Towards a sustainable cleanroom: is the energy efficiency guidance of ISO 14644-16 still sufficient for purpose?

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Biography

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Pier Angelo Galligani, mechanical engineer, is **President at Techniconsult**, an engineering company based in Florence and active in the life-science field, area in which provides engineering, commissioning and validation services.
Pier Angelo is **also President at TECMA**, a maintenance and installation company focused on providing services to pharmaceutical industry.
Formerly Technical Director at Techniconsult and TECMA, Pier Angelo is now **Sustainability and Innovation Manager** of the two companies.
During the past 35 years Pier Angelo has got a deep experience in pharmaceutical processes and plants, clean systems engineering, HVAC applications, contamination control and validation. He is Member of the UNI working group on Clean Rooms Technology. He is **Vice-President and Past-President of ASCCA** (Italian Clean Rooms Society). He was the Italian delegate in ISO/TC 209 - Working Group N.13: Energy Saving for Cleanrooms. He is one of the Italian delegates in ISO/TC 209 - Working Group N.4: Cleanrooms design and construction.

PART 1

ISO 14644-16 Genesys and main features (*)

(*) Further details on this topic can be found in: «ISO14644-16: How the standard can help optimizing HVAC systems and reducing energy consumption in cleanrooms - Pier Angelo Galligani, ASCCA Seminari on air 2021 - 13 Luglio 2021».

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Background

ISO 14644-16: ENERGY EFFICIENCY IN CLEANROOMS AND SEPARATIVE DEVICES:
WHY THIS STANDARD?

CLEANROOMS CAN BE DIFFERENT FOR DIMENSIONS AND INTENDED USE BUT IN GENERAL ARE INSTALLATIONS WITH HIGH ENERGY INTENSITY; SOME EXAMPLES:

- ENERGY CONSUMPTION IN A CLEANROOM CAN BE UP TO 10 TIMES THE CONSUMPTION OF AN OFFICE BUILDING WITH THE SAME DIMENSIONS
- IN ORDER TO REACH THE PREFIXED CONTAMINATION STANDARDS, HVAC SYSTEMS FOR C.R. MOVE BIG AIR FLOW RATES OF AIR PREVIOUSLY CONDITIONED AND FILTERED ON HIGH EFFICIENCY PARTICULATE AIR FILTERS (HEPA FILTERS) THAT TYPICALLY ABSORB FROM 35% TO 50% OF THE GLOBAL ENERGY CONSUMPTION OF ALL EXISTRING HVAC SYSTEMS
- ENERGY CONSUMPTION OF CLEANROOM HVAC SYSTEMS CAN REACH UP TO 80% OF THE TOTAL ENERGY CONSUMPTION OF THE SITE IN WHICH THE C.R. IS LOCATED

Genesis of ISO 14644-16

ISO 14644-16 HAS BEEN PUBLISHED OFFICIALLY IN MAY 2019

THE DOCUMENT IS FINALIZED TO THE REDUCTION OF ENERGY CONSUMPTION IN CLEANROOMS AND FOLLOWS PREVIOUS NATIONAL STANDARDS RELATED TO THE SAME TOPIC:

- THE GERMAN STANDARD VDI 2083 - Cleanroom technology - Energy efficiency (2011)
- THE BRITISH STANDARD BS 8568 - Cleanroom energy - Code of practice for improving energy efficiency in cleanrooms and clean air devices (2013)
- THE RUSSIAN STANDARD GOST R 56190 - Cleanrooms Energy efficiency (2014)

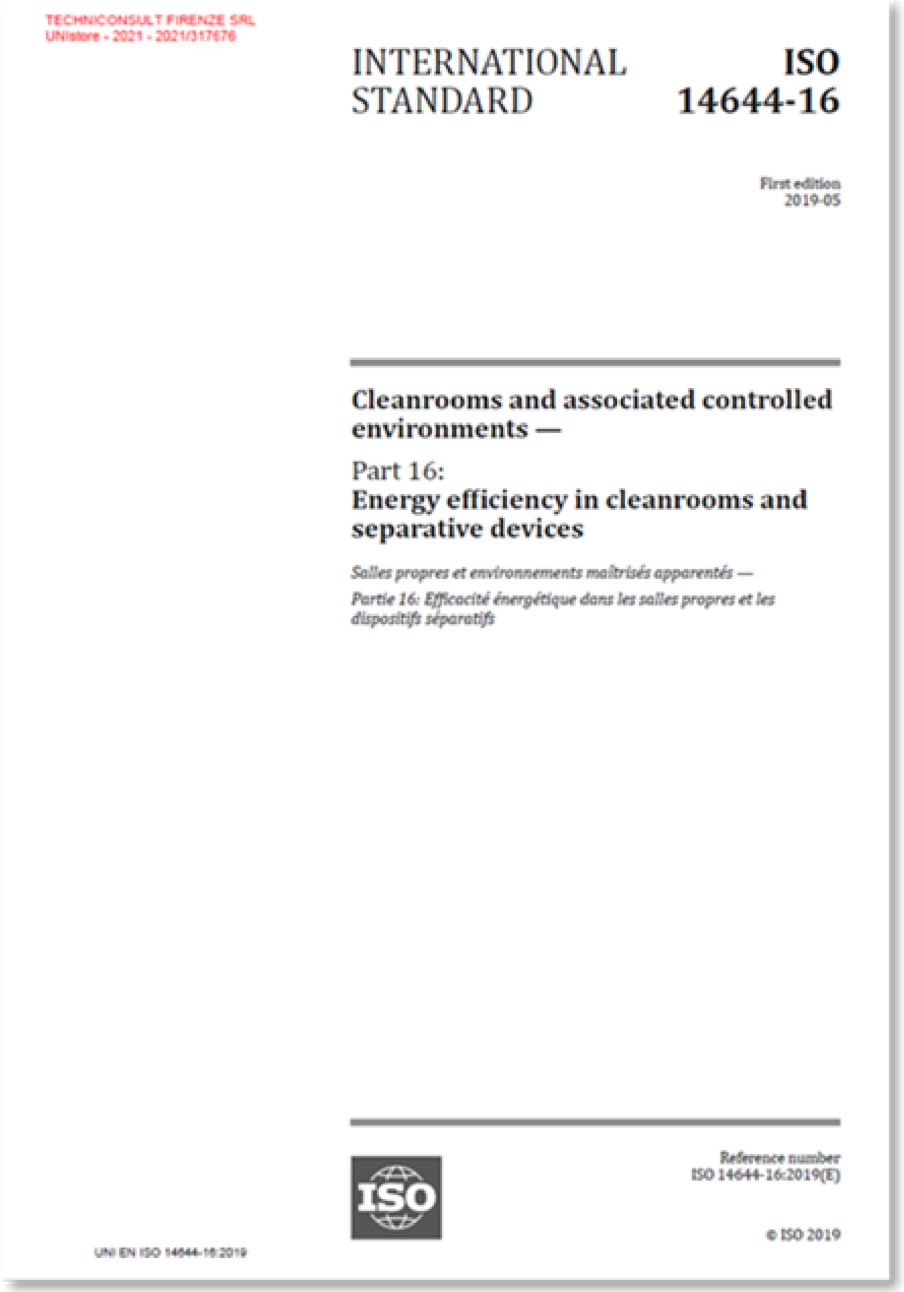
ENERGY REDUCTION IN CLEANROOMS IS A GLOBAL TARGET AND IT'S PARTICULARLY RELEVANT IN COUNTRIES WITH A HIGH INDUSTRIAL GROWTH

