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RADIATION PROTECTION IN THERAPIES WITH IODINE-131

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ICTP The Abdus Salam International Centre for Theoretical Physics

IAEA International Atomic Energy Agency

Joint ICTP-IAEA Workshop on Radiation Protection in Diagnostic and Therapeutic Nuclear Medicine | (smr 4112)

Disclosures

Travel
- Nothing to declare

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- AAA/Novartis
- Oncobeta
- Life Molecular

Honorarium
- GE Healthcare
- Oncobeta

Advisory Board/Consultant
- GE Healthcare
- Novartis
- Lilly

Agenda

- Principle Aspects of radiation Protection in I-131-Therapies
  - General Rules
- I-131-treatment
  - Preparation of the treatment
  - Administration
- patient care
- Stay in the hospital
- Waste-Management

Radiation Protection – Whom do we have to protect?

Patient

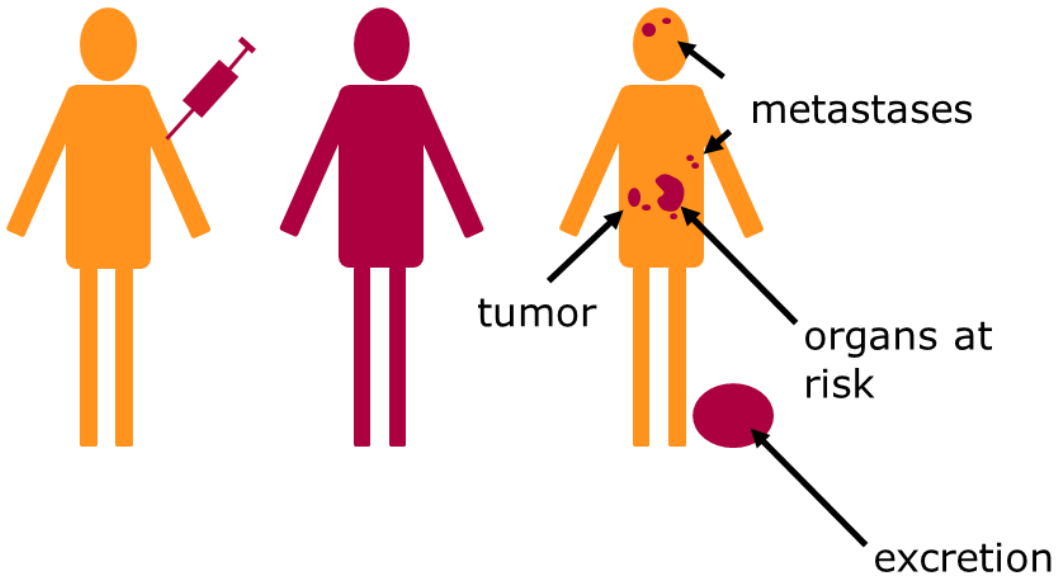
Members of the staff

Relatives

Members of the public

Environment

Principle of Radionuclide Therapy – Radiation Protection

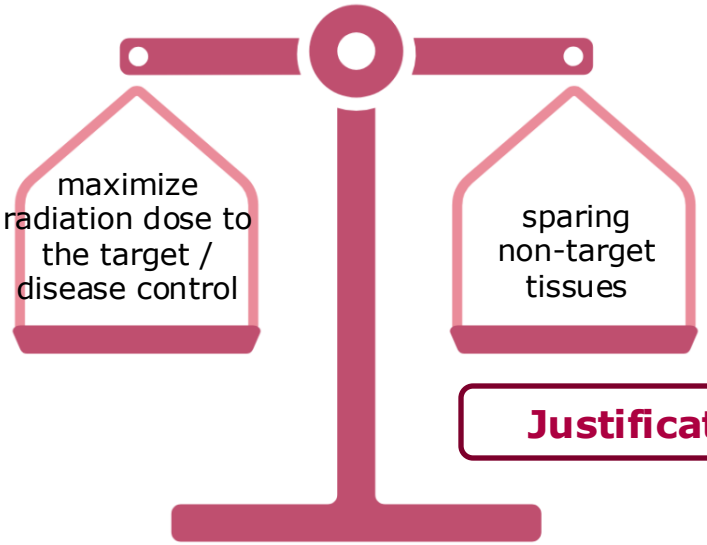


- Accumulation in target tissue
- Short range irradiation
  → Ionization (β^-, α, Auger-Emitter)

