deviation. Assuming λ =constant, we obtain:

$$\lambda = -\frac{\ln(1-k_{24})}{8} \quad (2)$$

$$MTTF = \mu = \int_0^\infty t \cdot f(t) dt = \frac{1}{\lambda} \quad (3)$$

$$\sigma = \sqrt{\int_0^\infty (t - MTTF)^2 \cdot f(t) dt} = \sqrt{\int_0^\infty \left(t - \frac{1}{\lambda}\right)^2 \cdot \lambda e^{-\lambda t} dt} \quad (4)$$

where $f(t) = \lambda e^{-\lambda t}$ is the failure probability density function when λ =constant (table 1).

Table 1. Generic Tasks.

GGT	k (t=8h)	λ [1/h]	μ [h]	σ [h]
A1 Carry out simple single manual action with feedback. Skill-based and therefore not necessarily with procedure.	0.0050	6.266·10 ⁻⁴	1596.00	618
A2 Start or reconfigure a system from the Main Control Room following procedures. with feedback.	0.0010	4.169·10 ⁻⁵	23988.00	6010
A3 Start or reconfigure a system from a local control panel following procedures. with feedback.	0.0030	1.252·10 ⁻⁴	7987.99	2800
A4 Reconfigure a system locally using special equipment. with feedback; e.g. Closing stuck open boiler SRV using gagging equipment. Full or partial assembly may be required.	0.0300	1.269·10 ⁻³	787.94	413
A5 Judgment needed appropriate procedure to be followed. based on interpretation of alarms/indications. Situation covered by training at appropriate intervals.	0.0100	4.188·10 ⁻⁴	2387.98	1004
A6 Completely familiar well designed highly practiced. Routine task performed to highest possible standards by highly motivated. Highly trained and experienced person. Very aware of implications of failure with time to correct potential error.	0.0001	4.167·10 ⁻⁶	239988.0	59995
B1 Routine check of plant status.	0.0300	1.269·10 ⁻³	787.94	413
B2 Restore a single train of a system to correct operational status after test following procedures.	0.0070	2.927·10 ⁻⁴	3416.56	1316
B3 Set system status as part of routine operations using strict administratively controlled procedures	0.0007	2.918·10 ⁻⁵	34273.71	8566
B4 Calibrate plant equipment using procedures; e.g. adjust set Point.	0.0030	1.252·10 ⁻⁴	7987.99	2800
Carry out analysis.	0.0300	1.269·10 ⁻³	787.94	413
C1 Simple response to a key alarm within a range of alarms/indications providing clear indication of situation (simple diagnosis required). Response might be direct execution of simple actions or initiating other actions separately assessed.	0.0004	1.667·10 ⁻⁵	59988.00	14995
C2 Identification of situation requiring interpretation of complex pattern of alarms/indications. (Note that the response component should be evaluated as a s	0.2000	9.298·10 ⁻³	107.55	117

Step 3: Basic Human Error Probability (HEP_{basic})

The calculation of the basic error probability (influenced by GTTs) follows the Logit distribution (eq. 1). The nominal distribution is theoretical and does not take into account the external environment factors. HEP_{basic} takes into account only the k value (table 2). The human unreliability value (Table 2) is the input value for equation (1), where μ and σ are calculated using equations (3) and (4). The basic HEP_{basic} is determined as:

$$[HEP_{basic}]_{t_1}^{t_2} = \int_{t_1}^{t_2} 1 - \frac{e^{\left(\frac{t-\mu}{\sigma}\right)}}{1+e^{\left(\frac{t-\mu}{\sigma}\right)}} dt = \frac{1}{t_2-t_1} \left[t - \sigma \ln(1 + e^{\left(\frac{t-\mu}{\sigma}\right)}) \right]_{t_1}^{t_2} \quad (5)$$

Equation (5) considers a working time greater than eight hours, because in several emergencies some operators could work even 24 hours consecutive.