Scope of the standard

- ISO 14644-16 IS A GUIDE FOR OPTIMIZATION OF ENERGY USAGE AND MAINTAINING ENERGY EFFICIENCY IN NEW OR EXISTING CLEANROOMS AND SEPARATIVE DEVICES
- IT PROVIDES GUIDANCE FOR THE DESIGN, CONSTRUCTION, COMMISSIONING AND OPERATION OF CLEANROOMS
- IT COVERS ALL THE CLEANROOM-SPECIFIC FEATURES (*), IN ORDER TO OPTIMIZE USAGE OF ENERGY IN ELECTRONIC, AEROSPACE, NUCLEAR, PHARMACEUTICAL, HOSPITAL, MEDICAL DEVICES, FOOD INDUSTRIES AND OTHER CLEAN AIR APPLICATIONS

(*) NOTES:

- PROCESS SYSTEMS IMPACT ON ENERGY CONSUMPTION IS OUT OF SCOPE
- IN GENERAL THE STANDARD IS FOCUSED MORE ON ENERGY IMPACT OF HVAC SYSTEMS RATHER THAN UTILITIES PRODUCTION & DISTRIBUTION SYSTEMS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INTERNATIONAL STANDARD

ISO 14644-16

First edition
2019-05

Cleanrooms and associated controlled environments —

Part 16:
Energy efficiency in cleanrooms and separative devices

Salles propres et environnements maîtrisés apparentés —
Partie 16: Efficacité énergétique dans les salles propres et les dispositifs séparatifs

Reference number
ISO 14644-16:2019(E)

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UNI EN ISO 14644-16:2019

Structure of the document - 1/2

ISO 14644-16 INCLUDES 15 N. CHAPTERS IN THE NORMATIVE SECTION; FOLLOWING THE MAIN TOPICS COVERED:

- SCOPE, NORMATIVE REFERENCES, TERMS AND DEFINITIONS
- ENERGY REDUCTION EVALUATION AND IMPLEMENTATION PROCESS
- IMPACT OF URS ON ENERGY CONSUMPTION
- AIRFLOW VOLUME (CALCULATION) AND COMPENSATING FACTORS
- POWER MANAGEMENT (TURN-DOWN, TURN-OFF AND RECOVERY), ADAPTIVE CONTROL
- HEATING AND COOLING LOADS (CALCULATION), FAN &FILTER SELECTION, LIGHTING LEVELS
- TRAINING, OPERATION AND MAINTENANCE, DECOMMISSIONING.

Structure of the document - 2/2

ISO 14644-16 INCLUDES 6 N. ANNEXES IN THE INFORMATIVE SECTION; FOLLOWING THE MAIN TOPICS COVERED:

- SOURCE STRENGHT EVALUATION, WORKED EXAMPLE ON AIR VOLUME CALCULATION
- ENERGY SAVING OPPORTUNITIES CHECKLIST
- IMPACT ASSESSMENT
- BENCHMARKING: ENERGY PERFORMANCE INDICATORS FOR CLEANROOMS.

Novelties & Most debated topics

NOVELTIES:

- Impact of URS on energy consumption (from Life-sciences)
- Air change rate/Air volume supply calculation based on source strenght
- Power Management & Adaptive control
- Benchmarking, Performance indicators

MOST DEBATED TOPICS:

- (Contamination) source strenght
- Air change rate/Air volume supply
- Quality risk management (from Life-sciences)
- Benchmarking, Performance indicators

Energy saving opportunities identification

ENERGY REDUCTION EVALUATION PROCESS IS SUPPORTED BY THE «ENERGY SAVING OPPORTUNITIES CHECKLIST» (ANNEX «B»)

EXAMPLE OF «ENERGY SAVING OPPORTUNITIES CHECKLIST»

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref
Source strength Evaluation	Contamination sources	Avoid overdesigning	Identify all the relevant contamination sources and evaluate their strength to optimize air flow	Errors in evaluating sources and/or their strength	Enhance study of process; literature, design of experiments	A…
URS/ Specification	Performance requirements	Avoid Over specifying	Specify correct operational parameters for the process (i.e.: cleanliness class, recovery time, room pressure-T/RH, lighting levels, occupancy levels, etc.)	Loss in flexibility for possible changes in process	Set a small, reasonable margin, differentiate parameters for different criticalities	5.169
	Facility size Requirements	Avoid Over-sizing	Specify correct dimensions of the process areas, correct occupancy levels, etc.	Loss in flexibility for possible changes in process	Set a small, reasonable margin, allow for modular expansion of the areas and HVAC systems	5.26G…
	Occupancy levels	Optimize occupancy	Optimize people number in order to save space and reduce contamination by particles and MCPs	Operations can be more Complicated	Enhanced procedures and control	-

Energy saving opportunities - 1/8

IMPACT OF U.R.S. ON ENERGY CONSUMPTION:

- U.R.S. AND CLEANROOM SPECIFICATIONS DEEPLY INFLUENCE ENERGY EFFICIENCY AND ARE THE VERY FIRST CHANCE TO PROMOTE ENERGY SAVING!!
- FOCUS ON ENERGY BURDEN CAUSED BY OVERSPECIFYING AND OVERSIZING CLEANROOMS
  - RELEVANT REQUIREMENTS TO BE CAREFULLY DEFINED:
  - LEVEL OF CLEANROOM CLEANLINESS (Is it correctly established? Regulated environment? Etc.)
  - ROOM DIFFERENTIAL PRESSURE, TEMPERATURE AND RELATIVE HUMIDITY
  - FLOOR SPACE AREAS (Is it possible to reduce? Can ISOLATION TECHNOLOGY be an alternative? Etc.)
  - CONTAMINATION SOURCE STRENGHT (Is it correctly evaluated? Correct choices on garments? Etc)
  - PROCESS HEAT LOSSES (Are they correctly evaluated? Are diversity and utilization factors considered?)
- FLEXIBILITY OF FACILITIES SHOULDN’T LEAD TO OVERSPECIFYING AND OVERSIZING CLEANROOMS!!

Energy saving opportunities - 2/8

SOURCE STRENGHT EVALUATION!!