Steps to be considered in Radiation Protection

- save preparation and application
- handling of waste
- patient care
- stay in the hospital (inpatient vs. outpatient) - How long?
- protection of relatives, caregivers and the general public

Radiation Protection of the Patient – General Aspects



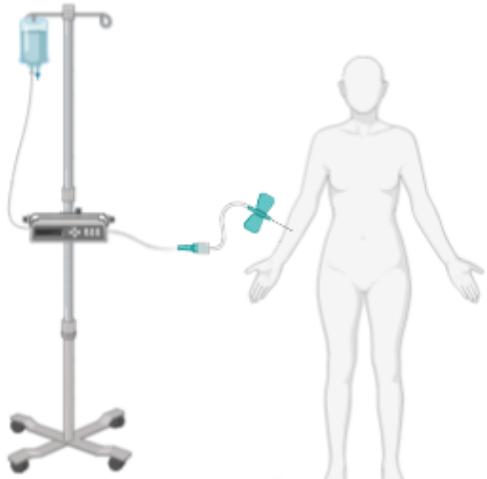
Justification

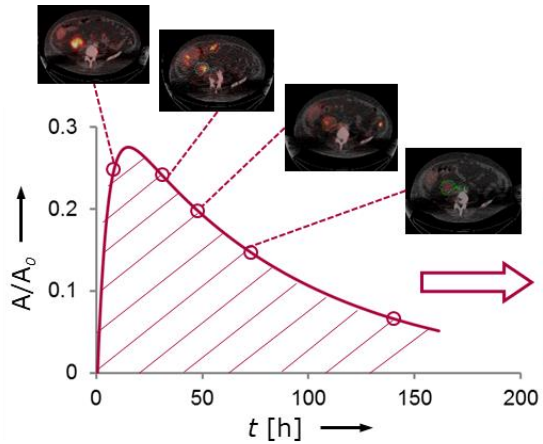
Quality Control of the Radiopharmaceuticals