Step 4: Identification of External Factors

The environmental influences are modelled with the use of Performance Shaping Factors (PSFs). The PSFs increase the HEP values. The PSFs analyzed are: Available time; Stress/Stressor; Complexity; Experience and training; Procedures; Ergonomics and Human machine interface; Fitness for duty; Work processes. However, PSFs dependencies are not considered in the NARA model. Boring (2010) proposes a table of PSFs dependencies (Table 2).

Table 2. - PSFs dependence

	Available Time	Stress Stressors	Complexity	Experience Training	Procedures	Ergonomics HMI	Fitness for Duty	Work Process
Available Time	1							
Stress Stressors	0.50*	1						
Complexity	0.38*	0.35*	1					
Experience Training	0.31*	0.21*	0.32*	1				
Procedures	0.05	-0.01	0.12*	0.08*	1			
Ergonomics HMI	0.10*	0.04	0.08*	0.08*	0.29*	1		
Fitness for Duty	0.20*	0.29*	0.22*	0.17*	0.12*	0.27*	1	
Work Processes	0	0.13*	0.16*	0.20*	0.35*	0.12*	0.15*	1

Step 5: PSFs Correlation (PSF_{cor}).

The PSF_{cor} value is evaluated from the product of all PSFs and their value of independence. The PSF_{cor} represents the external environmental conditions as the following Equation 6:

$$PSF_{cor} = \prod_{i=1}^n [PSF_i (1 - \sum \text{dependence_indexes}) \cdot \text{State}(PSF_i)] \quad (6)$$

where “n” is the total number of PSFs that are considered in the approach. The state of each PSF has been assessed by an Expert Judgment (0<State(PSF_i)<1).

Step 6: PSFs correct by time (PSF_{time}).

The results obtained from Eq.6 are corrected by time factors:

$$T = \frac{t}{8} \quad (7)$$

where $1 \leq t \leq 24$

Applying the following equation 8, we obtained the PSFs corrected by time:

$$PSF_{time} = PSF_{cor} \cdot T \quad (8)$$

Eq.8 is able to increase PSFs after the 8th of work. In this condition, the influence of external factors is more several to operators.

Step 7: LHR Model (HEP_{LHR}).

Starting from NARA formulations the real HEP is calculated. The combination of human factors and environmental factors returns the HEP_{LHR} value:

$$HEP_{SHRA} = HEP_{basic} \cdot [PSF_{time} + 1] \quad (9)$$

The HEP_{SHRA} is the unreliability value of the operator during an accident scenario, depending of the influencing factors.

4. CASE STUDY: LHR APPLICATION IN A PHARMACEUTICAL PLANT

A pharmaceutical plant is considered to validate our model. To develop LHR approach, we used NARA and SPAR-H methods (designed for nuclear plants) because the consequences of disaster in a pharmaceutical plant are very several for environmental and operators. In particular, the HEP in a control room is analyzed.

Step 1: Preliminary Analysis

The emergency activities of the decision makers in the control room of a pharmaceutical plant during a fire are summarized in nine steps: emergency alarm activation, activate the emergency signal, activate of the protection system, evacuation of personnel, system block, activate the external alarm, insolation damaged area, internal Emergency Team activation and request for external aid.

Step 2: Identification on Human Activities.

The choice of four GTTs was carried out through interviews with an Expert Judgments. Applying eq. (2), (3), and (4) the four GTTs are related to the activities managed by the decision maker described in step 1 (Table 3).

Table 3. GTTs of the control room operator.

GGT	K24 (t=24h)	λ [1/h]	μ [h]	σ [h]
A5 Judgment needed for appropriate procedure to be followed, based on interpretation of alarms/indications. situation covered by training at appropriate intervals.	0.0100	4.188·10 ⁻⁴	2387.98	1004
A6 Completely familiar, well designed highly practiced, routine task performed to highest possible standards by highly motivated, highly trained, and experienced person, totally aware of implications of failure, with time to correct potential error. Note that this is a special case.	0.0001	4.167·10 ⁻⁶	239988.00	59995
B5 Carry out analysis.	0.0300	1.269·10 ⁻³	787.94	413
C2 Identification of situation requiring interpretation of complex pattern of alarms/indications. (Note that the response component should be evaluated as a separate GTT)	0.2000	9.298·10 ⁻³	107.55	117

Step 3: Basic Human Error Probability (HEP_{basic})

Using Equation (5), HEP_{basic} for four GTTs is calculated. Table 4 describes HEP_{basic} values during 24 working hours.

