**Table S1.** Presentation of corrective measures for each failure mode that was scored with a RPN value greater than or equal to 40. In the second column under the heading “CORRECTIVE MEASURES ALREADY IN PLACE” are presented the measures that have been in place since 2006. In the third column under the heading “ADDITIONAL CORRECTIVE MEASURES are listed the measures that must be implemented in the future in order to improve the current PGHG Unit preparation process.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  | | --- | --- | --- | --- | |  | | | | | DYSFUNCTIONAL POINTS/FAILURE MODES | **CORRECTIVE MEASURES ALREADY IN PLACE** | **ADDITIONAL CORRECTIVE MEASURES** | | Error in Body Weight, Height and BSA calculations (Stage: Medical Prescription) | - | * Re-evaluation of patients’ somatometric characteristics from a second doctor * Re-evaluation of BSA from the responsible pharmacist | | Incorrect patient name written on the label (Stage: Labeling of final products) | * The writing of the label is done using patient’s data directly from the patient’s treatment sheet and not from the record that the responsible pharmacist keeps. During this process, the patient's treatment sheet overlays the record’s data to prevent the wrong combination of patients’ names and drugs * There is a short break during work to rest the Unit’s working staff | * Re-check of the label by a second pharmacist * Re-check and verification of all label data from nursing staff prior to administration to the patient * Avoiding interruption of Pharmacist’s authoring work for answering questions to third parties. If there is an urgent need to stop the authoring process, then the unfinished label must be re-examined with regard to the information given | | Incorrect medication dose written on the label (Stage: Labeling of final products) | * Nurses compare medicines that are prepared for the patient with those listed in the patient's treatment sheet and ask the pharmacist if there is any doubt | * Avoiding interruption of authoring work for answering questions to third parties. * Re-check of the label by a second pharmacist or other partner | | Coating of the Biological Safety Chamber (BSC) Surface with sterile fields without taking safety precautions related to microbial contamination (Stage: Preparation of Biological Safety Cabinet) | * Prior to taking up duties at the Unit, all healthcare professionals (pharmacists and technicians) involved in the preparation of solutions, follow a complete theoretical and practical training on the preparation of sterile intravenous solutions including the operation of the biological safety chambers (BSC) and how they are prepared to work | * Preparation of written instructions (SOPs) about the process of preparing the BSC. Employees will strictly adhere to the written instructions * Control and certification of employees’ practical and theoretical skills at regular intervals * Installation of video surveillance systems (cameras) in the workplace, in order to monitor and verify that the actions of employees who prepare the BSC comply with the given recommendations * Coating of BSC surfaces and arrangement of materials and drugs inserted in the BSC, must be done only using sterile gloves | | Placing materials in the BSC without taking safety measures for microbial contamination (Stage: Preparation of Biological Safety Cabinet) | * All materials inserted in the BSC are sterile * Sterile materials insertion in the BSC is made in such a way that they do not come into contact with bare hands or other unclean surfaces * The arrangement of the vials into the BSC is done with clean but not sterile gloves | | Importing drug vials and containers into the cabinet without having them previously sprayed with a suitable antimicrobial solution (Stage: Preparation of Biological Safety Cabinet ) | * All drug vials are sprayed with an appropriate disinfectant. This does not apply to normal saline or 5% dextrose containers. Because of that, employees are advised to avoid finger contact with containers’ caps and syringe tips | | Non-compliance with aseptic technique rules (Stage: Preparing staff for the preparation of sterile solutions of cytotoxic drugs) | * Sufficient practical and theoretical training of workers in aseptic technique * Microbiological testing of the solutions at a frequency of one to three times a week | * Preparation of a set of written instructions (SOPs) on the process of aseptic technique, which employees will strictly adhere to * Control and certification of employees’ practical and theoretical skills at regular intervals * Μicrobiological testing of prepared solutions on a daily basis * Installation of video surveillance systems (cameras) in the workplace, in order to monitor and verify that employees prepare the solutions according to the rules of the aseptic technique | | Incorrect medication volume is added by the staff in the final solution container during solution preparation (Stage: Preparation of sterile cytotoxic drug solutions) | * Sufficient practical and theoretical training of employees * Writing clean and easy-to-read labels * All volume