

Risk Assessment & Management Decision-making: The Johnson & Johnson Approach

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In absentia

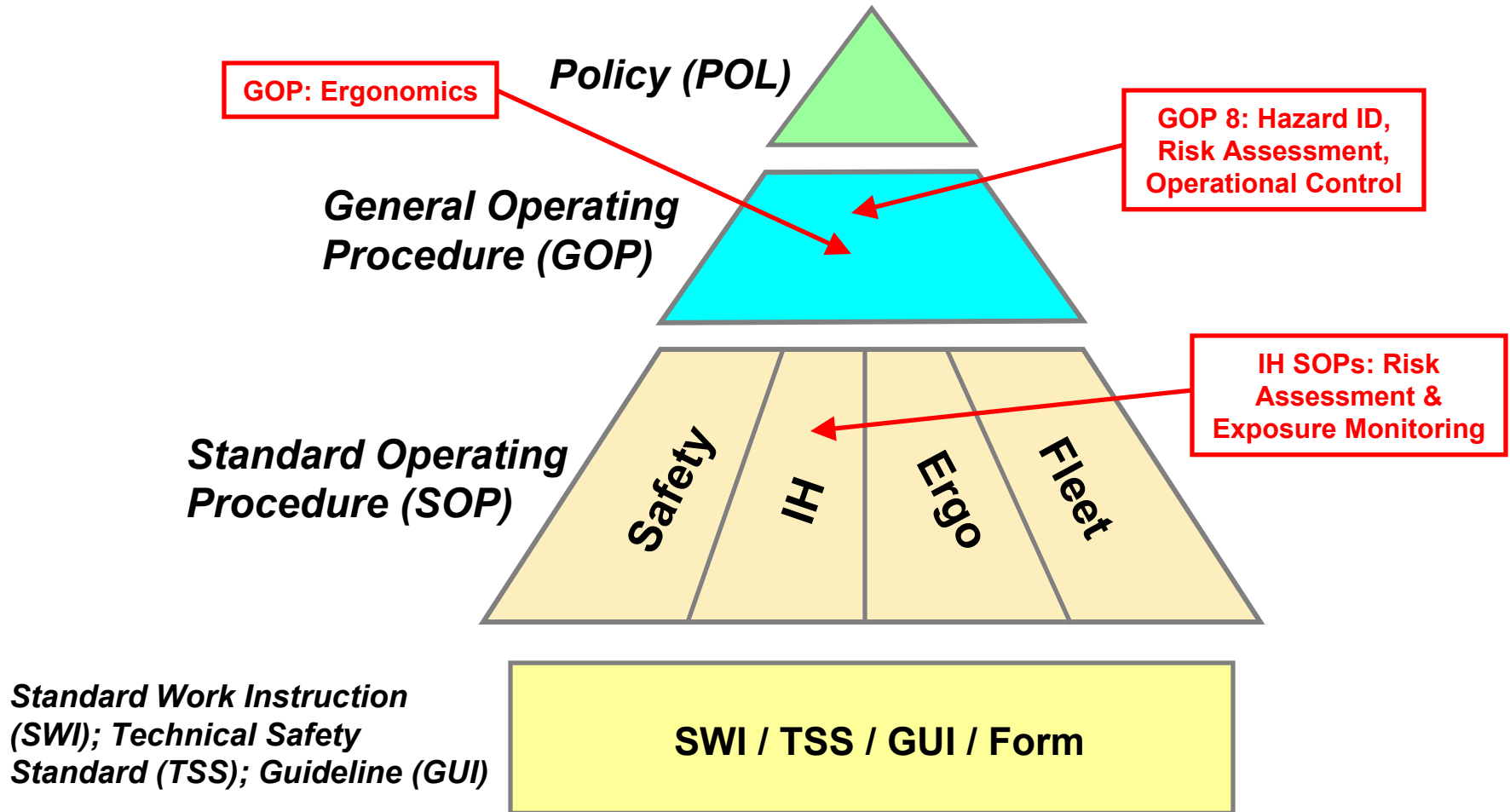
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- **Origins of the J&J Approach**
- ***“Hazard Identification, Risk Assessment, and Operational Control”***
- **Ergonomics Risk Control and Success Metrics**
- **Industrial Hygiene Risk Control and Success Metrics**