Table B.1 — Energy saving opportunities checklist

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Source strength evaluation	Contamination sources	Avoid over-designing	Identify all relevant contamination sources and evaluate their strength to optimize airflow	Errors in evaluating sources and/or their strength	Enhance study of process; literature, design of experiments	Annex A

- THE KNOWLEDGE OF SOURCE STRENGHT CAN ADDRESS ENERGY SAVING IN A NON-UNIDIRECTIONAL AIRFLOW CLEANROOM (FOR A GIVEN CLEANLINESS CLASS TO BE OBTAINED, NEEDED C.R. SUPPLY AIRFLOW RATE IS PROPORTIONAL TO SOURCE STRENGHT OF PERSONNEL AND EQUIPMENT)
- AN ACCURATE EVALUATION OF SOURCE STRENGHT CAN HELP AVOIDING C.R. OVERDESIGN
- PERSONNEL SOURCE STRENGHT EVALUATION IS STILL A COMPLEX TASK; IN LITERATURE ARE PRESENT MANY COMPREHENSIVE EXPERIMENTAL STUDIES BUT THE RESULTS FROM DIFFERENT AUTHORS ARE OFTEN DISCORDANT AND/OR HARDLY COMPARABLE

SOURCE STRENGHT EVALUATION - MEASUREMENT OF PARTICULATE GENERATED BY PERSONNEL AND PROCESS EQUIPMENT IN A «BODY-BOX» (COURTESY AIRLAB – POLIMI)

Energy saving opportunities - 3/8

SUPPLY AIRFLOWRATE REDUCTION (NON-UDAF SYSTEMS)

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
	Airflow: non-UDAF	Reduce airflow volume flow rate	Consider possibility of airflow volume reduction by evaluating contamination sources/strength, ventilation effectiveness and heat loads	Insufficient particle dilution, presence of dead spots and poor room temperature control. High value of recovery time	Use of CFD in design. Provide a small, reasonable margin. Validation and subsequent monitoring of contamination levels and environmental data	6, 7.1
	Make-up air	Reduce make-up air use	Consider possibility of make-up air optimization by careful evaluation of HSE needs, process needs (exhaust offset), room air leakages	Poor HSE conditions, poor pressure control	Provide a small, reasonable margin. Verification and subsequent monitoring of room pressure and HSE data	6, 10
	Extract airflow rate	Reduce extract airflow rate from process equipment	Consider possibility of extract airflow rate optimization by suitable design; consequent reduction in make-up air requirement.	Poor HSE conditions	—	6, 10

- SUPPLY AIRFLOWRATE REDUCTION IN A NON-UNIDIRECTIONAL AIRFLOW CLEANROOM IS AN IMPORTANT OPPORTUNITY FOR ENERGY REDUCTION. HOWEVER, THIS TECHNIQUE MAY CAUSE ADVERSE IMPACT ON C.R. PERFORMANCES; CONSEQUENTLY, GOOD ENGINEERING EVALUTIONS AND APPROPRIATE RISK MITIGATION TOOLS SHALL BE PERFORMED BEFORE THE IMPLEMENTATION OF THIS STRATEGY

Energy saving opportunities check list - 4/8

SUPPLY AIRFLOWRATE CALCULATION (NON-UDAF SYSTEMS)

- SUPPLY AIRFLOWRATE CALCULATION HAS BEEN ONE OF THE MOST DEBATED TOPICS DURING THE DOCUMENT DEVELOPMENT
- THE STANDARD SUGGEST TWO DIFFERENT CALCULATION METHODS:
- THE FIRST ONE IS BASED ON SUPPLY AIRFLOWRATE CALCULATION BY MEANS OF FORMULAS, DERIVED BY CONTAMINANT DILUTION EQUATIONS, RECENTLY MODIFIED AND IMPROVED BY SEVERAL AUTHORS (I.E.: BILL WHYTE, WEI SUN AND OTHERS)

Due to the lack of consensus between experts, two alternative definitions are proposed in the standard to evaluate the ventilation effectiveness ε

$$Q = \frac{D}{\varepsilon \times C}$$

$$\varepsilon = ACE = \frac{RR}{RRT} = \frac{RR}{Q/V}$$

Or:

$$\varepsilon = CRE = \frac{Ce}{Cs}$$

- Q = air supply rate (m3/s)
- D = total particle dispersion rate from personnel and machinery (counts/s)
- ε = ventilation effectiveness (-)
- C = required airborne particle concentration in the location (counts/m3)
- ACE = Air change effectiveness (-)
- CRE = Contaminant removal effectiveness (-)
- RR = recovery rate at a location or locations in the c.r. (1/s)
- RRT = overall recovery rate in the c.r. (1/s) [1]
- V = Cleanroom volume (m3)
- Ce = particle concentration in the exit air (counts/m3)
- Cs = mean particle concentration in the cleanroom (counts/m3)

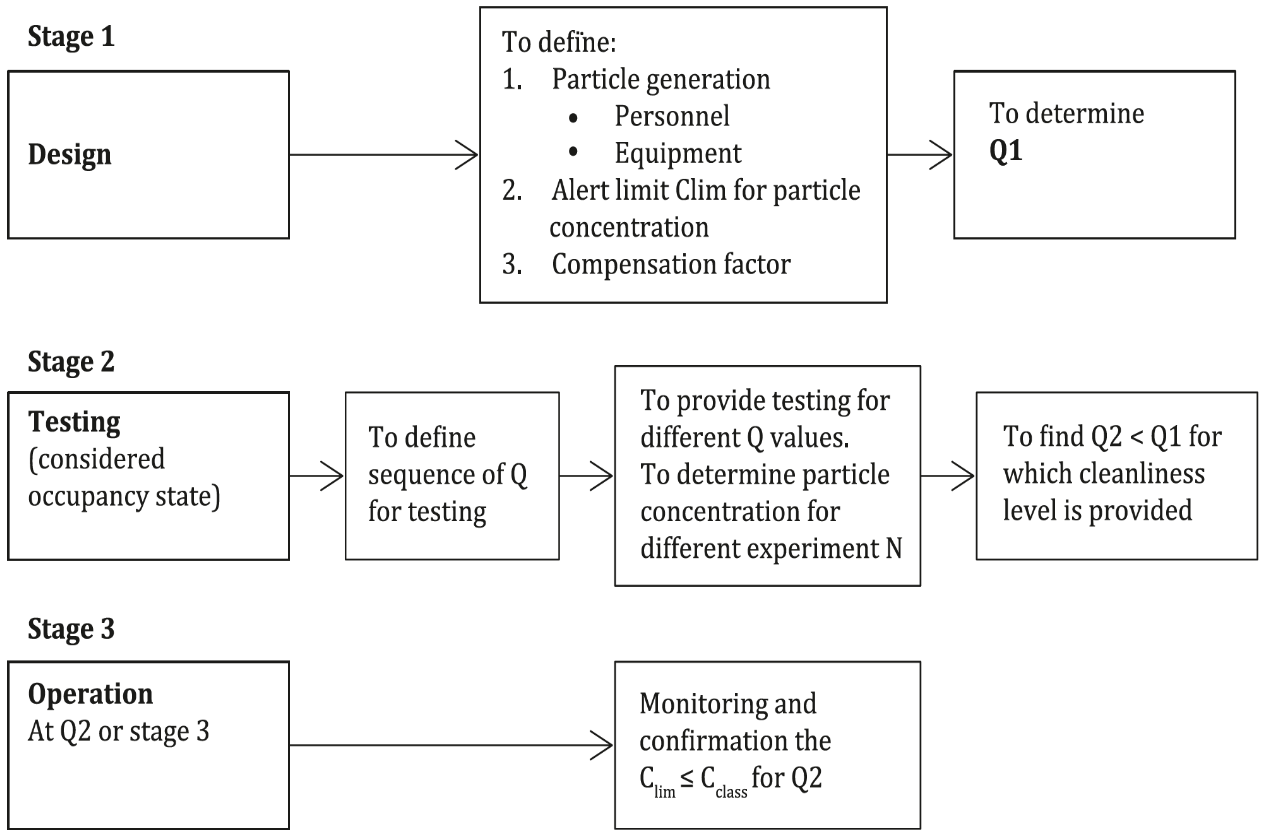
[1] In case of perfect mixing between air and contamination in c..r. at the beginning of the test, RRT= Q/V

