

ISASI Guidelines for Investigation of Human Factors in Accidents or Incidents



ISASI
“Air Safety through Investigation”

Foreword and acknowledgement

The International Society of Air Safety Investigators' (ISASI) wishes to express its deep appreciation to the Transport Safety Board of Canada (TSB Canada) for allowing ISASI to form these human factors accident/incident investigation guidelines based on a five day course taught at TSB Canada. All TSB Canada investigators are required to complete this course. ISASI wishes to recognize the valuable ICAO document cited in the TSB Canada course manual.

ISASI has attempted to provide a document for use by accident investigators in charge (IIC) specifically on the subject of human factors. The guidelines are not a substitute for specialists in human factors but instead are meant to highlight issues of human factors or performance in accidents or incidents.

ISASI especially wishes to provide these basic concepts to IIC's who have not an opportunity to attend formal courses in accident investigation or human factors.

Introduction

Background

Accident statistics show that issues associated with human performance are major contributors to incidents and accidents in commercial aviation and can become the subject of much controversy. World-wide, investigations vary significantly with respect to the beliefs about the role of humans and appropriate methods for investigating human factors. Ideally, an investigation will seek to understand the context of human performance and how it contributes to the observed behaviors and decisions. Whether designing equipment, planning training programs, integrating new aircraft into a fleet or finding out what went wrong in an accident or incident, understanding the human component is critical to developing and maintaining a safe air operation.

Accident and incident investigation presents a real opportunity to examine the interactions between the human and the other system components. While human factors expertise is available to inform investigations, this expertise is not uniformly applied. By developing new guidelines ISASI intends to enhance existing guidance documents now available to investigators. ISASI hopes these guidelines will highlight critical areas which affect human performance.

General statement of suggested policies

To provide for optimum investigation of the role played by humans in accidents or incidents we suggest:

- That all agencies involved in accident investigation endorse the policy that the investigation of human performance proceeds without the presumption of human error or negligence. An investigative process that seeks to ascertain what occurred rather than who was at fault will yield more vital and accurate information. It is currently true that accident investigators can begin an investigation by sifting through pieces of aircraft wreckage and have no presumption of a mechanical fault. It should also be true that investigators can gather data on human performance and the conditions of human performance without presuming human error or negligence.
- The identification of a human “error”—which simply refers to a deviation between the behavior observed or decisions made by a human (e.g., pilot) and the behavior or decision that, **in hindsight**, seemed most appropriate—is the starting point of the investigation into the precursors of human performance contributions to an accident or incident. The identification of “human error” is not a stopping point.
- The collection of human performance data should not be seen as implying that human error is a working hypothesis for the investigation. Initial interviews of operational personnel involved in the accident or incident (e.g., pilots, air traffic controllers, maintenance technicians) should be conducted in a way to maximize the retrieval of information about the event; they should not focus on finding fault with the actions taken or decisions made.

- Legal or disciplinary action taken against persons who report air safety violations or concerns impacts air safety negatively and should be avoided. Unless criminal intent is proven States should welcome these reports and protect reporting individuals. Further, states should enact legislation protecting reporters of hazards and risk from punishment in any form for making such reports.
- Every accident or incident investigation should initiate human performance data collection, as soon as possible, for these data are easily lost or tainted with the passage of time.
- That appropriate human factors expertise is brought to bear on all investigations of human performance issues.
- Accident and incident databases worldwide share a common taxonomy for identifying and listing human performance issues so that the databases can be used to track trends over time.
- Investigations to assess criminal behavior alleged to have occurred in an aircraft accident should be carefully conducted so as not to impact negatively the air safety investigation. States that have attempted to conduct both an air safety and criminal investigation concurrently, particularly where human performance is involved, have found negative effects to both investigations.

Quality Assurance

How Much Information is Enough?

In conducting the human factors investigation, the question "How much data is enough?" frequently arises. How many peers, relatives, supervisors, etc. of the individual should be interviewed? How far back in time should personal activities be investigated? To what extent should inter-personal relationships (including spousal) be examined? At what point does past behaviour cease to influence current behaviour? How high in management should the investigation proceed?

Criteria

There are no clear criteria as to how far back the investigator should probe. In constructing a detailed understanding of the accident, the questioning process of "why?" and "so what?" can be carried to extremes.

Practically, it is reasonable for the investigator to stop where corporate and regulatory authorities no longer have any power to change the underlying situation in the interests of accident prevention.

Factors of Influence

Investigators must focus on the factors most likely to have influenced actions. However, in practice, the dividing line between relevant and irrelevant human factors issues is often blurred.

Data that initially seem to be unrelated to the occurrence could prove to be extremely important after other relationships are uncovered by further analysis.

Gather, Then Analyse

It has often been said that accident investigators only gather facts during the course of their investigation and do not analyse until all the facts, conditions and circumstances of the accident have been obtained. While this may seem like a sound and objective approach to an investigation, it is not realistic. The field phase of an investigation involves a continuous, selective, analytical process.

Although a formal methodology may not been adopted, investigators quickly develop some form of ongoing reasoning process. The field investigator learns to continuously

formulate and test hypotheses to explain the known or suspected facts. This ongoing analytical process determines the direction of the investigation.

Level of Detail

Remember, you are investigating; you are not doing academic research.

It is not necessary in most investigations for the established facts, analysis, and conclusions of investigators to stand the test of a court of law.

The Task

The task is to explain how the causal event sequence was initiated and why it was not interrupted before the mishap. The critical question is WHY - not WHO was to blame.

If the information does not help to answer this question, then it is not relevant to the purpose of the investigation.

Resource Limitations

Although the number of causes and contributing factors revealed in an investigation will be a function of the resources allocated to the investigation, an open-ended approach to the investigation may be justified only following a major disaster.

For smaller investigations, the available resources may mean that efforts must be concentrated on the principal individuals, and that less information is collected on the more peripheral players in an occurrence.

Since the purpose is accident prevention, the resources dedicated to an investigation should be guided by the scope and likelihood for safety action. Deeper investigation should be confined to those safety issues with potential for further preventive action.

INTRODUCTION TO HUMAN FACTORS

Investigation: The Link to Accident Prevention

Introduction

For decades accident investigators have recognized the importance of the human being in accident causation. Indeed, the focus of accident investigations has traditionally been on the unsafe acts committed by individuals which ultimately culminated in tragedy.

While investigators might uncover a number of unfortunate circumstances surrounding the accident, typically blame is centred on those closest to the accident.

When no tangible technical evidence can be found to explain the occurrence, investigators have found it difficult to deal with the contextual human issues that might

facilitate understanding why these ordinary people were unable to safely cope with the circumstances in which they found themselves.