- Activity
- Identity

proper application

- avoid Extravasation
- shielding
- speed of application





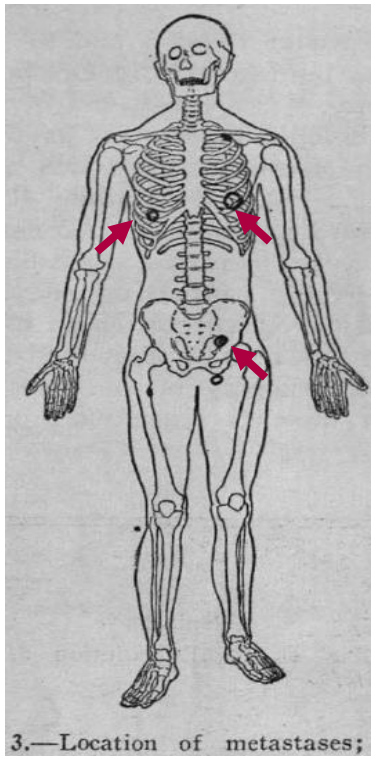
$$\tilde{A}(r_S) = \int_0^\infty A(t)$$

Dosimetry, if possible

IODINE-131 - TREATMENT

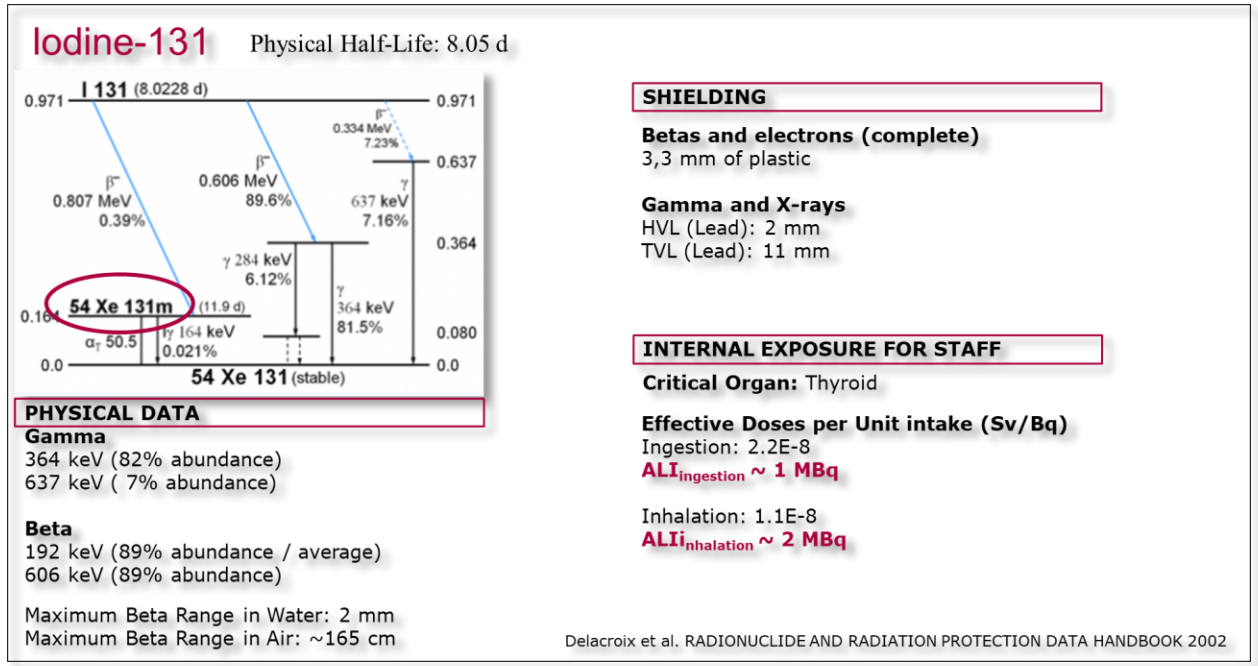
Radioiodine Therapy for the Treatment of Thyroid Diseases – A Little Bit of History

1st century	Pliny the Elder: seaweed or algae for struma treatment
1475	Wang Hei: anatomical description of thyroid gland → function unknown; treatment of struma with with chopped, dried thyroid gland of animal
1811	discovery of elemental iodine (Courtois, Clément & Gay- Lussac or Davy)
1820	goiter treatment with elemental iodine (Coindet)
1895	Iodine as a component of thyroid hormone (Baumann)
1916	isolation of L-thyroxine (Kendall)
1917	successful struma prophylaxis with iodide (2000 students), basis for introduction of iodized table salt (Marine)
1923	Radioindicator method (de Hevesy)
1934	Production of iodine-128 (HL: 28 min) (Fermi)
1938	Production of iodine-131 (Livingood & Seaborg)
1938	Diagnosis of thyroid disease using iodine-131 (Hertz, Roberts & Evans)
1941	1st radioiodine treatment of benign thyroid disease with iodine-130 or iodine-131 (Hertz, Roberts, Hamilton, Lawrence & Evans)
1946	1st radioiodine treatment of thyroid cancer with iodine-131 (Seidlin, Marinelli & Oshry)



Theranostics in 1946
Documentation of mets
(Seidlin et al. JAMA 1946)

Radioiodine – Iodine-131



PHYSICAL DATA

Gamma
364 keV (82% abundance)
637 keV (7% abundance)

Beta
192 keV (89% abundance / average)
606 keV (89% abundance)

Maximum Beta Range in Water: 2 mm
Maximum Beta Range in Air: ~165 cm

- Benign thyroid disease
  - Thyrotoxicosis, Graves disease , toxic goitre — ^{131}I-NaI (150 – 1.500 MBq)
- Malignant thyroid disease
  - Thyroid cancer, metastasis , thyroid ablation — ^{131}I-NaI (2 – 20.000 MBq)
- Other malignant diseases
  - pheochromocytoma, neuroblastoma — ^{131}I-MIBG (1.8 – 11.000 MBq)

