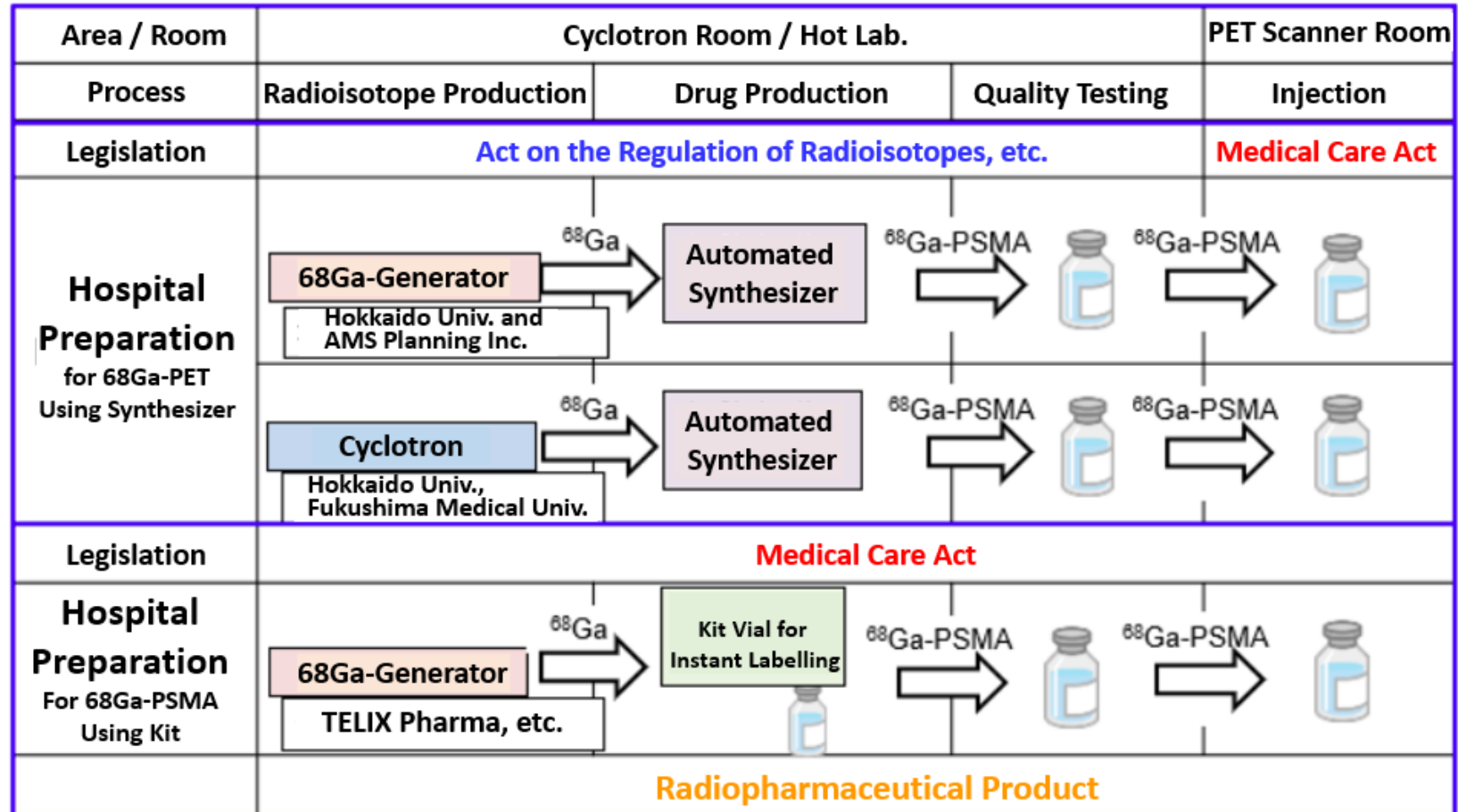
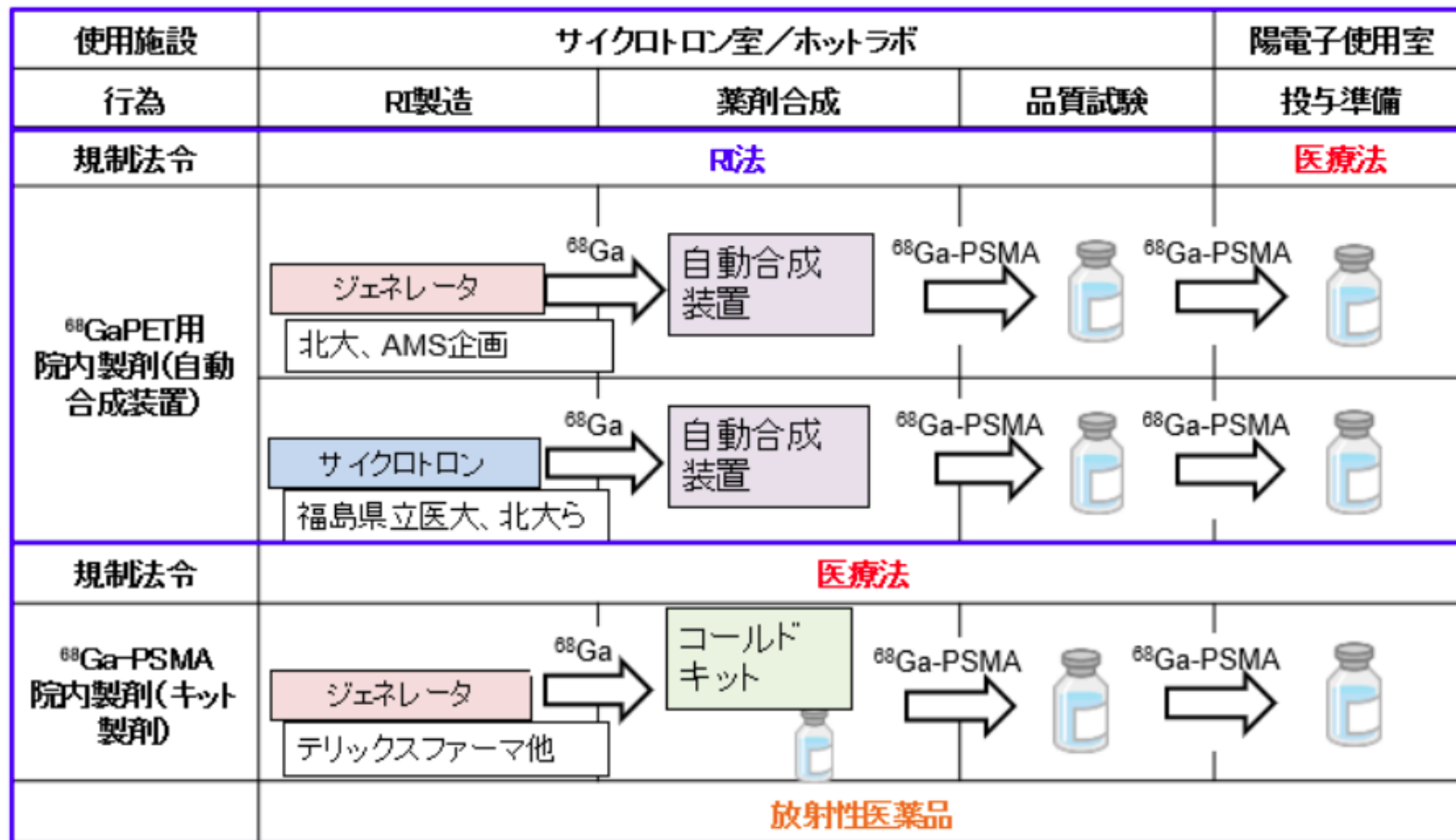


6. Regulatory Framework of ^{68}Ga -Based PET-Radiopharmaceuticals



- ✓ If the authority controls the generator as a medicine, the user of a used generator might need particular steps to return the used generator body to a manufacturer outside Japan as medical waste.
- ✓ ^{68}Ga has not defined yet as one of “PET Radioisotopes” that “7-days rule” can be adopted.

6. ^{68}Ga -PET製剤化の形態



- ✓ ジェネレータが医薬品扱いとなる場合、使用後の海外返却が課題
- ✓ ^{68}Ga は、7日間ルールが適用できるPET4核種に該当しない

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AMS Planning, Inc. : 1-15-29 Shirokane, Minato-ku Tokyo 108-0072 Japan