- **A Worldwide Document Management System (DMS) was established to codify long-standing J&J Safety & Industrial Hygiene standards.**
- **The General Operating Procedures (GOPs) represent our Safety Management System requirements and are modeled after the OHSAS 18001 Specification.**



Hazard Identification processes shall:

- **be conducted by persons competent...**
- **include a comprehensive survey of workplace... hazards;**

Risk Assessment processes shall:

- **be conducted by persons competent...;**
- **include a systematic evaluation...that considers a combination of the likelihood (*probability*) and consequence (*severity*) of a specific hazardous event;**


Risk Assessment processes shall:

- include a classification of risks that shall be used to determine the appropriate level of operational controls;
- *“Existing hazard identification and risk assessment processes shall be utilized for specific technical challenges that include, but are not limited to, machine guarding, fall prevention, **ergonomics**, **industrial hygiene** and process safety management.”¹*

¹This statement is unique to J&J.

Ergonomics Risk Control



- In 2001, J&J leadership endorsed a strategy that promoted the use of consistent metrics and assessment criteria for the mitigation and prevention of ergonomics risk.
-  J&J's approach to ergonomics, ensures that sites which employ all elements of this process will achieve a "Cultural Ergonomics Program."



- **Standardized assessment tools were created:**
 - Ergonomics Job Analyzer – EJA
 - Manual Handling EJA
 - Computer Workstation EJA
 - Laboratory EJA (being developed)
 - EJA Toolkit for use with EJA
- **The EJA assesses the risk of the “task” (versus a “job”) and categorizes it as a “*high,*” “*moderate*” or “*low*” ergonomics risk.**

- A global Ergonomics Standard Operating Procedure (SOP) was developed...
- Risk Mitigation Strategy for Manufacturing tasks focused on:
 - “High Risk Tasks with Solutions”
 - “High Risk Tasks Awaiting Solutions”
- The global leadership team defined a **“solution”** as an engineering solution. Any other solution, e.g. employee rotation, means the task will be rated as a “High Risk Task Awaiting Solutions.”



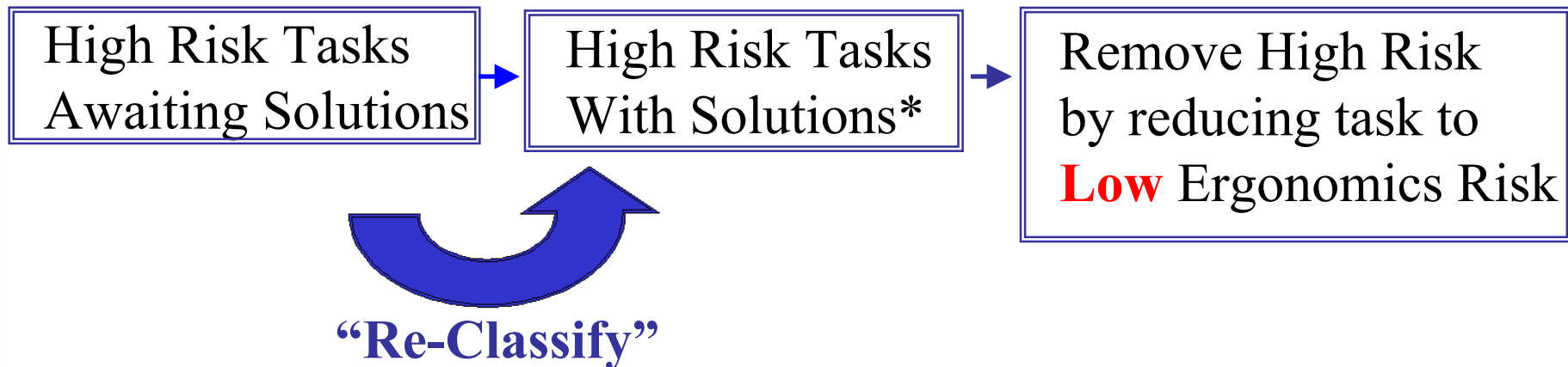
México - Manual Packaging

← **High** Risk Task



↑
Low Risk Task

Effectively and efficiently mitigate High Risk Ergonomics Tasks



- **Strong leadership**
- **Consistency in process**
- **Focus on risk mitigation and prevention**
- **Simple ergonomics dashboards with realistic strategic long term goals**
- **Development of culture in the prevention of ergonomics issues**