What, When, Who

Accident investigation reports usually depict clearly what happened, when, and especially who caused the accident. In too many instances the reports stop short of fully explaining how and why the accidents occurred.

Operator Error

Attempts to identify, analyze and understand the underlying problems that led to the breakdowns in human performance and thus to the accidents are sometimes inconsistent. By stating that a pilot, master or engineer did not follow the rules implies that the rules are well-founded, safe, and appropriate.

Hence, investigation reports often limit conclusions to phrases such as "operator error", "failed to see and avoid", "improper use of controls", or "failed to observe and adhere to established standard operating procedures (SOP's)."

Human Contribution to Accidents

Humans are not only the source of accidents, they are the key to accident prevention.

A better understanding of the contextual factors that can affect human performance in transportation occurrences can be significantly enhanced by a thorough and competent investigation of these.

Human Factors Investigated

Investigation of human factors must be an integral part of any accident or incident investigation.

As such, the collection and analysis of human factors information should be just as methodical and complete as the collection and analysis of information pertaining to the mode of transportation, its systems, or any of the other traditional areas of investigation.

The human factors investigation requires trained and disciplined investigators, who apply their skills in a systematic way, and their resources according to basic management principles.

The size and scope of the human factors investigation depend on the circumstances of the occurrence, but it must be coordinated and integrated with the other elements of the investigation.

A Systems Approach to Accident Causation

Defined

A system can be defined as an organization of people and the machines they operate and maintain in order to carry out the tasks needed to meet the aims of the system.

A systems approach acknowledges that all elements of the system may have a role to play in the occurrence.

Why?

Traditionally, investigators have examined a chain of events or circumstances which ultimately led to someone committing the unsafe act that triggers the accident. Following this approach, accident prevention efforts are concentrated on finding ways of reducing the risk that the unsafe acts will be committed in the first place.

However, the unsafe acts or triggering events leading to an accident seem to occur randomly; these same unsafe acts may have been committed hundreds of times without ill effect. Hence, safety efforts to reduce or eliminate random events may not be effective.

Adopting a systems approach to the investigation of accidents or incidents allows the investigator to better identify the underlying causes and contributing factors.

It allows for a breaking down of the real world into recognizable components in order to better understand how these components interacted to result in an accident, and in so doing points the way to remedial action.

The People Involved

Who Should Investigate?

Currently generalists, usually with operational backgrounds, investigate accidents. When warranted, specialized technical staff support investigators by providing technical advice or research. The same model should be applied to the human factors aspects of investigation.

If generalist investigators are to meet the challenges of human factors investigation, they require training in the fundamentals: what information to collect, how and where to collect it, and how to analyze it. This training should also include information on when, where, and how to get help.

Human Factors Specialists

In many cases, the investigator will need human factors specialist support and advice in the collection, analysis and reporting the associated human factors issues.

Human Factors Investigators

Good investigators can become good human factors investigators. They must possess a sound working knowledge of their transportation mode. This knowledge must be complemented by a basic understanding of techniques and principles from the human factors realm.

Often, an investigator must single-handedly plan and conduct the whole investigation, taking care to ensure that all perishable evidence pertaining to human performance is quickly gathered.

On larger investigations, a human factors specialist may be assigned responsibility for the human factors portion of the investigation under the direction of an investigator-in-charge (IIC). The same basic principles apply regardless of the size of the investigation team. Objectives and priorities must be established. There must be close cooperation with other team members since information relevant to human factors issues will be collected by investigators working in other areas.

What Information Needs to be Collected?

Immediate Information

In general, the data that must be collected fall into two broad categories. The first area is information which will enable investigators to construct a detailed chronology of each significant event known to have occurred prior to the accident or incident and, in some cases, afterwards. In the context of the human factors investigation, this chronology must place particular emphasis on behaviour and the effects these behaviours may have had.

Background

The second area includes that information which will explain what may have influenced or led to particular behaviour. This information should include all the relevant conditions under which the operations were being conducted. The Shel model is a model which can assist you in identifying the relevant human factors related information that needs to be collected.

In summary, investigators must collect sufficient information to enable them to determine what happened and why. The data collected must encompass the decisions and actions of all of the people concerned with the particular occurrence, not just the actions of the operational personnel.

Attitudes

A belief that includes an evaluative and emotional component.

- Attitudes are more resistant to change than opinions.
- Attitudes are often related to behaviour. People will, however behave in ways inconsistent with attitudes if sufficient reward or sanction are present.
- Generally
 - A belief that a certain behaviour will have mostly positive outcomes will foster a positive attitude towards that behaviour.
 - A belief that a certain behaviour will lead to mostly negative outcomes will foster a negative attitude toward that behaviour.

Attitudes - Change

Attitude change strategies can be summarized under four headings:

1. Communication of additional information
2. Approval and Disapproval
3. Group Influences
4. Being Induced to Engage in Discrepant Behaviour

Illusion

- **A false perception.**
- **A perception that does not correspond with the objective situation.**

Illusions are most commonly divided into two categories:

1. Visual Illusions

- **Autokinesis:** Erroneous perception that a single stationary source of light in a dark visual field is moving; occurs after staring at the light for a long time.
- **Chain Link Fence Illusion:** Nearby objects become less distinct (out of focus) and blend into the foreground when focus is devoted to a distant object
- **Circularvection:** Erroneous sensation of rotation; caused by movement in the visual field, especially in the peripheral vision area
- **Flicker Vertigo:** Adverse effect caused by flickering light; common sources of flicker are rotating propeller or rotor blade between the operator and the sun, and rotating or strobe type anti-collision lights reflecting off haze or cloud; there is considerable variability in peoples' susceptibility; symptoms can range from discomfort to nausea, or in extreme cases total disorientation and incapacitation; it appears that suffering flicker vertigo once increases likelihood of future occurrence
- **Horizon Misplacement:** Illusion resulting in which ground lights are

mistaken for stars or vice versa; can also happen that clouds or sloping terrain are mistaken for horizon

- **Geometric Perspective Illusion:** Erroneous perception of being closer to or further away from an object than actual; results from equating actual retinal image size of an object to distance from that object, e.g., an 8,000 foot runway may from 1000 feet away appear to be the same size as a 10,000 foot runway would appear from 1500 feet; geometric perspective illusion creates a tendency to flare high on a wider than usual runway
- **Refraction:** Refraction is the bending of light as it passes through a medium, such as the glass in a windscreen or window; refraction can cause distortion, so that objects are not where they appear to be; can result in objects appearing higher, lower or displaced laterally from objective reality; refractory effects increase as the angle at which the light enters and leaves the medium departs from perpendicular
- **Black Hole Illusion:** Erroneous perception that you are higher than you actually are or, are further away from an object (e.g., another ship) than you actually are; occurs at night over unlighted terrain; in response to the illusion, pilots have been known to increase their rate of descent
- **Linearvection**
- **Oculographic Illusion**

