

35.300 SUBCATEGORIES [from 35.390(b)(1)(ii)(G)]

Subcategory #1: 10 CFR 35.392	Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required
Subcategory #2: 10 CFR 35.394	Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131
Subcategory #3: 10 CFR 35.396	Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

35.300 AUTHORIZED USER (AU) AUTHORIZATIONS

Qualifications	Proposed User Authorization
Meets the requirements for subcategory #1, e.g. 35.392; or 35.390 with a minimum of three cases orally administering sodium iodide I-131 in quantities less than or equal to 33 millicuries, for which a written directive is required	“10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries”
Meets the requirements for subcategory #2*, e.g. 35.394; or 35.390 with a minimum of three cases orally administering sodium iodide I-131 in quantities greater than 33 millicuries, for which a written directive is required	“10 CFR 35.300, limited to the oral administration of sodium iodide I-131”
Meets the requirements for subcategory #3, e.g. 35.396; or 35.390 with a minimum of three cases parenterally administering any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required	“10 CFR 35.300, limited to the parenteral administration of unsealed byproduct material”
Meets the requirements for both subcategory #2 and Subcategory #3	“10 CFR 35.300”
Does not meet the requirements for 35.390, 392, 394, or 396, but used I-131 under 35.200 prior to October 24, 2002 (e.g., whole body scans for thyroid carcinoma patients whose thyroids were removed) (Note that this authorization is not applicable for any new AU. New AU’s or licensees or are no longer authorized solely for I-131 diagnostic uses.	“10 CFR 35.300, limited to the oral administration of sodium iodide iodine-131 for imaging and localization studies”

* Note that experience with at least three cases in subcategory #2 also qualifies the user for subcategory #1