Industrial Hygiene Risk Control



- Hazard Assessment of a new chemical agent
- Industrial Hygiene risk assessment
- Industrial Hygiene exposure assessment
- Exposure Control
 1. Engineering controls
 2. Work practices and administrative controls
 3. Personal protective equipment
- Medical Surveillance
- Endpoint of the Industrial Hygiene Process is Risk Control using *Engineering Controls*

Exposures to chemical agents are controlled with minimal reliance on respiratory protection

New products in existing processes

New products are introduced into existing processes that are capable of controlling exposures

New products in new processes

New processes and facilities are designed and process equipment specified to control exposures

Existing products in existing processes

Existing processes gap assessed; engineering control plans developed and implemented

New Product Introductions

Existing Products

- **Identifies facilities requiring additional IH focus**
- **Pinpoints opportunities for IH process improvement**
 - Integrate “Industrial hygiene through design” into the new product development process
- **Identifies IH areas in need of improvement**
 - Execution of engineering control action plans

- **Assists in allocation of appropriate resources**
 - Assure IH competency
 - Capital
- **Evaluates and reports IH performance by region, group, company or business**
- **Supports our IH vision and strategic plan**

Reduction in Reliance on PPE¹

- **% reduction in reliance on respiratory protection**
 - By unit operation and job title
 - Metric does not include “non-routine” or emergency use respirators
- **% reduction in reliance on hearing protection**

¹10% reduction required each year

- **% of operations resulting in exposures > “action limit” that have engineering control action plans**
- **% of engineering control action plans funded**
- **% success in controlling exposures to below the “action level”**
 - Requires verification of success following project commissioning

- **Tracking occupational illness rates will not drive industrial hygiene risk reduction**
- **Improvement in IH performance must be driven by measuring progress in activities that control risk**
- **J&J is driving towards ultimately eliminating reliance on respiratory protection**

Back-up Slides



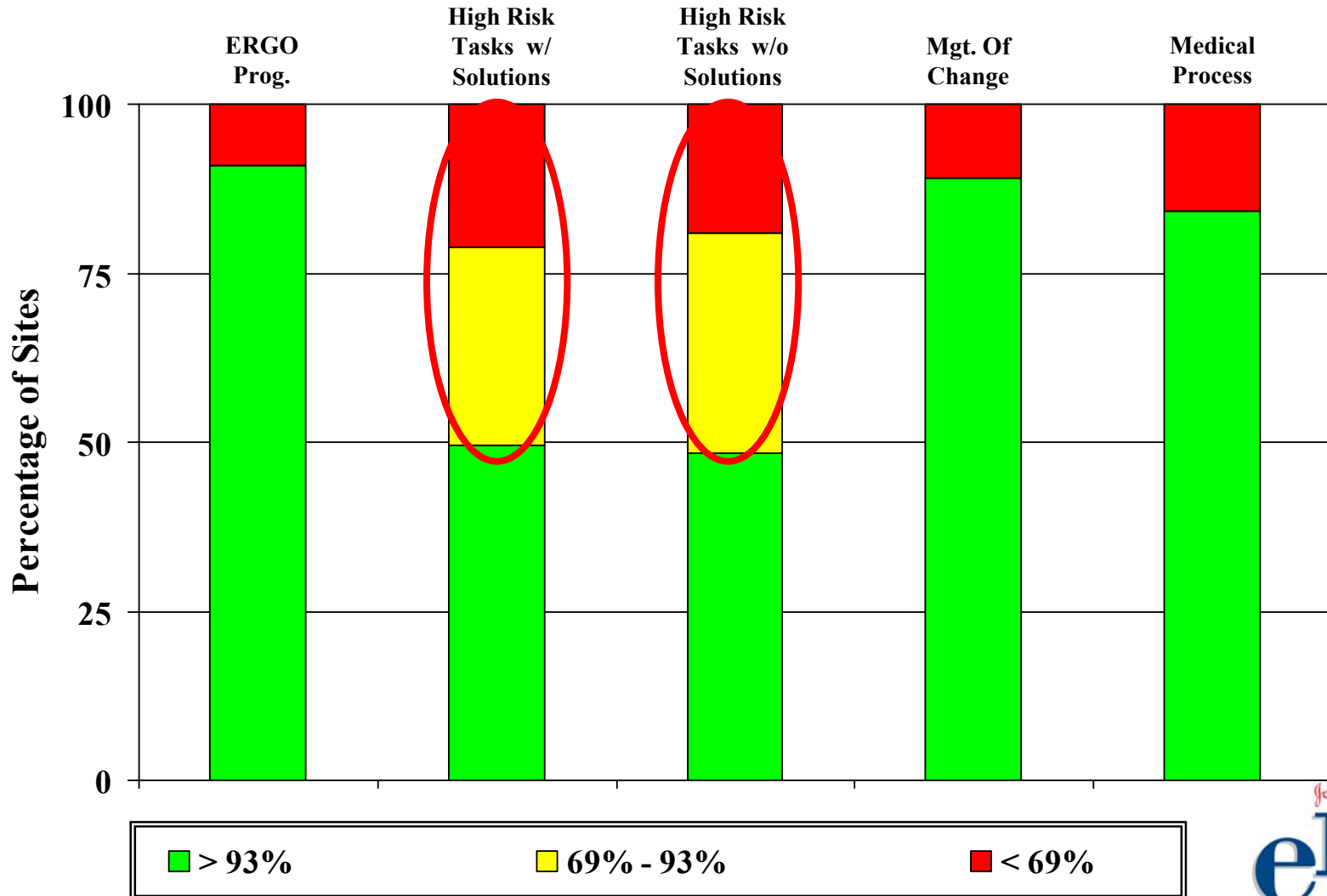
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- **Out of 7,500 manufacturing tasks, 1800 are high risk tasks affecting approximately 9000 employees (out of J&J 109,900 employees worldwide).**
 - **Impact is measured by the reduction of employees exposed to high risk.**
 - **60% of the high risk tasks have solutions**