Radioiodine – Iodine-131

- ^{131}I (Radioiodine) therapy of hyperthyroidism → still the main form of therapy in nuclear medicine, performed all over the world
- In 2008, in Germany about 54.000 nuclear medicine treatments were performed, of which about 45.000 were radioiodine therapies
- Mechanism of action is somewhat dependent on the size of the thyroid

- thyroid with a mass of ~ 20g
- majority of the absorbed dose is delivered by beta particles
- photons contribute to ~ 5% of the total dose

- a more impressive thyroid gland ~ 100 g
- photon contribution doubles → ~10%

RADIATION PROTECTION ON RADIONUCLIDE THERAPIES - GENERAL RULES

Radiation Protection – General Aspects

- Treatment with radionuclides has to be performed according to International Basic Safety Standards (IBSS or BSS)
- IBSS require that legal entities apply to the regulatory authority for a license
  - radioactive material license (RAM) → accordance with national regulations and laws

The licensee has to ensure that the staff (physician, medical physicist, technologist):

- follow any applicable rules and procedures for the protection and safety of patients as established by the licensee
- are competent in the operation and use of the equipment and radiation sources, of the equipment for radiation detection and measurement and of the safety system and devices
- know how to react in the case of patient emergencies

→ Expertised and well trained staff

→ Quality control of the equipment used

→ Appropriately equipped clinics/departments

  → corresponding premises

  → Equipment for radiation protection and emergeny situations

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Radiation Protection – General Aspects /II

The licensee shall ensure that:

- No patient is administered a medical exposure unless the exposure is prescribed by a medical practitioner
- Medical practitioners are assigned the task and obligation of ensuring overall patient safety in the prescription of and during the delivery of the medical exposure
- Medical and paramedical personnel are available and are either health professionals or have appropriate training to discharge their task in the conduct of therapeutic procedure
- The exposure of comforters and caregivers of patients undergoing treatment is constrained as specified in the regulations

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Radiation Protection in Radionuclide Therapy

Safe handling of radionuclides

- ordering
- receipt and unpacking
- storage
- dispensing
- internal transports
- radioactive waste

Safe administration

- Identification
- pregnancy
- breastfeeding

Patient preparation

The radioactive patient and dose constraints

The hospitalized patient

- instructions to nursing staff
- visitors instructions
- discharge of the patient
- decommissioning of hospital ward
- radioactive waste

Emergency procedures

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Radiation Protection in Radionuclide Therapy - Safe handling of radionuclides

Ordering, receipt and unpacking

It has to be ensured:

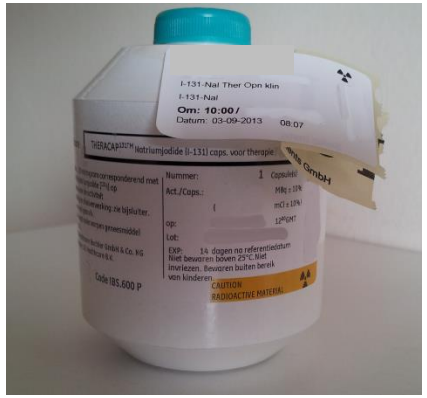
- That the hospital routines for ordering radionuclides should be followed
- That the package is expected and that no unauthorized person will open it upon arrival
- That the package is checked before unpacking
- That in case of damage a radiation protection officer is contacted if there are doubts on how to act
- When ordering, be sure the delivery service knows where in the hospital to deliver the material

→ Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)

Radiation Protection in Radionuclide Therapy - Safe handling of radionuclides

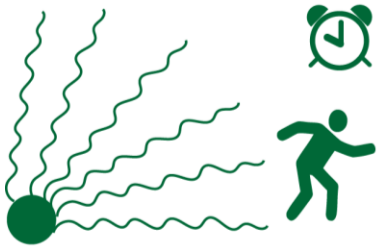
Storage

- The radionuclide should be stored in a controlled area, according to national regulations and local rules → Protection Classes against burglary
- The radionuclide should be labeled (nuclide, activity, calibration date, patient name)
- The radionuclide should always be stored in a lead container and preferably in a fridge to prevent evaporation
  - If this is not possible, Iodine-131 should be stored in fumed hood
- To reach an acceptable external dose rate, a thickness of 1…4 cm lead is generally required (for Iodine-131)