2. Vestibular Illusions

- **Coriolis Illusion:** Tumbling sensation; set off by movement of the head into a plane of angular or linear acceleration which induces fluid movement in the semi-circular ducts; one analogy to describe coriolis is to imagine watching a toilet flush. Now imagine that the water is stationary and it is your head that is moving. That is what this effect feels like. This effect can vary from mild disorientation to severe incapacitation, especially if the pilot is not trained to recognize and counter it.
- **Elevator Illusion:** Erroneous sensation of (a) pitch-up after leveling off from a steep descent; (b) Pitch-down after leveling off from a steep climb, or (c) either pitch-up or pitch-down in turbulence
- **Giant Hand Illusion:** Sensation that the controls will not respond to inputs, even with seemingly great effort; the source of resistance is the operator attempting to respond to conflicting sensory cues
- **Graveyard Spin:** False sensation, after recovering from a spin that the aircraft has entered a spin in the opposite direction; often results in the pilot trying to recover from this perceived spin and reverting to a spin in the original direction
- **Leans:** Erroneous perception of roll attitude or bank; most frequently associated with recovery from a coordinated turn to level flight when flying on instruments; even though you are straight and level, you feel like you are banking, or, if in a bank the perception may be very inaccurate

Information Processing

The tasks involved in operating and supporting transportation systems involves observing and reacting to events that take place within the system component being operated and in the outside environment. The aim of this section is to develop an awareness of how we receive and process information in order to make and implement decisions.

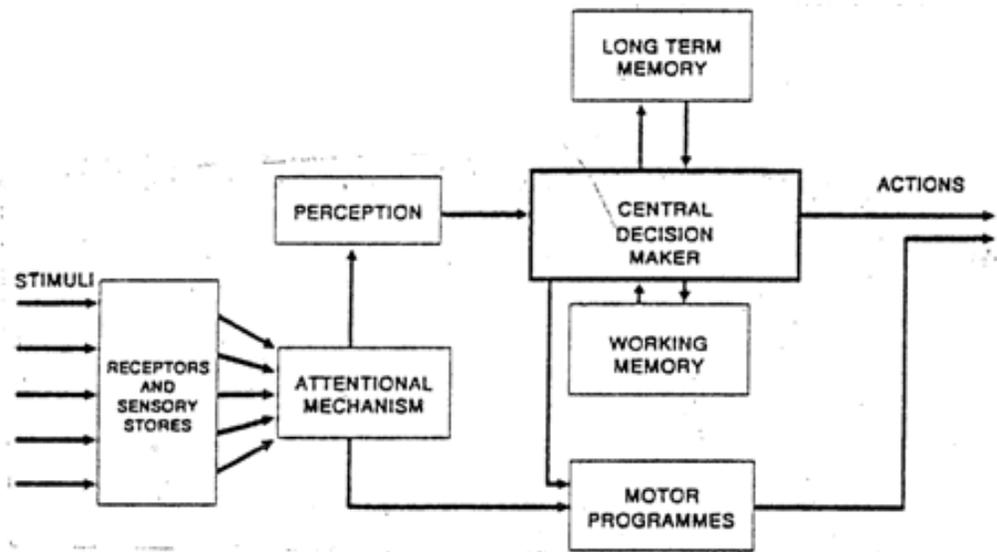
In this section we will describe:

1. A basic model of human information processing
2. Attention
3. Perceptual processing
4. Decision Making
5. Workload

Information Processing Model¹

- Inputs are physical stimuli, sight, sound, etc., which are received by receptors (eyes, ears). Inputs which are received, pass into sensory stores which decay and disappear very quickly.
- Visual sensory store information lasts from .5 to 1 second and auditory sensory store information lasts from 2 to 8 seconds. This short term storage allows us to retain the information until we have processing capacity to deal with it.
- The inputs are attended to or not depending on the situation and environment, the nature of the stimuli, and the mental and physical state of the operator.
- Perception converts the physical stimuli into meaningful structures, e.g., vibrations are converted into words. Perceptions are based both upon the information sensed by our receptors (eyes, ears, etc.) and our expectations of the world and the current situation.

1 Source: Green, R.G., Muir, H., James, M., Gradwell, D., & Green R.L. Human Factors for Pilots. Avebury Technical, Aldershot, U.K. 1991.



- Once information is perceived, a decision must be made about what to do with it. Respond immediately, disregard it, or enter it into part of the memory process while searching for a cause or selecting the most appropriate action.
- There are two kinds of memory; working memory and long term memory. Working memory (also called short term memory) is limited in how much information it can retain. (The normal limit is 7 plus or minus 2 bits of unrelated information. Capacity can be increased by arranging information into related "chunks"). Information is maintained in working memory by a process of rehearsal. Unless actively rehearsed, information in working memory will be lost in 10 to 20 seconds.
- Long term memory retains information and meaning as well as information about particular events. The investigator should note that memory of events does not remain static but is heavily influenced by our expectations about what should have happened. Witnesses are subject to this effect. This makes eyewitness evidence very volatile and can account for different reports of the same event by different people. The best defence against these tricks of memory is to conduct interviews and take statements as soon as possible.
- For many tasks, even complex ones, practice reduces the amount of central processing required and may even lead to the execution of the task becoming automatic. These automatized actions or "motor programs" allow for efficient operations of systems and free central processing resources for other activities, but are open to particular types of error, usually called slips or lapses. (See Human Error)
- At the last stage of the model, decisions are translated into actions, which may be conscious actions or execution of "motor programs".

In a situation where there is pressure to make a rapid response, there may be a trade-off between speed and accuracy:

1. In situations where delay can have very serious consequences, there will be pressure to make a response before sufficient information has been

- processed;
2. Conditions which increase arousal level lead to faster but less accurate responding;
 3. Auditory stimuli are more likely to attract attention than visual stimuli and are more likely to be responded to in error;
 4. If one expects a stimulus and has prepared a response, the response will be more rapid if the stimulus occurs. If an unexpected stimulus occurs, there will be pressure to make the prepared response;
 5. Increasing age from 20 to 60 tends to be associated with slower, but more accurate responding.

Attention

Can be considered as selected consciousness for the purpose of information processing.