Step 4: External Factors Definition.

According to an Expert Judgment, PSFs values have been selected (8)

Table 4. HEP_{basic}.

	HEP _{basic}			
	GTT-A5	GTT-A6	GTT-B5	GTT-C2
t=2h	4.17·10 ⁻²	6.15·10 ⁻²	1.01·10 ⁻¹	1.17·10 ⁻²
t=4h	7.10·10 ⁻²	7.18·10 ⁻²	1.25·10 ⁻¹	3.10·10 ⁻²
t=6h	9.23·10 ⁻²	1.33·10 ⁻¹	1.93·10 ⁻¹	6.23·10 ⁻²
t=8h	1.26·10 ⁻¹	2.28·10 ⁻¹	2.98·10 ⁻¹	8.26·10 ⁻²
t=12h	1.51·10 ⁻¹	2.81·10 ⁻¹	3.11·10 ⁻¹	1.11·10 ⁻¹
t=10h	2.26·10 ⁻¹	3.36·10 ⁻¹	3.86·10 ⁻¹	1.25·10 ⁻¹
t=14h	2.89·10 ⁻¹	3.81·10 ⁻¹	3.99·10 ⁻¹	1.99·10 ⁻¹
t=16h	3.41·10 ⁻¹	4.10·10 ⁻¹	4.45·10 ⁻¹	2.31·10 ⁻¹
t=18h	3.91·10 ⁻¹	4.61·10 ⁻¹	5.23·10 ⁻¹	2.56·10 ⁻¹
t=20h	4.25·10 ⁻¹	4.99·10 ⁻¹	5.99·10 ⁻¹	3.05·10 ⁻¹
t=22h	5.15·10 ⁻¹	5.91·10 ⁻¹	6.02·10 ⁻¹	3.99·10 ⁻¹
t=24h	5.98·10 ⁻¹	6.17·10 ⁻¹	6.19·10 ⁻¹	4.21·10 ⁻¹

- Available time: the time needed to make the decision;
- Stress: the degree to which you feel overwhelmed;
- Complexity: the complexity of task performing;
- Experience: the competence of the decision maker;
- Procedures: risk management of nuclear plants.

Table 5 describes the PSFs values and Table 6 reports the PSFs correlation (Boring, 2010).

Table 5. PSFs Values.

PSF	Low Hazard	Medium Hazard	High Hazard
Available time	0.1	1	10
Stress	0.2	2	20
Complexity	0.1	1	10
Experience	0.1	1	10
Procedures	0.3	3	30

Table 6. PSFs dependence.

	Available Time	Stress Stressors	Complexity	Experience Training	Procedures
Available Time	1				
Stress Stressors	0.50*	1			
Complexity	0.38*	0.35*	1		
Experience Training	0.31*	0.21*	0.32*	1	
Procedures	0.05	-0.01	0.12*	0.08*	1

Step 5: PSFs Correlation (PSF_{cor})

According to equation 6 and considering State (PSF)=0.2 for each Performance Shaping Factor, PSF_{cor} index was calculated:

$$PSF_{cor}=0.192$$

Step 6: PSFs corrected by time (PSF_{time}).

According to equation 7 and 8, we obtained the PSFs corrected by time (table 7). PSF_{time} value is equal to PSF_{cor} value at the 8th working hour but is a triple value at 24th working hour.

Step 7: LHR Human Error Probability (HEP_{LHR})

Applying equation 9, HEP_{LHR} has been evaluated combining internal operating conditions (HEP_{basic}) with

external environment conditions corrected by T factor (PSF_{time}).

Table 7. Time Factor.