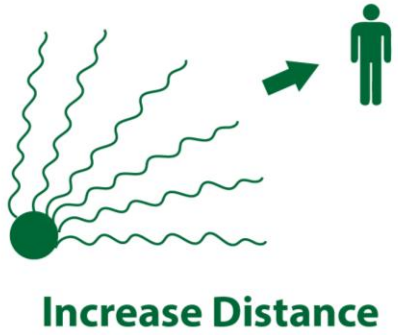
Radiation Protection in Radionuclide Therapy - Safe handling of radionuclides

- **T**ime



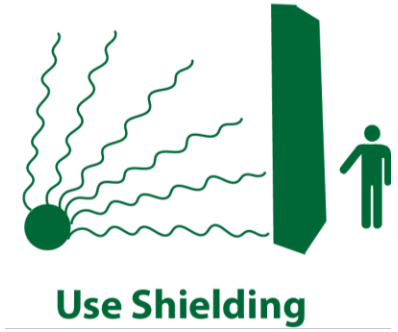
Experienced workers will generally(but not necessarily) habe lower exposure of the hands
→ TRAINING

- **D**istance



Inverese square law (ISL)
Dose rate ~ 1/distance²

- **S**hielding



Never touch an unshielded vial or syringe

Knowledge

United States Environmental Protection Agency
https://www.epa.gov/radiation/protecting-yourself-radiation

Radiation Protection in Radionuclide Therapy - Safe handling of radionuclides
Preparation

- Wear Protective clothing (disposable gown and gloves)
- Check the activity
- Use shields of lead (bench top, vial, syringe)
- Keep the vial in the fume hood (ideally on a tray or in a larger laboratory dish), lined with plastic backed adsorbent pads
- Handle the vial with forceps or similar long instruments
- Cover the vial with lead after use and put to storage
  - For Iodine-131 → e.g. 2cm of lead provides 2 order of magnitudes on dose reduction
- Work fast, work safe
- Documentation - Fill in the necessary forms

Radinuclide Fume Hood

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Internal Transport

- If the administration of radiopharmaceutical to the patients take place far away from the dispensing room, use a transport container with adsorbent pads and a trolley with high “fences”
- Make sure that the container is labeled
  - warning signs
  - information on radionuclide
  - activity and date
  - patient name
  - name of the responsible staff
- Mark the Release for Administration of the Radiopharmaceuticals
- Travel by the most direct route avoiding more heavily occupied areas

Lynax

Radiation Protection in Radionuclide Therapy - Safe handling of radionuclides

Radioactive waste from the laboratory, examples

- "empty" vials → Remnants of the radionuclide are still present; adherence to the walls
- Needles and syringes used for dispensing or injection
- Adsorbing pads, paper towels
- Used needles for pipettes
- Waste Segregation is recommended

Short-lived isotops (e.g. Tc-99m) Spharps

Needles
Glass Vials

Short-lived isotops (Tc-99m) Non-sharps

Gloves, Gowns
Wipes, …

Long-Lived (e.g. I-131) Spharps

Long-Lived (e.g. I-131) Non-sharps

Precautions before administration

- Be prepared for an emergency situation
- **Careful identification of the patient**
- Questions to the patient
  - Pregnant?
  - Breastfeeding?
  - Incontinent?
  - Nausea? → intravenous administration to be considered
  - Living conditions
    - number of people in house, children?
    - pregnant women?
    - separate room, separate toilet?
  - Type of work?
    - working close to other people?
    - working with children?
    - pregnant co-workers?
  - Public transportation back home?
- Verbal and written individual instructions to the patient
- Record all necessary information

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PREPARATION OF I-131 THERAPY