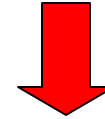
- **85% of all high risk tasks with solutions will be mitigated to low ergonomics risk by year end 2005.**
- **The remainder will be mitigated by 2008.**
- **A strategy is in place to mitigate High Risk Tasks *awaiting solutions* by using a core team of experts.**

- **Simplified Ergonomics Dashboards with strategic goal in place through 2008**
- **6 elements are measured for the success of a program.**
 - **ERGO (Measures Compliance at all levels of an ergonomics program)**
 - **Computer Workstation Risk Assessments
Manufacturing/Equipment Risk Reduction Process – With Solutions (Measures Compliance with Site Action Plans)**
 - **Manufacturing/Equipment Risk Reduction Process – Without Solutions (Measures Compliance with Site Action Plans and Strategy for solution development)**
 - **Management of Change (Risk Mitigation & Prevention)**
 - **Medical Processes for Treatment and Prevention**

Metric of Success – Worldwide Ergonomics Dashboard



- **Industrial Hygiene exposure assessment**



- **Personal protective equipment**

- **Design appropriate containment into process**
 - Establish control and containment requirements and acceptable process leaks
 - Include HVAC, facility design, materials of construction and process containment
 - Select equipment capable of required containment
 - Include containment targets in equipment specifications
 - Verify containment design targets during
 - Factory Acceptance Testing using surrogate
 - Operational Qualification using surrogate
 - Process Validation with chemical agent

- **New product introduction should include IH drivers**
 - Include IH exposure control in the Management of Change process
- **Understand the containment capabilities of existing facilities and process equipment**
 - Gap assessment
 - Containment required vs. existing
 - Prior exposure assessment results
- **Retrofit containment based on hazards associated with new product**

New Products in New or Existing Processes

- **Verification testing of containment**
 - During qualification and process validation
 - On-going testing
 - Verify qualification parameters
 - Detect deterioration in containment
- **IH exposure assessment**
 - Controlled to 0.5 x the exposure limit
 - No reliance on respiratory protection

- **Prescribe “interim controls”**
 - Respirators and skin protection
 - Job rotation to minimize opportunity for exposure
 - Work practice controls and training
- **Determine engineering control gaps**
 - Use qualitative risk assessment and exposure monitoring survey results
- **Develop priority list and budgets for retrofits**
 - Develop IH action plans to reduce reliance on respirators
 - Close out identified “gaps”
 - Focus on risk reduction using practical solutions
 - Prioritize operations with potential for exposure greater than 10x exposure limit and/or operations with exposures that can cause irreversible health effects
 - Develop process for management updates