

EANM's Shared Audit and Supplier Assessment Initiative

SASAI

Preliminary list of potential companies that could be approached for auditing through the SASAI project (updated version). Risk based categorisation of companies dependent on the kind of delivered products; Categorisation of the delivered products:

	Product category	Product description	Risk	Potential suppliers
Chemicals	APIs	active pharmaceutical ingredients, in radiopharmacy this means precursors and radionuclides	Highest Risk	ABX, Eckert&Ziegler, Trasis, IRE, ITG, Scintomics, Rotem, Huayi, Pharmasynth, GE Healthcare
	Other ingredients	Excipients, ingredients and all chemicals, which become part of the radiopharmaceutical or comes into direct contact with the radiopharmaceutical BEFORE application (e.g. pushing gas, 0.9% NaCl)	High Risk	ABX, B.Braun, Sigma-Aldrich, Merck, Trasis, Eras Labo
	Reagents and reference material	Chemicals which are used in quality control and therefore influence the results for approval	Moderate Risk	
	Hygiene	Chemicals which influence the hygiene and the monitoring results (e.g. disinfectants, culture medium)	Moderate Risk	
Material	Direct material	Material intended to be in direct contact with the radiopharmaceutical or its ingredients BEFORE application (e.g. tubes, syringes, cassettes, primary packaging material)	High Risk	ABX, Eckert&Ziegler, Trasis, Scintomics, Rotem, Merck Millipore, Macherey-Nagel, Waters, Beckton Dickonson, Terumo, Eppendorf, GE Healthcare
	Indirect material	All other material which could influence the quality and safety of the radiopharmaceutical	Moderate Risk	