^{131}I-therapy – optimization, dosimetry

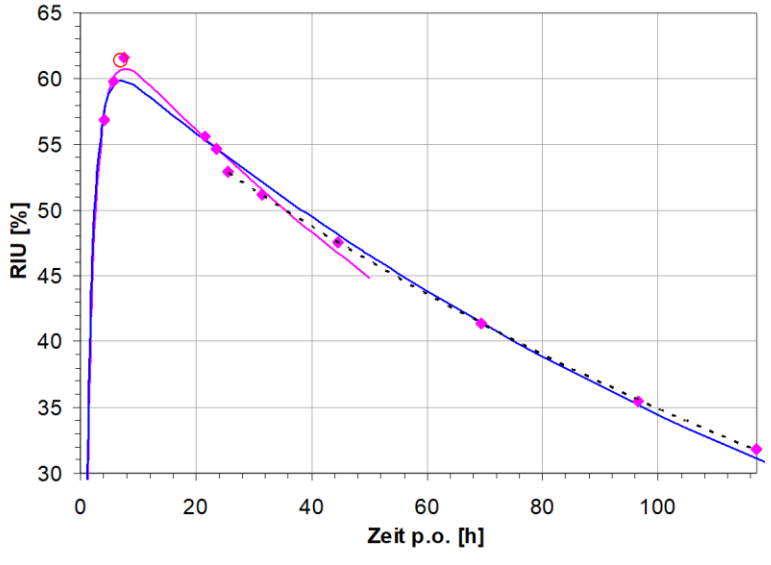
- Pre-calculation of the activity to be administered
- We need
  - bio-kinetic parameters such as local uptake and effective half-life (biological and physical half-life)
  - at least the mass (volume) of the thyroid tissue
- physician (nuclear medicine physician, endocrinologist or oncologist) prescribes an absorbed dose to the thyroid based on individual medical parameters for the patient
- Diagnostic procedure
  - uptake measurement with oral intake of small amount of ^{131}I NaI (A ~ 1 …2 MBq)
  - determination of volume of thyroid (ultrasound or ^{99m}Tc-uptake scintigraphy)
- Calculation of the activity corresponding to the prescribed thyroid absorbed dose , based on the uptake and retention of ^{131}I in the thyroid of the patient as well as the volume of the active thyroid

Preparation of ^{131}I-therapy for benign diseases - Diagnostic procedure

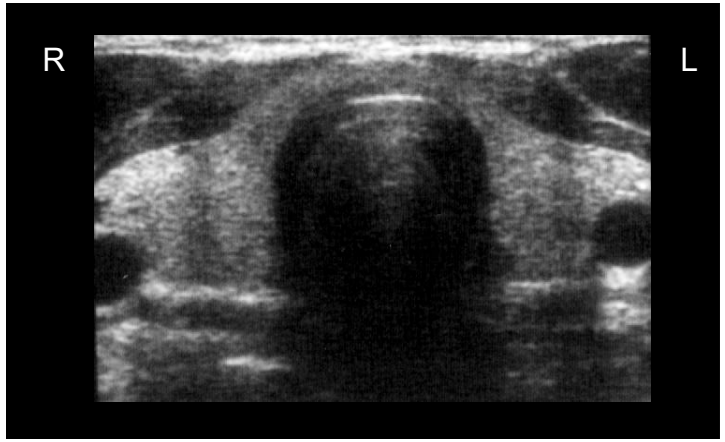
- Determination of patient specific bio-kinetic parameters

- The usual way to quantify thyroid uptake and retention of ^{131}I after an intravenous or per oral administration of a small activity (1 … 2 MBq), is to place a detector over the thyroid, where the activity very soon concentrates → Radioactive Iodine Uptake Test

Measurement of iodine-uptake at several time-points



Calculation of Uptake an effective half-life



determine volume based on ultrasound

Calculation of ^{131}I-activity

Unifocal/multifocal autonomy: 400/150 Gy
Graves' disease (thyroablation): 250-300 Gy
diminishing of the goiter: 120 Gy

ultrasound
or ^{99m}Tc-scintigraphy

$$^{131}I - Activity\,[MBq] = \frac{Target\ Dose\,[Gy] \cdot TargetVolume\,[ml] \cdot 24.67}{^{131}I - Uptake[\%] \cdot HL_{eff}[d]}$$

Formula of Marinelli

RAIU

RAIU-Test
or empirical

Note: This procedure is usually only necessary for the therapy of benign diseases; in the therapy of thyroid cancer, therapy is mostly performed with prescribed activities.