Two factors limit information processing capacity:

1. The number of items that can be maintained in working memory
2. The rate at which information can pass through the system

Often described in terms of two types of attention:

1. **Selective Attention:** The process by which inputs are sampled to ensure that info which receives detailed processing is relevant to the task in hand.
2. **Divided Attention:** When not able to devote all perceptual and decision making resources to one input or output on a continuous basis, attention can be divided; e.g., monitoring speed and attending to signals or directions at the same time.

Stress and Attention

- Usual effect of stress is to increase the level of arousal or general activation
- Level of arousal influences the scanning pattern and hence the perception of information
- Under conditions of high stress and arousal, the scanning or sampling rate may increase but the pattern of scanning is reduced to a narrower range of inputs
- Attention is restricted to the primary task
- This can lead to important information being missed because the stress response caused attention to be restricted to the primary cause or a perceived primary aspect of the problem.
- This effect is sometimes called 'CONING OF ATTENTION' or 'NARROWING OF ATTENTION'

Decision Making

The rational model of decision making holds that people should:

1. Define their goal
2. Determine alternative actions
3. Evaluate all possibilities

4. Select best alternative
5. Implement selected plan

Research on decision making in operational contexts, however, indicates that real-life decision makers do not go through these steps in every case. Real life operational decision makers are more likely to rely on their experience and ability and:

1. Monitor the information presented by the system
 2. Transform the information into a set of manipulations appropriate to the goal
 3. This activity has been referred to as MAINTAINING SITUATIONAL AWARENESS
- For the skilled operator, the transformation of information into appropriate manipulations may take place virtually automatically (skill based behaviour).
 - The next level of complexity involves choices or selections which must be made. The typical pattern involves assessment of the situation and selection of an appropriate procedure according to a set of: if (condition) then (action) set of rules (Rule based behaviour).
 - An unexpected or unfamiliar situation may require the operator to develop a new or creative approach to achieve the goal. This final level of complexity involves recognition that the set of rules available is inadequate. Then the decision maker engages in high effort deliberate processing of information, centred on the development of plans (knowledge based behaviour).

Workload

- When the relationship between workload and performance is plotted on a graph, the line forms an inverted U
- When workload is too low, performance is not good. When we do not have enough to do, we become bored and tend to lose interest in the task.
- As workload increases, performance improves until an optimum level of workload and performance is achieved.
- At levels of workload which are too high, performance deteriorates.
- Errors associated with low workload often stem from missing information because of lack of sampling of inputs from the environment (instruments, signals, location).
- At extremely high levels of workload, information is often missed because of narrowing or focusing of attention on one aspect of the task.

Management Policies

Management policies have profound effects upon the safety of transportation systems. The following information will highlight some of the policy areas which can directly affect safety in positive or adverse ways.

1. Personnel Policies
 - a. Recruiting and Selection
 - b. Training and Development

- c. Employee Relations
 - d. Pay and Benefits
- 2. Operational Policies
 - a. Goals and Values
 - b. Procedures
 - c. Standardization
 - d. Productivity Pressures
- 3. Safety Policy
 - a. Role, Profile and Image
 - b. Quality Assurance
 - c. Accountability

Personnel Policies

An organization's personnel policies have great potential to advance or retard safety within the organization in several ways. A transportation organization is made up of human and capital resources, directed towards a defined goal or set of goals. The model⁴ below portrays graphically how factors internal and external to the organization interact to determine organizational effectiveness, of which safety is an important component. The following information will highlight how components of the model contribute to safety.

Personnel Policies – Recruiting and Selection

- Each person is a complex product of inherited characteristics and environmental influences. Abilities, attitudes, and learning work together to determine how an individual will tend to behave in various situations.
- An organization develops a particular climate or personality of its own. This climate is both expressed and determined by policies, procedures, and norms. Norms are standards of accepted or expected behaviour which may be formalized as rules or regulations or may just be understood by employees. Regardless of whether they are expressed or understood, norms exert very powerful influence on behaviour.
- This climate projects beyond the boundaries of an organization as an organizational image. The organizational image can influence who will apply for employment and who will seek another organization which will be more comfortable.
- The climate can also influence personnel selection decisions, so that an organization, through its personnel selection practices, preserves its climate.
- An effective personnel selection system will ensure that those who are hired possess the abilities and aptitudes necessary to perform the job.
- An ineffective personnel selection system will produce haphazard results. The workforce will not be consistently reliable.

4 Source: Glueck, W.F. Personnel: A Diagnostic Approach. Dallas. Business Publications, Inc. 1974.

Personnel Policies – Training and Development

- Training programs should be designed to develop the skills of employees and improve the operations of the organization.
- Training programs should be designed to develop the skills which are required to perform the job. This requires that the demands of the job are well understood in terms of what the employee must:
 1. Know
 2. Do
 3. Believe or feel
- In some industries and activities it is sufficient for an employee to learn skills and a few basic facts. Transportation systems, however are complex, use advanced technology, and require precise co-ordination of activities. Complexity and the need for coordinated action demand standardization of procedures. If we expect certain standards in on-job performance, training must be standardized.
- Training standardization does not require that the training program be identical in all aspects for all trainees. What is essential is that the performance standards specified and evaluated at the completion of training be uniform or compatible.
- Haphazard training procedures, without specified standards will lead to inconsistent performance in the field and attitudes among employees that are not conducive to safe operations.

Personnel Policies – Employee Relations

- Employees and companies can have goals which are in conflict or lead to conflict.
- Conflict within an organization is a fact of life, to be neither condoned nor condemned, but accepted.
- What is important for safety is how conflict is handled. If employee groups and management groups can work together, conflict can be resolved in a manner which benefits everyone. If conflict is handled poorly, it can adversely affect safety by leading to less than optimal procedures and/or fostering attitudes which lead to unsafe acts.
- In extreme cases, industrial conflict can lead to sabotage.

Operational Policies – Goals and Values

- An organization exists to achieve a specific goal or set of goals. Goals determine, in large part, what the organization does.
- Organizations, like individuals, hold certain values. Values influence how the organization does things.
- For example, Rolls Royce and Ford both build cars. The value sets of these two companies are different. Their values are reflected in their different approaches to automobile production, and in their products.
- Goals and values can conflict. For instance, a decision to maximize safety may cut into profit. When goals are in conflict, an employee may feel pressure to compromise one value in favour of another.

- Organization values and pressure to compromise can be made clear to employees without formal statements. Pressure to compromise a value, such as safety can be in two forms which alone, or in combination, are very powerful influences on behavior
 1. Direct, observable pressure in the form of orders or directions, discipline for failure to meet a particular goal, or rewards for particular action (eg., on time performance) without accountability for risks incurred.
 2. Indirect pressure exerted by an employee's perception of the climate or norms of the organization.