	T	PSF_{time}
t=2h	0.25	0.048
t=4h	0.50	0.096
t=6h	0.75	0.144
t=8h	1.00	0.192
t=10h	1.25	0.240
t=12h	1.50	0.288
t=14h	1.75	0.336
t=16h	2.00	0.384
t=18h	2.25	0.432
t=20h	2.50	0.480
t=22h	2.75	0.528
t=24h	3.00	0.576

Table 8 shows the HEP_{LHR} values for four GTTs during the high hazardous scenario and Figure 1 describes the HEP_{LHR} trends.

Table 8. HEP_{LHR} .

	HEP_{LHR}			
	GTT-A5	GTT-A6	GTT-B5	GTT-C2
t=2h	4.37%	6.45%	10.58%	1.23%
t=4h	7.78%	7.87%	13.70%	3.40%
t=6h	10.56%	15.22%	22.08%	7.13%
t=8h	15.02%	27.18%	35.52%	9.85%
t=10h	18.72%	34.84%	38.56%	13.76%
t=12h	29.11%	43.28%	49.72%	16.10%
t=14h	38.61%	50.90%	53.31%	26.59%
t=16h	47.19%	56.74%	61.59%	31.97%
t=18h	55.99%	66.02%	74.89%	36.66%
t=20h	62.90%	73.85%	88.65%	45.14%
t=22h	78.69%	90.30%	91.99%	60.97%
t=24h	94.24%	97.24%	97.55%	66.35%

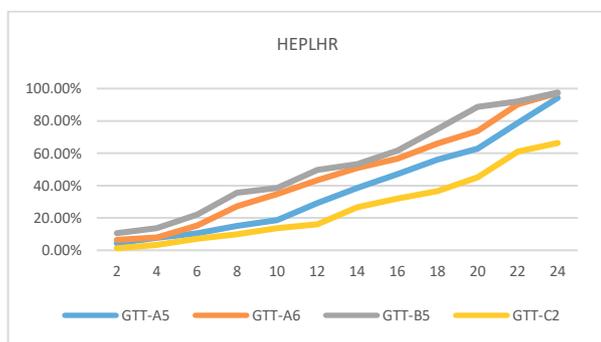


Figure 1. HEP_{LHR} .

5. DISCUSSION

The operator's choices in emergency conditions depend on many factors. In this condition, HEP is influenced by human factors, the environmental factors (PSFs) and working time.

The proposed model HEP_{LHR} increases with operating time due to human factors, because the decision maker will be tired during the working time. HEP_{LHR} for GTT-A5 in the 2th hour it is 4.37%, while at the 24th hour it is 94.24%. However, the human unreliability depends also on the

GTTs. The results highlight that GTT-B5 is the most relevant task – $HEP_{LHR}(t=24h)=97.55\%$ while GTT-C2 is the less relevant task $HEP_{LHR}(t=24h)=66.35\%$.

The HEP_{LHR} output highlighted the following improves: improve the work processes (e.g.: work breaks, ergonomics, statistical process control, logistic quality, etc.); improve of reliability system; improve of safety system; improve of maintenance system; improve by training on the job.

6. CONCLUSION

The aim of the present paper is to propose a hybrid method to evaluate HEP, called Logit Human Reliability (LHR). This study was done for identifying and evaluating of the human error in control rooms in a pharmaceutical plant. The proposed approach considers all factors that influence the decisions and actions of the operator: internal, external factors and time indexes. GTT_S represent internal factors. PSFs represent external factors. T represent the time index. HEP is the output. Starting from Logit Normal distribution, the new approach is based on NARA model and on PSFs dependence. HEP_{LHR} increases with operating time due to human factors, because the decision maker will be tired during the working time. In the other hand, the human unreliability depends also on the GTTs.

However, we find some disadvantages for applying this method. They include ambiguity and overlap in definitions of the PSFs. Future research aims to develop a statistic function on evaluate States (PSFs), using multi-decisions model (e.g., AHP/ANP or Fuzzy Logic).

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