^{131}I-Therapy - Administration

Unsealed radioavtivity has to be:

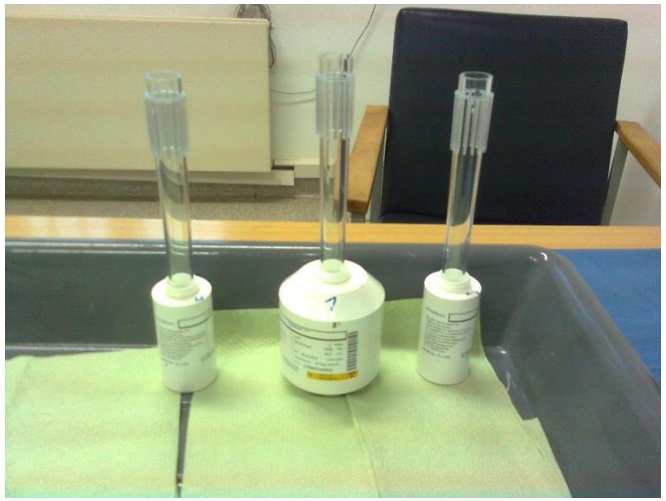
- calibrated in terms of activity of the radiopharmaceutical to be administered
- determined and recorded at the time of administration

Important: different geometries of vials or capsules and different liquid volume may require different calibration settings of the dose calibrator → calibration in advance necessary → references needed

!!! Preparation of ^{131}I (also capsules) have to be performed under fumed hood → volatile, since gaseous!!!

Procedure for oral administration

- ^{131}I should be administered in a controlled area (hot lab or the patients hospital room)
- plastic bag for contaminated items should be available as well as paper tissues
- The patient is asked to sit at a table covered with adsorbent pads and the floor beneath the patient should be covered by adsorbent paper
- If the ^{131}I is administered in capsules, they should be transferred to the patient mouth by tipping from a small shielded container (thickness > 1cm Pb)
- Liquid ^{131}I is administered in an oral solution (50 ml) is preferable ingested through a straw from the shielded vial by the patient. The vial should be flushed with water several times
- patient should drink several glasses of water to clean the mouth



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Procedure for intravenous administration

- Dispense the radionuclide into a shielded syringe
  - Administer the syringe directly or via perfusion pump
  - use a secure i.v. access to the vein
- Keep the patient in bed until the infusion has ended
- Remove syringe, the catheter and the infusion line and dispose them as radioactive waste

Room for Iodine-131 treatment (controlled area)

- Only one patient in the room
- Easily cleanable surfaces and utensils
- Door closed
- Restriction for visitors
- Warning signs outside the room
- Extra lead shields
- Decontamination equipment

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HOSPITALIZATION FOLLOWING IODINE-131 THERAPY

Release of patients following Iodine-131 therapy

- Decision to hospitalize or release a patient should be determined on an individual basis
- In addition to residual activity in the patient, the decision should take many other factors into account.
- Hospitalization will reduce exposure to the public and relatives, but will increase exposure to hospital staff
- Hospitalization often involves a significant psychological burden as well as monetary and other costs that should be analyzed and justified
- Patients travelling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours.

Hospitalized Iodine-131 patient

- Separate room with toilet and shower, labeled as controlled area
- Patient instructions (verbal and written)
- Local rules for nursing the patient
- Local rules for visitors
- Local rules for decontamination
- Local rules for emergency situations

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Instructions to a hospitalized Iodine - 131 patient

- Follow the recommendations given by the staff
- Ideally, stay in the room
- Drink more than usual (1… 2 litre more)
- Use only the private toilet in the room and flush 3 times
- Men should sit down on toilet to avoid splashing
- Wash hands well in soapy water after using the toilet
- Wear footwear when leaving the bed
- In event of vomiting or incontinence notify the nurse immediately