Operational Policies – Procedures

- Standardized Operating Procedures help prevent errors in decision making and execution. Decision rules of the "if (condition) then (action)", variety provide criteria against which situations can be measured. This eliminates or limits the influence of attitude, experience, or lack of in-depth knowledge in particular areas.
- Standardized routines, such as check lists for routine and emergency procedures help ensure that execution is error free. These routines can be practised so that once the decision is made to invoke a procedure, execution is automatic. In emergencies, this allows central processing resources to be devoted to situational monitoring or problem solving.
- If an organization does not provide for standardized operating procedures, responsibility for decisions is left to the operator. This is not wrong in principle and operators do need some discretionary authority. Without standardized guidance, however, an operator may be prone to unsafe acts because of pressure, lack of experience, or inadequate information to make an informed decision.

Operational Policies – Productivity Pressures

- Economic forces can lead to significant pressure to maximize revenue and minimize costs.
- Symptoms of sub-optimal policies and procedures can be manifested in pressure to maintain high levels of productivity without accountability for the safety of resulting decisions, inadequate or questionable maintenance procedures, inadequate training, inadequate standardization, poor communication, insufficient staff levels to meet commitments, etc.
- Operators of transportation systems require clear lines of authority and communication. If these lines of authority and communication are not clearly understood and respected within an organization, operators, maintainers, and other support staff can be subject to pressures from people concerned about their own areas of responsibility, but who lack understanding and accountability for safe operations. These pressures can be intense and lead to unsafe acts which would not occur if lines of communication and authority were respected.

Communication

- Communication is the transmission of information between two or more persons.
- Information is encoded into words, symbols, or signals by the sender. The message is

decoded to derive its meaning by the receiver.

- Communication can be transmitted by several media, face to face or over considerable distance.

Fog

- In fog, objects can appear larger and further away than they actually are

White Out

- Spatial disorientation in situations where featureless terrain blends into an overcast sky
- It becomes impossible to locate a horizon. Lack of external cues lead to spatial disorientation

SHEL from an Aviation Perspective

This is a reprint of ICAO MANUAL OF INVESTIGATIONS - HUMAN FACTORS

Data Collection Using the SHEL Model

The SHEL Model was originally developed by Edwards (1972) and modified by Hawkins (1984, 1987). It has been found to be a useful means of defining information requirements during an occurrence investigation. Once the information requirements are identified, the investigator can gather the facts from appropriate sources.

There are four components to the model:

- Liveware - L
- Hardware - H
- Software - S
- Environment - E

The SHEL Model is commonly depicted graphically (see Figure 1)² to display, not only the four components, but also the relationships, or interfaces, between the Liveware and all the other components. The SHEL figure attempts to portray the fact that the match or mismatch of the interfaces is just as important as the characteristics of the blocks themselves. A mismatch can be a source of human error and identification of a mismatch may be the identification of a safety deficiency in the system.

Liveware (Central Component)

The most valuable and flexible component in the system is the human element, the Liveware, placed at the centre of the model. Each person brings his or her own capabilities and limitations, be they physical, physiological, psychological, or psychosocial. This component can be applied to any person involved with the operation or in support of the operation. The person under consideration interacts directly with each one of the four other elements. The person and each interaction, or interface, constitute potential areas of human performance investigation.

Liveware (Peripheral)

The peripheral Liveware refers to the system's human-human interactions, including such factors as management, supervision, crew interactions and communications.

Hardware

Hardware refers to the equipment part of a transportation system. It includes the design of workstations, displays, controls, seats, etc.

² From Hawkins, F.H. Human Factors in Flight. 1987.

Software

Software is the non-physical part of the system including organizational policies, procedures, manuals, checklist layout, charts, maps, advisories, and increasingly, computer programs.

Environment

Environment includes the internal and external climate, temperature, visibility, vibration, noise and other factors which constitute the conditions within which people are working. Sometimes the broad political and economic constraints under which the aviation system operates are included in this element. The regulatory climate is a part of the environment in as much as its climate affects communications, decision making, control, and coordination.

Data Gathering Guidelines

The investigation of human factors attempts to determine what people did and why they did it. The investigator concentrates effort on the behaviour of the people involved. Key events or actions are highlighted, and often these key actions will be unsafe acts. It may be tempting to stop when these unsafe acts are identified, but safety is not well served by doing so. As noted by Chapanis (1965), when causes of accidents are attributed to carelessness, faulty attitude, inattention, or some other such label, little is achieved in preventing recurrence. Safety can be better served by explaining the behaviour behind the label.

To this end, the following guidelines are structured to help investigators determine whether a factor, such as attention, was an antecedent to an occurrence, by providing the possible effects of the factor on performance. Following the performance effects for each factor is a listing of the type of information to consider gathering during the data collection phase to corroborate the factor's existence and effect. Some of the information to be considered for corroboration will be self-evident to the investigator; the relevance of other information may be found in standard texts (such as those found in the bibliography); still other information may require consultation with a human factors specialist to determine that information's significance on performance. It should be noted that the listing of factors for consideration is not definitive.

For ease of use, the guidelines are structured to reflect the components of the SHEL Model, beginning with the central component, the Liveware, followed by the SHEL interfaces..

The Liveware (Central Component)

This area is concerned with the physical, physiological, psychological, and psychosocial factors unique to the central component, the individual.

Liveware Physical Factors

This area deals with the physical capability of the individual to perform required actions and movements: Physical limitations influence the ability to see, to act, to move, to reach, and to grab.

Consider such factors as age, sex, strength, weight, sitting height, reach, etc.

Liveware Physiological Factors

This area is concerned with the physiological condition of the individual, including stable and transitory states such as disease, fatigue, stress or other internal factors which could affect the individual's situational awareness and/or behaviour. Discussion of several physiological factors which can affect performance follows.

Nutritional factors can potentially affect an individual's ability to respond to action, concentrate on a task, or resist fatigue.

Consider factors such as time since last meal, food intake in last 24 hours, recent weight loss, recent dietary habits, etc.

Health can have an effect on the individual's ability to perform. Health problems can lower performance, reduce motivation, lead to distraction.

Consider such factors as the effects of diseases, pains, dental conditions; pregnancy; obesity; recent blood donation, etc.

Stress can have an impact on health, resulting in sleep disorders, gastrointestinal problems, headaches etc.; on behaviour, causing restlessness, impulsive behaviour, etc.; on cognitive processes, making it more difficult to concentrate on a task, to perceive cues, to determine priorities, etc.; on feelings, making one anxious, aggressive, moody, etc.