Energy saving opportunities check list - 5/8

SUPPLY AIRFLOWRATE CALCULATION (NON-UDAF SYSTEMS)

- THE SECOND METHOD FOR AIRFLOWRATE CALCULATION, MORE EMPIRIC, IS BASED ON THE FOLLOWING PROCEDURE:
  - ESTIMATE OF AIRFLOWRATE VALUE Q1, DERIVED BY THE CALCULATED VALUE Q INCREASED BY A COMPENSATION FACTOR
  - TESTING OF THE C.R. TO EVALUATE THE POSSIBILITY TO REDUCE THE CALCULATED SUPPLY AIRFLOWRATE BASED ON THE REAL PERFORMANCE OF THE SYSTEM
  - POSSIBLE AIRFLOWRATE REDUCTION (Q2<Q1), TESTING AND SUBSEQUENT MONITORING TO ASSESS THE POSSIBILITY TO IMPLEMENT THE REDUCTION

Design – Testing – Operation



NOTE *Q* = airflow volume in cubic metres per second.

Figure 3 — Sequence of actions to determine air volume flow rates while controlling particle concentration

Energy saving opportunities check list - 6/8

ADAPTIVE CONTROL

Table B.1 — Energy saving opportunities checklist

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Design, redesign, construction	Adaptive control	Reduce airflow volume flow rate according to contamination demand	Consider possibility of providing adaptive control systems to implement on-demand energy reduction measures	Failure in local control of contamination levels and environmental parameters	Select number/location of sensors by means of risk assessment	8

- ACTIVE CONTROL OF AIRFLOW VOLUME AND/OR FRESH AIR VOLUME IS A POWERFUL WAY TO SAVE ENERGY
- AIRFLOW IS ADJUSTED IN REAL TIME BASED ON FEEDBACK COMING FROM SENSORS POSITIONED AT REPRESENTATIVE LOCATIONS (CFD SIMULATION CAN HELP FIND THIS LOCATIONS AT DESIGN STAGE)
- C.R. ACTIVE CONTROL COULD BE VERY EFFECTIVE IN CASE OF SHORT PERIODS OF HIGH PARTICULATE GENERATION

TO BE EVIDENCED THAT IN LIFE SCIENCES INDUSTRIES, THE NEED TO ADDRESS ALSO AIRBORNE VIABLE PARTICULATE AS WELL AS TOTAL PARTICULATE CAN INFLUENCE THE APPLICABILITY OF THIS CONTROL APPROACH (AT LEAST UP TO NOW)

Energy saving opportunities check list - 7/8

TURN DOWN/SET-BACK

PROGRAMMES

Table B.1 — Energy saving opportunities checklist

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Operation and maintenance	Turn-down/set back Programmes	Run HVAC at reduced rate when not in operation	HVAC can be operated with reduced airflow rate in at-rest, unmanned condition	Unauthorized room entry	Enhance training of personnel, especially maintenance and cleaning teams Implement effective access control and alarm systems	7.1
	Switch-off	Documented switch-off of HVAC when cleanroom not operational	HVAC can be switched off when non-operational and unmanned for a long period	Unauthorized room entry Risk of overall contamination, particulate displacement from filters on restart and dew point increase	Enhance training of personnel, especially maintenance and cleaning teams Implement effective access control and alarm systems Impact assessments required, take great care on start-up	7.2

TURN DOWN/SET BACK:

- AIRFLOW VOLUME VALUE CAN BE REDUCED WHEN C.R. IS IN «AT REST» OR «UNOCCUPIED» STATE (CONTAMINATION SOURCE STRENGHTS ARE LESS THAN DURING OPERATIONAL CONDITIONS)
- REDUCING AIRFLOW RATE OPERATING VALUE STRONGLY AFFECTS THE VENTILATION POWER NEEDED (HALVING THE AIRFLOW VOLUME CAN REDUCE THE VENTILATION POWER BY A FACTOR OF EIGHT!)

IT HAS BEEN REPORTED THAT IN PHARMACEUTICAL COMPANIES THE BASE-LOAD (ENERGY CONSUMPTION AT ZERO MANUFACTURING OUTPUT) CAN REACH 70-80% OF THE TOTAL CONSUMPTION. HVAC AND LIGHTING CONTRIBUTE SIGNIFICANTLY TO THE BASE LOAD

Link to 14644-4 recently revised

AIR CHANGE EFFECTIVENESS (ACE) AND CONTAMINATION REMOVAL EFFECTIVENESS (CRE)

THE ISO/FDIS 14644-4:2022 REFERS TO THE ISO 14644-16:2019 FOR ENERGY SAVING PRINCIPLES AND METHODS AND FOR THE DEFINITION OF IMPORTANT PARAMETERS LIKE ACE AND CRE.

THERE IS A DIRECT REFERENCE IN THE NORMATIVE PART OF THE STANDARD (DESIGN CHAPTER) AND ALSO IN MOST OF THE RELATED ANNEXES A,B, C, D (GUIDANCE FOR REQUIREMENTS DEFINITION, DESIGN, CONSTRUCTION AND COMMISSIONING PHASES OF A PROJECT). IT'S RELEVANT NOTICE THE FOLLOWING:

- WHILE ACE DEFINITION OF ISO 14644-16 HAS BEEN MAINTAINED IN 14644-4, THE DEFINITION OF CRE HAS BEEN MODIFIED AND SEVERAL NOTES HAS BEEN ADDED INSTEAD (WORKING PLANE INTRODUCTION, VARIABILITY OF CRE IN THE C.R. VOLUME, ETC.)
- IN GENERAL, ACE HAS BEEN CONSIDERED MOST USED IN CLEANROOMS AND PREFERRED TO CRE WHEN PARTICLE CONCENTRATION HAS TO BE CONTROLLED IN CRITICAL LOCATIONS

ADOPTION OF COMPUTATIONAL FLUID DYNAMICS (CFD)

THE REVISED 14644-4, AS THE 14644-16, CONFIRMS THE IMPORTANCE OF USING CFD SIMULATIONS TO SUPPORT THE PROJECT OF A CLEANROOM IN VARIOUS PHASES OF THE DESIGN

Part 1 conclusions

SOME «TAKEWAYS»

- GIVE THE <u>DUE IMPORTANCE</u> TO URS DEFINITION (BIG INFLUENCE ON ENERGY CONSUMPTION OF C.R.!)
- DON'T RELY ON THE OLD «RULES OF THUMB» FOR AIRFLOW RATE CALCULATION (USE SUPPLY AIRFLOW RATE EQUATIONS RATHER THAN AIRCHANGE RATE «MAGICAL» NUMBERS); TO DO THAT:
    - YOU WILL NEED RELIABLE SOURCE STRENGHT DATA
    - YOU WILL NEED RELIABLE VALUES OF VENTILATION EFFECTIVENESS «ε»; CFD CAN HELP!
- LOOK AT THE CHECKLIST; TAKE ALL THE VIABLE OPPORTUNITIES YOU HAVE TO DESIGN AN ENERGY-EFFECTIVE AND SUSTAINABLE C.R.!
- CHANGE MINDSET ON POSSIBLE INNOVATIONS: ADAPTIVE CONTROL IS ALREADY A REALITY!
    - REALTIME MONITORING OF VIABLE PARTICULATE WILL BE THE CHALLENGE FOR LIFE-SCIENCES APPLICATIONS
- LAST BUT NOT LEAST: ENERGY SAVING IS A BUSINESS MATTER BUT ALSO AN ETHIC VALUE
    - RESOURCES ARE A SHARED GOOD AND SHALL BE PRESERVED!