measuring devices / syringes that are used during sterile cytotoxic solutions preparation, are certified for their quality * No technician produces drugs for more than 2 consecutive days in order to avoid burnout. | * Ensuring a sufficient number of workers in the unit to avoid burnout * Application of e-print labels to avoid errors because of unreadable letters/numbers * Limitation of speech and interruptions of work by third parties in order to avoid workers’ distraction * Control and certification of employees’ practical and theoretical skills at regular intervals * Installation of video surveillance systems (cameras) in the workplace * Careful selection of employees | | Skip installation of the sterile cytotoxic solutions that are to be administered in the coming days in a refrigerator (Stage: Storage solutions of cytotoxic drugs in hospital wards) | * Labeling of final solutions with labels that clearly indicate the storage conditions. | * Intense signaling of storage precautions on the final product’s label * Provision of written information on storage / preservation of the final products to the nursing staff | | The sterile cytotoxic solution production Unit does not comply with international standards (Stage: Areas - Equipment) | * The Hospital Board has been informed about the risks that could potentially threaten the health of both patients and employees when solutions of cytotoxic drugs are not prepared in accordance with the international guidelines * Obligatory use of personal protective and sterile equipment | * Reconstruction of the Unit in accordance with international guidelines for safe handling and effective preparation of sterile cytotoxic drug solutions | | Lack of a specific air clean-up system in the space of the Unit (Areas - Equipment) | * Installation and use of biological class II safety cabinet in the chemotherapy preparation room * Before starting up the unit, several attempts of preparing sterile solutions were carried out. Final products were then subjected to microbiological testing to ascertain their sterility. * The preparation process that was found to yield sterile solutions was recorded and constituted the current Unit's working protocol, which has been applied since then without any change * Microbiological testing of the solutions at a frequency of one to three times a week | * Installation of a special air sterility assurance system in the unit area:   + Air filtration through HEPA filters   + Two-way communication windows   + Security doors   + Door opening control mechanisms * Daily control of microbial contamination of space, equipment and solutions | | Conditioning of Unit Space from a hospital's central air-condition system rather than from the Cytotoxic Sterile Drug Production Unit (Stage: Areas-Equipment) | * Microbiological testing of the solutions at a frequency of one to three times a week | * Compliance with standards which indicate that the unit must have an independent air conditioning system * Installation of room temperature recorders and alarm systems * Daily control of microbial contamination of space, machinery and prepared solutions | | Lack of indicated coverage on walls, floors and furniture, relative to patients (Stage: Areas - Equipment) | * Microbiological testing of the solutions at a frequency of one to three times a week * The employee who compounds sterile cytotoxic drug solutions, must not touch surfaces or objects outside the BSC | * Daily control of microbial contamination of space, machinery and prepared solutions * Reconstruction of the UniIt in accordance with international guidelines | | Admission of unauthorized nursing staff to the area of cytotoxic substances management (Stage: Areas - Equipment) | * Oral warnings about the consequences of entering the space * Doors are kept locked during work | * Unit must be transferred to its own separate area inaccessible to unauthorized persons * Necessary use of alerting signs that prohibit unauthorized persons to entry * Enter the unit using an electronic entrance card that only authorized personnel will hold * Installation of an intercom system | | Increased particulate and microbial load in the area of the unit due to inadequate maintenance/control of Unit Space and equipment (Stage: Maintenance and inspection of facilities and equipment) | * Current conditions do not allow effective measures to be taken, as space cannot be effectively isolated * Organization and operation of a Chemotherapy Preparation Unit in accordance with international standards has already been proposed | * Organization and operation of a Chemotherapy Preparation Unit according to international standards (air purification through HEPA filters, zone separation, two-way communication windows for the import of materials and drugs, controlled entry system for workers at the manufacturing site, etc.) * Daily record of particulate and microbial load of the unit areas using special measuring devices which have audible alarm in case of temperature and humidity deviation from the desired limits * Daily monitoring and recording of temperature, humidity and pressure of the Unit’s area | |