Consider stressors such as environmental stressors, domestic stress, bereavement, financial and time commitments, work stress, relationships with colleagues and management, etc.

Fatigue chronic or acute fatigue can have an impact on memory, consistency in performance, motivation, concentration, information processing and decision-making, cooperativeness, communication skills, mood, reaction time, error rates, risk-taking, etc.

Consider such factors as time on duty, work schedule, workload demands, time zone shifts, shift-work, previous schedules, layover schedule, travel time to and from work, and other operational demands. Also consider time of rest, hours of rest, quality of rest, off-duty activities, stress, and sleep disorders.

Alcohol affects the ability to discriminate and perceive visual and auditory stimuli; it has an impact on memory, decision-making processes, judgment, coordination; it slows reaction times and increases risk-taking.

Consider such factors as time since last drink, alcohol consumption rate and amount, body weight, consumption of food, type of drink, blood/alcohol concentration, hangover effects, evidence of alcohol addiction; i.e., medical records, drinking and driving violations, etc. Consider also stress, fatigue, sleep and biological rhythm disturbance, and circadian effect.

Drugs can cause drowsiness and dizziness; they can affect mood and coordination; they can reduce mental functions and sensory perceptions.

Consider over-the-counter medication, prescriptions, illicit drugs, and other stimulants such as coffee, cigarettes, etc. Factors such as fatigue, stress, sleep and biological rhythm disturbance, circadian effect might be antecedent conditions to the use of drugs.

Partial incapacitation can be hard to detect and can result in a wide-range of symptoms such as dizziness, loss of consciousness, decrease in judgment and decision-making processes.

Consider such factors as carbon monoxide or food poisoning, medical conditions, fumes, motion sickness, hypoxia, hypoglycaemia, fatigue, stress, sleep and biological rhythm disturbance or medication.

Sensory limitations include visual, auditory, olfactory, kinaesthetic limitations.

Consider such factors as visual acuity requirements, focus time, light adaptation, depth perception and external cues, requirement for glasses or contact lenses; auditory threshold and range, etc.

Illusions occur when an individual's mental model differs from the real world. There are three sensory systems that contribute to the perception of orientation: the kinaesthetic sensors, vision, and the vestibular organs in the inner ear. Illusions of orientation can be brought on by misinterpretation of visual information, by limited peripheral vision, and by the sensitivity of the vestibular organs to linear and angular acceleration.

Consider such factors as fatigue, flying with a cold, crew expectancy and experience, anthropometric considerations, instrument monitoring and actions, environmental conditions at the time of the occurrence, geographical peculiarities of the location, runway characteristics, lighting intensity, and flight manoeuvres.

Liveware Psychological Factors

Maintaining an accurate mental model, that is, maintaining situational awareness, is paramount to ensuring safe flight. Situational awareness develops on three different levels. First the person must perceive the situational elements from information displays,

communication, or from viewing the scene; the person then integrates the information by using his/her experience and knowledge; finally, the person projects the information into the future to make and modify plans as tasks are completed or delayed and new developments arise (Endsley, 1994). The following factors directly influence the individual's ability to process information so that accurate situational awareness is maintained.

Information Processing: The way in which humans process information can be represented by a series of stages wherein information is received, decisions are made, and responses are selected and executed. Failures can occur at any of the mental operations involved in information processing; as a result, situational awareness becomes faulty and errors are made. The stages and limitations of information processing are discussed below:

Sensation: The sensory receptors (e.g., eyes, ears) detect physical stimuli in the form of sounds and shapes which is stored for a brief period of time. Should the stimuli not be sensed by the sensory receptors or should the information decay before it is processed, decisions and actions will be made and carried out without all the information.

Consider such factors as sensory system threshold and range, distractions, workload, expectation.

Perception: Perception involves converting the sensory information into meaningful messages. Delayed perceptions and inaccurate perception (mental picture) of a task to be performed can lead to slow or wrong reaction.

Consider such factors as clarity and accuracy of information received, expectation, experience, habit, workload, opportunity for visual and vestibular illusions.

Decision Making: Decision-making follows perception. Decision-making can be appropriate or inappropriate depending upon a number of factors such as the conclusions about the meaning of the message, the type and amount of information available to the individual, previous experience, group influences, etc.

Consider such factors as experience and expectation, training, distractions, workload, fatigue, stress, medication, motivation, operational pressures.

Action and Feedback: Action and feedback are the stages in the information process where decisions are translated into responses (or non-responses) and mechanisms that provide the individual with feedback are activated. Responses are in the form of actions or words or both, or execution of automatic motor programs. Feedback can be direct as in the form of tactile feedback or it may be indirect as takes place in advanced work stations where the operator must monitor the instruments to obtain feedback of his/her actions.

Consider sources of error at this stage as those errors that originated earlier in the processing system, design-induced error, errors due to attention limitations, distractions, etc. or inadequate or inappropriate feedback.

Attention limitations of the central decision-maker restrict the number of stimuli humans are able to attend to. Normal limitations can be further exacerbated by such factors as the operating environment, causing the individual to omit, mistime, misorder, forget, repeat or commit the wrong action.

Consider such factors as sources of interruptions and distractions, design-induced errors, previous experiences, ambiguous cues, delays between planning an action and executing that action, stress, fatigue, workload, etc.

Memory, both working and long term, can potentially limit the processing of information. Working memory is limited in how much information it can retain; information is maintained by a process of rehearsal. If it is not rehearsed, information will be lost in 10 to 20 seconds. Memory of events stored in long term memory is not static but is influenced by many factors, including what the individual expected should have happened. Automatic motor routines stored in long term memory can be carried out without conscious control. Errors can occur when the automatic motor routines are not monitored.

Consider the number of unrelated items presented, whether the information, related or not, was chunked or clustered, whether the stimuli were verbal or visual, whether delays occurred, whether biases were induced as a result of long term memory, as well as such factors as previous experiences, training, distractions, etc.

Workload can limit the processing of information. Low workload levels can induce boredom, inattention, cause slow reaction time, and lead to poor monitoring; high workload can result in missing of important cues, stress/panic, incorrect prioritization of tasks, task shedding, etc.

Consider such factors as task priorities, operating procedures, equipment design, phase of the operation or flight, crew complement, distribution of duties, crew actions that might have increased or decreased the perceived workload, actions of others, stress, fatigue, etc.

Attitudes of individuals toward their work, mission, others, and themselves can affect performance. Attitudes can influence quality of work, judgment, decision-making, motivation, risk taking, etc.

Consider such factors as knowledge about the object of the attitude, strength of belief held about the attitude, and, if applicable, the behaviour displayed. Consider the influences of group, job demands, monetary gain, training, previous experiences, etc.