PART 2

Sustainability and energy efficiency

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ONU's SDGs =
Sustainability Development Goals - 1/3

ONU’s SDGs =
Sustainability Development Goals - 2/3

- FOLLOWING OTHER GLOBAL INITIATIVES ON SUSTAINABILITY OF THE PAST YEARS, DURING THE ONU WORLD SUMMIT HELD IN NEW YORK, SEPTEMBER 2015, THE 2030 AGENDA FOR SUSTAINABLE DEVELOPMENT WAS ADOPTED WITH ITS 17 SUSTAINABLE DEVELOPMENT GOALS (SDGs). PARIS AGREEMENT ON CLIMATE CHANGE FOLLOWED IN DECEMBER OF THE SAME YEAR
- THE AGENDA WAS DEFINITED AS «A SHARED BLUEPRINT FOR PEACE AND PROSPERITY FOR PEOPLE AND THE PLANET…THE 17 SDGs ARE AN URGENT CALL FOR ACTION BY ALL COUNTRIES - DEVELOPED AND DEVELOPING – IN A GLOBAL PARTNERSHIP. THEY RECOGNIZE THAT ENDING POVERTY AND OTHER DEPRIVATIONS MUST GO IN-HAND WITH STRATEGIES THAT IMPROVE HEALTH AND EDUCATION, REDUCE INEQUALITY AND SPUR ECONOMIC GROWTH – ALL WHILE TACKLING CLIMATE CHANGE AND WORKING TO PRESERVE OUR OCEANS AND FORESTS»
- MANY INDUSTRIES HAS RECOGNIZED THE NEED AND THE URGENCY TO PURSUE ALL - OR AT LEAST A PART - OF THOSE GOALS. AMONG THEM, LIFE-SCIENCES COMPANIES HAVE BEEN PROBABLY THE FIRST ONES TO START THIS PATH SETTING UP VERY AMBITIOUS SUSTAINABILITY PROGRAMS AND ESTABLISHING THEIR INTERNAL PRIORITIES AND GOALS, OFTEN INVOLVING ALSO THEIR EXTERNAL PARTNERS AND SUPPLIERS IN THIS ACTION

ONU’s SDGs =
Sustainability Development Goals - 3/3

- ALL THE 17 GOALS ARE RELEVANT FROM THE SOCIAL, ETHIC, ECONOMIC AND TECHNICAL POINT OF VIEW
- EMERGENCY DUE TO CLIMATE CHANGE, NATURAL RESOURCES PRESERVATION (AND NOW ALSO NATURAL GAS SHORTAGE) HAVE GIVEN AND ARE GIVING PRIORITIES IN THE ACTION
- COMPANIES ARE CONSEQUENTLY FOCUSING ON CLIMATE CHANGE (SDG 13) AND NATURE AND RESOURCES PRESERVATION (SDG 6 AND 12), SETTING UP SPECIFIC PLANS OF ACTION AND CREATING SUPPORTING GUIDELINES AND STANDARDS
- IN THE REALITY THIS ACTIONS ARE LINKED AND TRASVERSAL AND INCLUDE OTHER CONCURRENT ACTIONS FINALIZED TO PURSUE OTHER GOALS IN A GENERAL, COLLABORATIVE SCHEME:

Climate action - 1/12

«NET ZERO CARBON» CONCEPT

- CO_2 EMISSIONS LARGELY DETERMINE THE EXTENT OF GLOBAL WARMING, THAT IS DEFINITELY RECOGNIZED AS THE PRINCIPAL CAUSE OF CLIMATE CHANGE
- SOME CO_2 EMISSIONS ARE PRODUCED BY «HARD-TO-TREAT» SECTORS, SUCH AS AVIATION AND MANUFACTURING, WHERE REDUCTION TO ZERO MAY BE TOO EXPENSIVE, TECHNOLOGICALLY TOO COMPLEX OR EVEN NOT POSSIBLE
- «NET ZERO CARBON» TARGET (OVERALL BALANCE BETWEEN EMISSIONS PRODUCED AND ACTIONS TAKEN FOR REMOVAL OF CO_2 AND OTHER GREENHOUSE GASES FROM THE ATMOSPHERE– PARIS AGREEMENT) IS THEREFORE MORE REALISTIC THAN «GROSS ZERO» TARGET (REDUCTION OF EMISSIONS TO ZERO)
- IN A NET ZERO SCENARIO RESIDUAL EMISSIONS ARE OFFSET BY REMOVING EMISSIONS USING NATURAL OR ENGINEERING «SINKS» (I.E.: GROSS NEGATIVE EMISSIONS); EXAMPLES:
    - NATURAL SINKS: AFFORESTATION AND REFORESTATION
    - ENGINEERING SINKS: UNDERGROUND SINKS, ETC.
- FURTHER RESIDUAL EMISSION CAN BE EVENTUALLY OFFSET PURCHASING «CARBON CREDITS» (CERTIFICATES)

Climate action - 2/12

- CO_2 EMISSION CHARACTERIZATION: SCOPE 1, 2 & 3
- (GHG Protocol - A Corporate Accounting and Reporting Standard, 2021)

World Business Council for Sustainable Development

WORLD RESOURCES INSTITUTE

SCOPE 1: DIRECT GHG EMISSIONS

- FOSSIL FUELS
- REFRIGERANTS

GHG EMISSIONS that a company makes directly from owned or controlled sources (fuels for power generation, process and refrigerants spillages)

SCOPE 2: INDIRECT GHG EMISSIONS:

- PURCHASED ELECTRICITY (AND POSSIBLE OTHER UTILITIES)

GHG EMISSIONS that a company makes indirectly like when the electricity or other kind of energy it buys for any scope is being produced by others on its behalf

