ABSTRACT

PT Sanbe Farma is a private group of companies engaged in the manufacture of pharmaceutical formulations and developing medical drugs, infusions and vaccines are safe and high quality. Intravenous fluids are one of the products of PT Sanbe Farma with the best quality that meets world standards such Pharmacopeia USP (US Pharmacopeia), EP (European Pharmacopeia), BP (British Pharmacopeia) and WHO (World Health Organization)(Of *et al.*, 2008)*, At every stage of the manufacturing process of intravenous fluids, there are several machines or components involved in one of the most crucial is R125 Filling machine with the highest number of failures as 184 among the others. The failure causes defects and fluctuate production quantities so it's required repairing action. In this study, the writer use methods of Risk Based maintenance and Cost of Unreliability. The purpose of this research to know the consequences and risk of filling machines R125 based on critical components which are tube tong, bag transfer and film transport. Beside it, knowing the cost and unreliability time to failures and design the next maintenance activity to minimize risk and cost. Results of the calculations obtained RBM consequences and risk based on system performance loss of the company is Rp2,462,150,809 of existing treatments or for 2.80% of production capacity for 1 year. It is out of risk acceptance criteria that set by the company which is 2%. While the calculation COUR unreliability of the critical components is Rp2,459,531,261 for corrective time, while the downtime is Rp3,452,164,146. That Values are felt directly by the company and is a big loss. Thus the writer propose the maintenance interval by considering total risk and cost of preventive maintenance based on equipment used in repairing action amounting to Rp1,718,125,370 or equal to 1. 95% of the production capacity for 1 year. The percentage is under acceptance criteria so it is acceptable towards the company. There is a change of the existing maintenance intervals from every 720 hours to do preventive maintenance becomes every 360 hours of preventive maintenance.*

Keywords: Risk Based Maintenance, Cost of unreliability, Critical components, System performance loss, Maintenance interval