Personality traits may predispose an individual to a certain response pattern in a given situation.

Consider such factors as risk assessment, risk taking, interactive styles of personnel, experience levels, training, etc.

Experience/recency includes suitability of individual's experience, knowledge, and training for the situation.

Consider the individual's overall or recent experience in the position, on the aircraft type, for the mission, on instruments, with the procedures, in the environment, etc.

Knowledge on the part of the individual may be inadequate, resulting in reduced confidence, confusion, or inappropriate actions.

Consider such factors as the individual's knowledge about the equipment, systems, procedures, or environment. Consider previous experiences, the individual's or the influencing effects of others' experiences, training, etc.

Training relates to developing skills, knowledge or attitudes. Insufficient, irrelevant and non-applicable training can affect performance. Poor learning and reduced performance may originate in the training program itself, in the work situation, or in social or domestic factors.

Consider such factors as the type of training received, training methods used, instruction materials, quality of instruction, instructor selection and training qualifications; any indications of positive or negative transfer, weaknesses observed during training, motivation, anxiety, stress, fatigue etc.

Liveware Psychosocial Factors

These factors may have a role in the investigation as they influence an individual's approach to a situation. Psychosocial factors include any event or condition in the individual's social environment (friends, family, peers, money, activities, life-style, work) which are important enough to influence on-the-job behaviour. Typically, these factors are not directly causal, but they can manifest physically as in loss of sleep, in poor eating habits, in feelings of anxiety, stress, etc.

Consider such factors as personal loss, interpersonal conflicts, financial problems, significant lifestyle changes, family pressure, culture differences.

The SHEL Interfaces

The central component, the liveware or individual, does not act alone, but interacts directly with each of the other SHEL components. Data collected during the investigation should include these interactions.

Liveware-Hardware Factors

This area includes any physical or mental interactions between the human and the machine, design limitations and peculiarities in work-station configuration. Design of system hardware can contribute, through design-induced errors, to unsafe acts. A hazard at the liveware-machine interface can increase the likelihood of error; increase the likelihood of non-use or misuse of the equipment; increase reaction time; induce negative transfer; increase delays and costs; increase workload; cause a decrease in operator satisfaction, cause discomfort, confusion, distractions, and lead to fatigue, injuries and attrition rates.

In evaluating the liveware-hardware interface, normal patterns of human behaviour should be taken into account. A sampling of these behaviours is as follows: most people cannot judge distances, clearances, or velocities very well, tending to over-estimate short distances and under-estimate large distances; people expect something to operate in a certain manner; many people carry out most tasks while thinking about something else; most people perform in a mechanical manner, employing previous habit patterns (under stress they almost always revert to these habit patterns); most people are reluctant to recheck their operational or maintenance procedures for errors or omissions; in emergency situations people often respond irrationally and with seemingly random behaviour patterns; and people are unwilling to admit errors or mistakes of judgement or perception and thus will continue a behaviour or action originally initiated in error (Nertney and Bullock, 1976).

In investigating the liveware-hardware interface, the following considerations can be evaluated:

Workspace and comfort are concerned with ensuring that human variability considerations are taken into account in the design of the workspace. Although people vary in body size and shape, there can be considerable variability in other measurements such as in physiological and psychomotor abilities, e.g., endurance and reaction time. Typically, design of a workspace will accommodate the 5th to 95th percentile range of the population. Use of anthropometric data in design is fundamental in determining whether given equipment design has appropriate clearance, reach, and visibility characteristics.

Consider such factors as adequate clearance for headroom, shoulders, and lower limbs, including space for entry and exit; adequate reach, both hand and foot, for operating controls; a common eye reference point for correct positioning relative to internal and external workstation sight lines to displays, environmental conditions, other operators, etc.

Physical space and arrangement considerations are concerned with workplace components, such as controls, displays, manuals, etc. being located and arranged to optimize vision, reach, and clearance requirements.

Consider the following four general principles for evaluating physical space and arrangement considerations: importance principle - the most important components should be placed within the primary reach envelope and field of view; the frequency of use principle - the most frequently used components are placed within the primary reach envelope and field of view (should frequency and importance conflict, importance should supersede); the functional grouping principle - related components should be grouped according to function and in accordance with importance and frequency of use principles; and the sequence of use/operation principle - after the initial three principles have been applied, components should be arranged in the order of their use and operation.

Control considerations are concerned with the transfer of information from the operator to the equipment.

Consider, in addition to the physical space and arrangement considerations listed above, control considerations such as visual or tactile dissimilarity for controls located in proximity to one another; symbolism in control design, wherein the control mimics the function; prevention of inadvertent use of control by recessing, guarding, locking, or isolating the control; control-display compatibility wherein the display actions match the control movements; control loading wherein controls do not require undue force to operate; and standardization of controls in their location and sense of use.

Display considerations are concerned with the transfer of information from the equipment to the operator. Primarily, there are two types of displays: visual and auditory. Visual displays include lights, markings, scales, alphanumeric, icons, and pictorial representations. Auditory displays include horns, bells, whistles, music, and synthesized speech.

Consider, in addition to physical space and arrangement considerations, display considerations such as display-control compatibility; standardization of displays; the match between the type of display and how the information the display provides is put to use by the operator; illumination of visual displays based on environmental conditions; location of displays that allows for acceptable viewing or hearing distances from the operator; viewing angle of visual displays; the size, font, resolution, contrast, etc. of alphanumeric displays.

User acceptability considerations are concerned with those factors that contribute to the determination by the operator as to what is acceptable for use.

Consider such factors as comfort, efficiency, reliability, safety, maintenance, mission, cost and aesthetics, etc.

Liveware-Liveware Factors

This field explores the nature of human interactions and communication breakdown between individuals.

Verbal communication can lead to misunderstandings, misinterpretations, etc., when information necessary for safe and effective operations and maintenance is not sent, received, or understood by the intended recipients in a clear, unambiguous and intelligible form. Communication involves all parties involved in the operation: front-line crew, back-end crew, maintenance, ground support, ATC, RTC, VTC, etc.

Consider such factors as ambiguity, pronunciation, improper language usage, frequency of word use, length of words used, relevancy of words, phraseology, noise interference, noise exposure, content and rate of speech, readback/hearback, language barrier, stress, fatigue, workload, operational pressures, quality of communication equipment, personal hearing deficiencies, age, hearing expectations, etc.

Visual signals can replace, support, or contradict oral and other information, and may include body language or other "non-verbal" cues.

Consider such factors as body language which can direct an action, cause confusion, stress, misunderstanding, or create negative emotions or pressures.