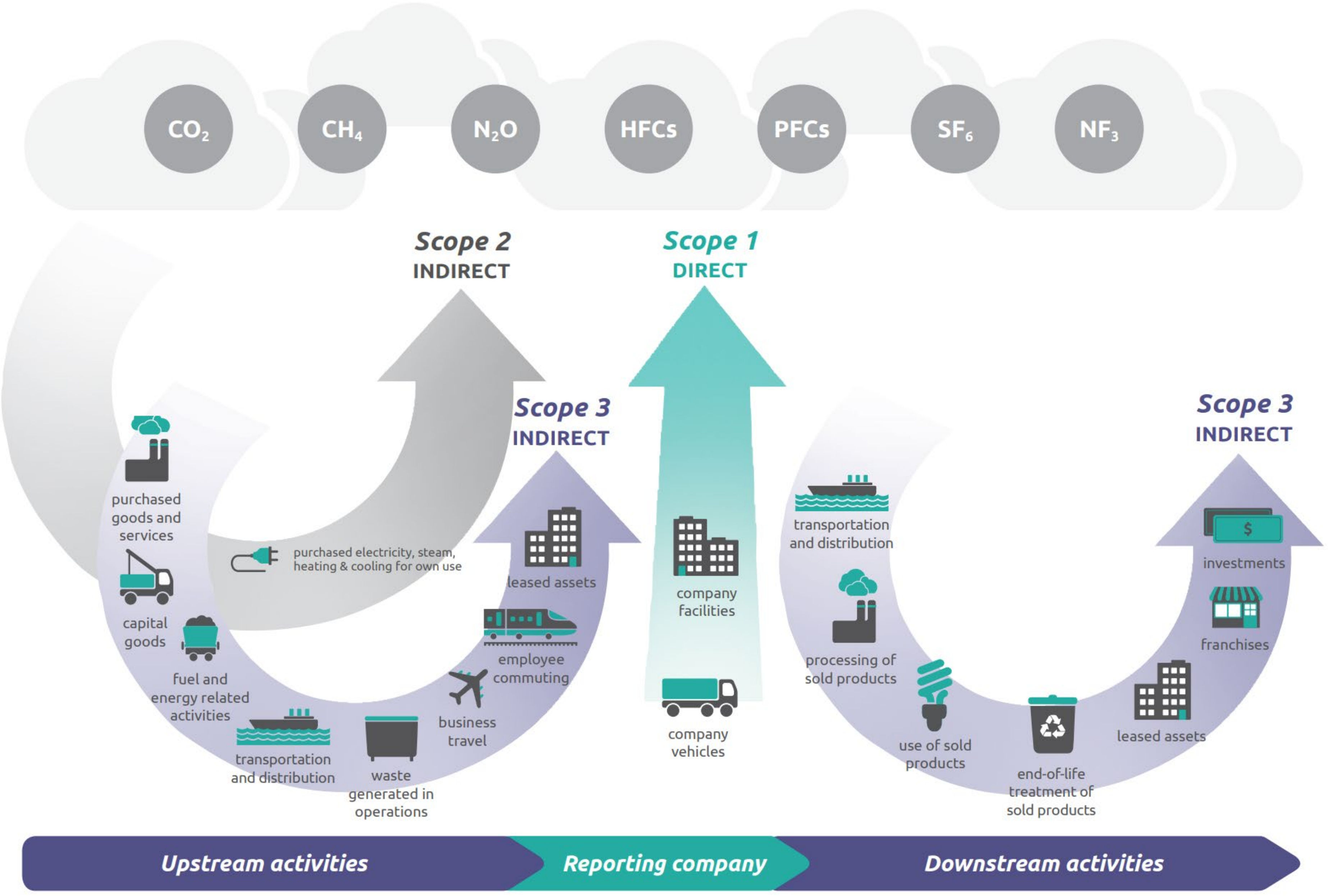
SCOPE 3: OTHER INDIRECT GHG EMISSIONS:

- UPSTREAM AND DOWNSTREAM INDIRECT SOURCES ACROSS ALL THE VALUE CHAIN

GHG EMISSIONS that a company is indirectly responsible for but that are associated to other entities (i.e.: suppliers, customers, etc), up and down its value chain