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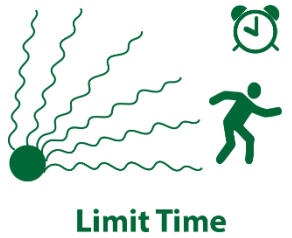
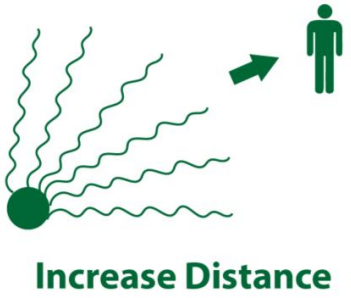
Instructions to nursing staff of a 131 I patient

- Reduce time spent with patient by planning ahead and working efficient



- Work as far away from patient as possible



- Follow preventative measures against contamination
  - wear protection gloves
  - wear shoe covers
  - wear a protective gown
- Remove protection clothing before leaving the room

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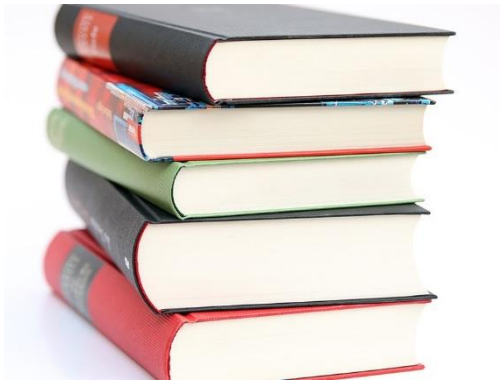
Decommissioning of the ward

- The radiation protection officer should supervise the removal of contaminated waste, the decontamination of the room and equipment and should make adocumented final survey of the room

- Monitoring and decontamination must be done prior to entry of nursing and housekeeping staff to prepare the room for the next patient

- When survey and decontamination procedures are complete, the radiation protection officer will remove the radiation warning sign and notify the nursing and housekeeping staff that the room is now clear for use

Radioactive waste - Type of waste



Radioactive waste

- All patient radioactive waste are placed in a plastic bag
- This plastic bag is properly tagged, labelled with isotope type and date
- All waste is stored until decayed to background levels (typically 6-12 half-lives). This is measured using a contamination monitor or ideally a dedicated measurement system for waste bags
- When the activity and the dose rate has decreased to below local limits it is fine to dispose the bag as ordinary garbage

radiation in the bag is monitored

Radioactive waste

mostly set to double background
→ Very sensitive

Liquid Radioactive waste

- Faeces, urine and other liquids should be disposed of via the toilet and further to sewage treatment plant or storage tanks

- Contaminated clothing, linen, food items etc should be stored in a separate plastic bag labelled “RADIOACTIVE” and should be removed daily to the designated radioactive waste storage facility

- Cutlery and dishes should be washed in the patient s room and reused by the patient

Plant for decay of radioactive waste water with underground tanks

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DEATH OF AN IODINE-131 PATIENT

Death of an Iodine-131 patient

Precautions that should be given are depending on the residual activity and may involve the following

- Preparation for burial or cremation should be controlled by a competent person
- Relatives should be prevented from coming into close contact
- People should not be allowed to linger in the presence of the coffin
- All staff involved in handling the corpse should be instructed and monitored if appropriate
- All objects, clothes, documents etc. that might have been in contact with the deceased must be tested for contamination
- Wrap the body in waterproof material immediately after the death to prevent spread of contaminated body fluids
- Embalming of the body should, if possible be avoided
- Autopsy of highly radioactive bodies should be restricted to the absolute minimum

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Death of an Iodine-131 patient

- In the event of death of a patient who has recently received a therapeutic dose of Iodine-131 care has to be taken to ensure that the involved personnel receive as low a dose as possible at all stages prior to the burial or cremation

	Activity limit (MBq)	
Radionuclide	**Burial**	**Cremation**
^{131}I	400	400
^{90}Y colloid	2000	70
^{198}Au colloid	400	100
^{32}P	2000	30
^{89}Sr	2000	200

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Thank you very much for your attention

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