Crew interaction may cause individuals to work for or against each other, or fail to use all available resources.

Consider such factors as crew compatibility/pairing in terms of personality, experience level and working habits, cultural differences, training, briefings, crew coordination, task assignment, age, transcockpit/transbridge authority gradient, group influences on decision-making, peer pressure, etc.

Passenger behaviour can have an impact on crew actions, attitudes, and behaviour.

Consider such factors as passengers who are physically challenged, as well as passenger pressure, cooperation, intoxication, apprehension, anxiety, etc.

Worker-management factors include the level where decisions and plans are formulated and resources allocated. Also included is the supervisory level where actions are monitored and instructions followed. Crew behaviour cannot be accurately assessed in isolation of the organizational climate. A discussion of the effects of the organizational climate on performance and the factors to consider follows.

Organizational factors may affect human performance by causing excessive workload or an unhealthy work environment, etc.

Consider such factors as organizational philosophy and policies; compatibility of organizational goals with safety; and the effect of the structure of the organization on internal communications between management and operations or maintenance. Consider the safety climate of the organization in terms of the identification and dissemination of information about known risks and their management; the provision, for personnel, of adequate detection and warning systems; and a commitment to ensuring an error-tolerant

system. Consider personnel selection and recruitment policies, staffing policies, personnel policies, training policies, remuneration/incentive structure, scheduling and crew pairing policies, seniority policy, etc.

Supervision factors are concerned with the practices that reflect the philosophy and policies of the organization. Deficiencies in an organization's operating philosophy and policies can lead to deficiencies in its practices.

Consider such factors as the existence, implementation, availability, currency, completeness, and accuracy of company policies, prescribed procedures, and quality controls. Consider also accepted operating or maintenance practices which differ from prescribed procedures, the adequacy of personnel monitoring and support programs, scheduling practices, remuneration practices, supervisory presence (or absence), supervisory style, supervisory duties, etc.

Work environment organizational policies can set up conditions that are conducive to committing unsafe acts or making safety-related errors due to psychological as well as physical conditions in the workplace which influence individual or team performance.

Consider such factors as real or perceived pressures due to operational policies, peers, management. Consider also turnover rates, company morale, compatibility of company policies and work practices, and work settings including reliable equipment, adequate lighting, etc.

Associations and unions can create conditions conducive to human error and unsafe acts.

Consider the effect of union philosophies, policies, and practices on workers, management, work habits; consider also post-merger negotiations, contract negotiations, etc.

Regulatory requirements and Overview include both the reaction of the operating organization to regulatory requirements as well as the adequacy of the role of the regulatory organization with respect to governing transportation operations and maintenance.

Consider, in so far as the operating organization is concerned, if regulatory requirements are relegated to a low importance in the organization's values or if members are encouraged to bend the rules. Consider, for the regulator, if there are deficiencies in the rules and regulations governing transportation operations and maintenance, deficiencies in the certification of equipment, personnel, and/or procedures, and deficiencies in surveillance, audit and inspection of transportation operations and maintenance.

Liveware-Software Factors

This field deals with the nature of the information transfer between the human and supporting systems found in the workplace. Data requirements span such subjects as

regulations, signage, manuals, checklists, publications, standard operating procedures, training programs, and computer software design.

Written information includes manuals, checklists, service bulletins, or any other written documentation. Poorly designed documentation can lead to increase response time, can create confusion, can increase the risk of items being missed, can be susceptible to distractions, can be conducive to shortcuts, etc.

Consider such factors as length, format, and content. Consider font type, font size, pitch, type face, character spacing, and use of colour. Consider also consistency, accuracy, availability, completeness, ordering of items, and redundancy of written information as well as timeliness of revisions. Consider appropriateness of checklist response requirements; i.e., a value vs. status, especially for critical items, e.g., "flaps 15" vs. "flaps set." Consider conflict of operational time constraints and use of checklists, etc. Consider stowage of documentation at the work station. Consider knowledge and training of individuals on documentation.

Automation ideally reduces operator's workload; however, automation can affect individuals' attitudes toward their work and their mental picture of the task, sometimes by impacting workload at critical times. Missing of important information, overreliance, mode confusion, increased reaction time, monotony and boredom, lack of knowledge to deal with failures of automatic systems, or blatant errors can be byproducts of automation.

Consider rate of false alarms, loudness of auditory warnings; consider also keyboard accessibility, compatibility of keyboards and displays, physical space and arrangement characteristics of automated equipment, control and display considerations, number of modes. Consider workload, training, knowledge, skill, procedures, etc.

Regulatory requirement issues centre on individuals' essential qualifications and certifications for the task.

Consider such factors as current licences or ratings, qualifications in position and on equipment type, infraction history, medical certification, etc.

Liveware-Environment Factors

This area deals with the relationship between the individual and the internal and external environment.

The internal environment is that of the work area. Physical environmental factors can affect the liveware-hardware interface of a system either by compromising the health or safety of an operator, or by causing a failure of the structure or function of the workstation. The physical environment can have an effect on the human component by contributing to degradation in operator performance, which in turn could lead to a hazardous situation.

Consider such factors as noise, its intensity, the individual's exposure rate to noise, and its effects on the ear, on the ability to communicate, and as a cause of fatigue and stress. Consider the detrimental effects of vibration - fatigue, stress, headaches, and muscular discomfort. Consider the stressful effects of temperature that is too hot or too cold, on the body - tiredness, difficulty in concentrating and a decline in decision-making ability. Consider also ambient light and air quality.

The external environment includes the physical environment outside the immediate work area, which can lead to illusions of the vestibular, visual or kinaesthetic perceptions, etc.

This area also includes the broad political and economic constraints under which the aviation system operates, which can lead to the taking of shortcuts, biased decisions, etc.

Consider the effect of delays, on the operator, caused by weather, dispatch, hangar, gate or aerodrome infrastructure. Consider the effects of geographical peculiarities of the location, runway characteristics, lighting intensity, etc.

Consider economic or regulatory pressures. For maintenance facilities, consider equipment, availability of parts, operational standards, procedures and practices, quality assurance practices, servicing and inspection practices, training, and documentation requirements.

Summary

The guidelines in this chapter are focused on gathering data using the systematic approach that the SHELL model provides. The chapter has dealt primarily with understanding the effect that various factors can have on performance; in addition, the chapter has provided a listing of the types of information investigators need to gather to determine if any of those factors were antecedent to an occurrence. The TSB Integrated Process for Investigating Human Factors describes a process which takes investigators from the data gathering phase of an investigation into the identification of unsafe acts and conditions and the latent unsafe conditions that facilitated their development, culminating in the identification of potential safety problems.

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