Climate action - 3/12

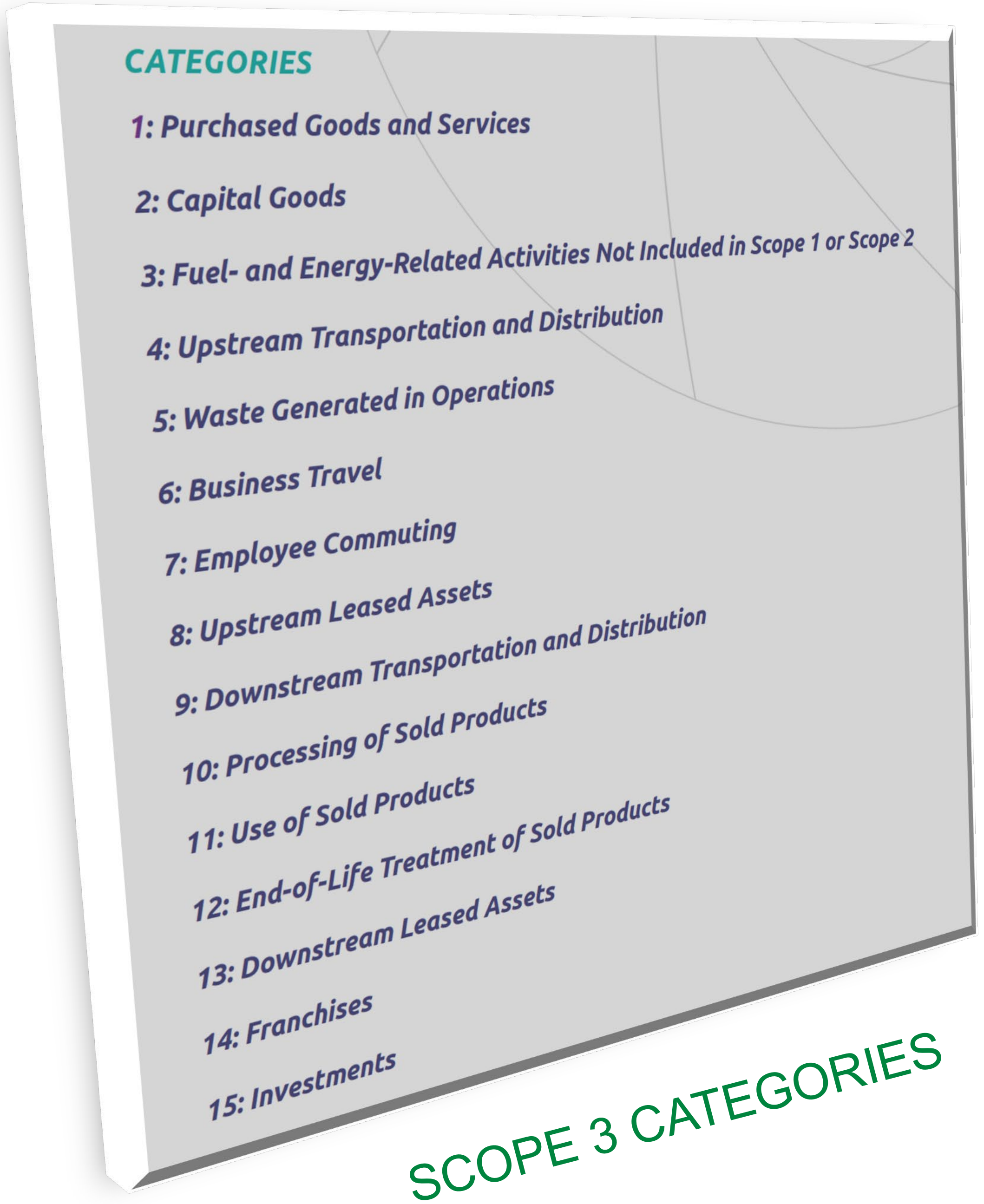
DIRECT AND INDIRECT
GHG EMISSIONS



Climate action - 4/12

SCOPE 3 EMISSIONS

- SCOPE 3 EMISSIONS ARE NEAR ALWAYS MUCH MORE RELEVANT COMPARED TO THE OTHER
- IN THE SAME TIME, SCOPE 3 EMISSIONS ARE VERY DIFFICULT TO BE CONTROLLED; DUE TO THIS REASON, COMPANIES USUALLY ACCOUNT FOR - AND REPORT - ONLY EMISSIONS FROM SCOPE 1&2
- ACCOUNTING AND REPORTING SCOPE 3 EMISSIONS IS OPTIONAL; HOWEVER, DESCRIBING AND ANALYZING FOR RELEVANCE SCOPE 3 EMISSIONS CAN BE A POWERFUL PRACTICE IN ORDER TO OPTIMIZE (EMISSION - WISE AND COST-WISE) PROCESSES, LOGISTICS AND EVEN PRODUCTS ALONG THE COMPANY'S ENTIRE VALUE CHAIN


CATEGORIES

1: Purchased Goods and Services
2: Capital Goods
3: Fuel- and Energy-Related Activities Not Included in Scope 1 or Scope 2
4: Upstream Transportation and Distribution
5: Waste Generated in Operations
6: Business Travel
7: Employee Commuting
8: Upstream Leased Assets
9: Downstream Transportation and Distribution
10: Processing of Sold Products
11: Use of Sold Products
12: End-of-Life Treatment of Sold Products
13: Downstream Leased Assets
14: Franchises
15: Investments

SCOPE 3 CATEGORIES

Climate action - 5/12

«NET ZERO» INITIATIVES: EXAMPLES FROM SUSTAINABILITY REPORTS OF LIFE-SCIENCES COMPANIES

Climate

Our goal is to have net zero impact on climate across our full value chain by 2030.[1]

The Science Based Targets Initiative has accredited that our carbon targets align to a 1.5°C pathway.

Our climate targets are:

- Net zero emissions across all operations by 2030 (scope 1 and 2)
- 100% renewable electricity by 2025 (scope 2)
- Net zero emissions across our full value chain by 2030 (scope 3)

GSK

Launching our 2030 climate ambitions

As one of the first companies to receive validation of our GHG reduction goal by the Science Based Target Initiative in 2015, Pfizer remains committed to ambitious long-term actions. We are therefore advancing our Science Based Target Initiative (SBTi) approved fourth-generation GHG reduction goals aligned with a 1.5°C pathway:

- By 2030, we aim to become carbon neutral across our internal operations, delivering a 46% absolute reduction in direct emissions from a 2019 baseline, including purchasing 100% renewable energy. Any remaining emissions will be offset through carbon credits.
- Recognizing that indirect emissions account for approximately 80% of our carbon footprint, we aim to use our influence to catalyze similar reductions across our value chain. We are implementing a multipronged approach, including embedding environmental sustainability criteria in our vendor selection processes, strengthening expectations within contracts and engaging with key suppliers of goods and services to drive the adoption of science-based GHG reduction goals.
- We also aim to reduce emissions related to upstream logistics by 10% and business travel by 25% by 2025 from a 2019 baseline.

Pfizer

Climate action - 6/12

SCOPE 1, 2 & 3 RELEVANCE – EXAMPLE

- TWO DIFFERENT PHARMACEUTICAL COMPANIES, BOTH MULTINATIONAL:
  - A-COMPANY SMALLER THAN B-COMPANY (REFERRING TO REVENUE, N. OF PRODUCTION SITES, N. OF EMPLOYEES, ETC.)
- ABSOLUTE VALUES OF GHG EMISSIONS ARE VERY DIFFERENT BUT EMISSION PERCENTAGES REFERRING TO SCOPE 1, 2 & 3 ARE ALMOST THE SAME. SCOPE 1 & 2 EMISSIONS ARE UNDER 10% OF THE TOTAL
- THOSE DATA COMES FROM 2020 CORPORATE ESG REPORTS; OTHER COMPANIES ESG REPORTS GIVE SIMILAR PERCENTAGES

COMPANIES RELEVANT DATA				
	COMPANY A		COMPANY B	
REVENUE	2,229	Billion €	34,099	Billion €
EMPLOYEES	6.389	N.	99.000	N.
MANUF. SITES	3	N.	36	N.

YEAR 2020 GHG EMISSIONS (Tons CO_2e)				
	COMPANY A		COMPANY B	
	QUANTITIES	%	QUANTITIES	%
SCOPE 1	45.117	5,5	719.000	5,0
SCOPE 2	2.030	0,2	227.000	1,6
SCOPE3	769.239	94,3	13.456.000	93,4
TOTAL	**816.386**	**100,0**	**14.402.000**	**100,0**

NOTE: both Companies A, B produce inhalers. GHG emission of propellant of inhalers sold by Company B account for 49% of the total SCOPE 3 emissions and for 87% of SCOPE 3 emissions due to all Company B purchased products

Climate action - 7/12

SCOPE 1, 2 EMISSIONS OFFSET – ACTIONS

SCOPE 1&2 EMISSIONS SEEMS NOT RELEVANT IF COMPARED WITH SCOPE 3 ONES, BUT WORKING ON THEM IS MUCH MORE SIMPLE, FASTER AND SOMETIMES GOOD RESULTS CAN BE OBTAINED WITH A REASONABLE TECHNICAL AND ECONOMIC EFFORT

NET ZERO CARBON – SCOPE 1&2 EMISSIONS OFFSET	
	POSSIBLE ACTIONS
SCOPE 1	• ELIMINATION OF FOSSIL FUELS (ELECTRIFICATION OF ENERGY FOR HVAC ,PROCESS, UTILITIES PRODUCTION, INTERNAL TRANSPORTATION) • OPTIMIZATION OF ENERGY PRODUCTION AND DISTRIBUTION SYSTEMS • OPTIMIZATION OF ENERGY USAGE • ADOPTION OF ZERO-ODP AND LOW-GWP REFRIGERANTS (*) • PREVENTION AND CONTROL OF REFRIGERANT SPILLAGES
SCOPE 2	• PURCHASE OF ELECTRICITY (AND/OR HEATING AND COOLING FLUIDS) PRODUCED BY RENEWABLE SOURCES • ESTABLISH POWER PRODUCTION AGREEMENTS • (PURCHASE OF CERTIFICATES)

(*) note:
ODP = Ozone Depletion Potential / GWP = Global Warming Potential

Climate action - 8/12

SCOPE 1, 2 EMISSIONS OFFSET – ACTIONS

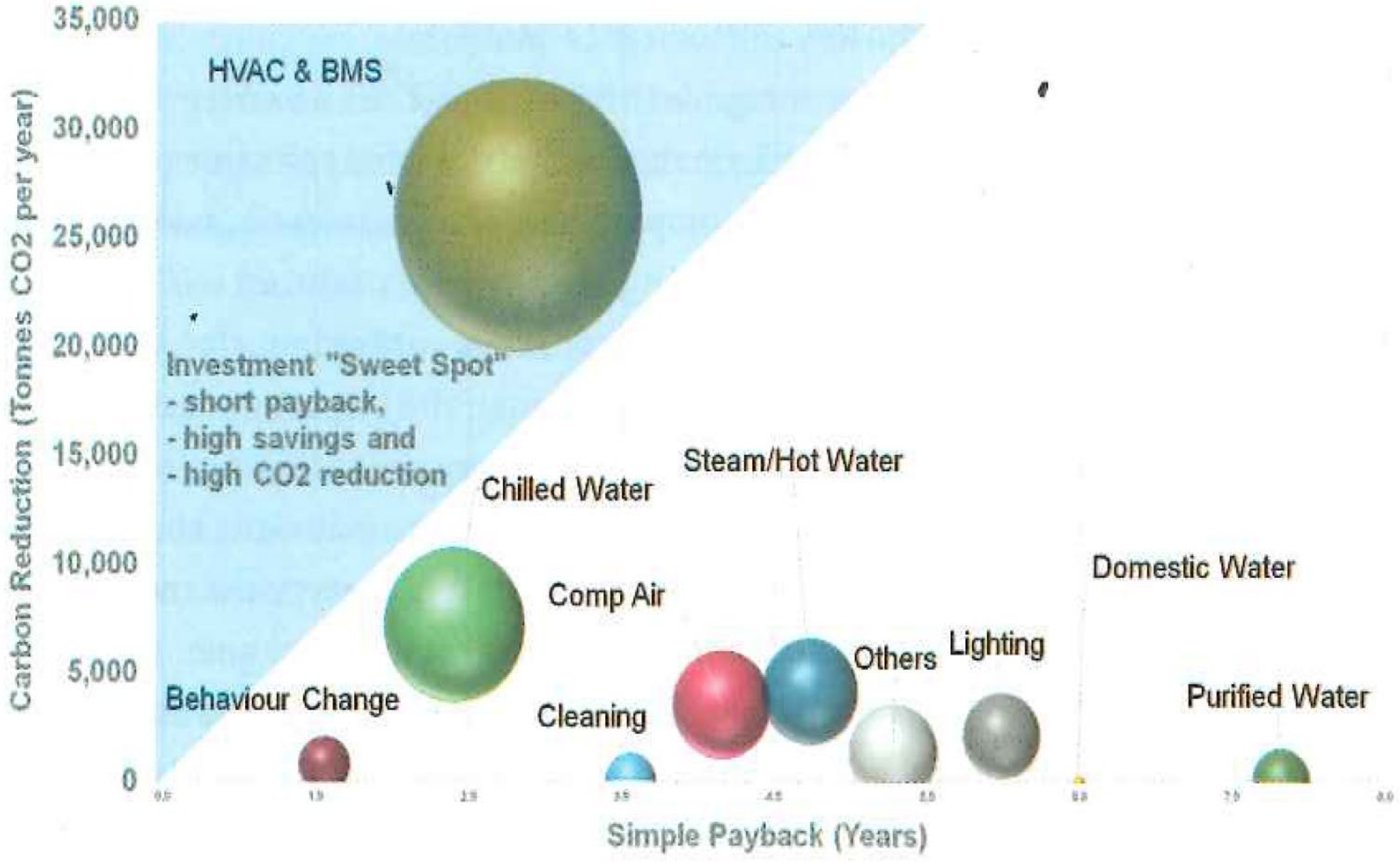
- OPTIMIZATION OF ENERGY PRODUCTION, DISTRIBUTION AND USAGE SYSTEMS CREATE TWO SIMULTANEUS AND POSITIVE EFFECTS ON BOTH SUSTAINABILITY AND BUSINESS:
  - CONTRIBUTE TO GHG EMISSION REDUCTION
  - CONTRIBUTE TO ENERGY SAVING
- IN A PHARMACEUTICAL PLANT, ENERGY USERS INCLUDE PROCESS SYSTEMS & EQUIPMENT TOGETHER WITH INDUSTRIAL AND CLEAN UTILITIES (HVAC, CHILLED AND HOT WATER, INDUSTRIAL STEAM, COMPRESSED AIR, PW, WFI, ETC.); IN GMP REGULATED INDUSTRIES OPTIMIZATION MEASURES ON PROCESS SYSTEMS ARE MORE DIFFICULT TO BE APPLIED RESPECT TO THE CORRESPONDENT ON UTILITIES. MOREOVER, OPTIMIZATION OF DIFFERENT ENERGY USER SYSTEMS HAVE GENERALLY DIFFERENT IMPACT IN TERMS OF CARBON EMISSIONS REDUCTION AND RETURN OF INVESTMENT
- IN THE NEXT FIGURE IS DISPLAYED AN EXAMPLE OF THIS IMPACT (ANNUAL CARBON SAVING BY UTILITY CATEGORY) FOR A PHARMACEUTICAL COMPANY BASED IN NORTH AMERICA; DATA COME FROM AN ENERGY AUDIT

Climate action - 9/12

SCOPE 1, 2 EMISSIONS OFFSET: EXAMPLE - UTILITIES OPTIMIZATION RELEVANCE -

- CASE STUDY OF A PHARMACEUTICAL COMPANY LOCATED IN NORTH AMERICA

- HVAC AND RELATED BMS CONTROLS REPRESENTS THE MOST ACTRACTIVE INVESTMENT AMONG THE UTILITIES (HIGH CARBON REDUCTION OPPORTUNITIES COUPLED WITH A GOOD R.O.I.)
- USUALLY ENERGY OPTIMIZATIONS ARE BETTER APPLICABLE TO «CNC», «D-GRADE» OR «C-GRADE» - CLASSIFIED AREAS DUE TO THEIR GREATER EXTENSION AND LOWER GMP CRITICALITY IF COMPARED WITH «B-GRADE» AREAS



ENERGY AUDIT SUMMARY FOR A PHARMACEUTICAL COMPANY
(K. Beattie: Two Real-World Experiences in Global Sustainability -ISPE - Pharmaceutical Engineering, March/April 2020)

Climate action - 10/12

SCOPE 1, 2 EMISSIONS OFFSET EXAMPLES: HOW TO AVOID FOSSILE FUELS CONSUMPTION TO PRODUCE STEAM - LIGHT AND SHADOW

- INDUSTRIAL STEAM (AND CONSEQUENTLY, CLEAN STEAM) ARE PRODUCED BY GAS OR OIL FIRED BOILERS
- STEAM USED FOR PROCESS IS ALMOST IMPOSSIBLE TO BE REPLACED WITH OTER FLUIDS
- STEAM HUMIDIFICATION FOR HVAC SYSTEMS CAN BE OFTEN REPLACED BY ADIABATIC HUMIDIFICATION. IN THIS CASE WE DON'T SAVE ENERGY BUT WE CAN USE HOT WATER FOR REHEATING SYSTEMS; HOT WATER CAN BE PRODUCED BY HEAT PUMPS

TODAY SOME DECARBONIZATION GUIDELINES OF PHARMACEUTICAL INDUSTRY SUGGEST TO PRODUCE STEAM BY ELECTRIC STEAM GENERATORS.

MY PERSONAL OPINION: PRODUCING STEAM WITH «JOULE EFFECT» (ELECTRIC RESISTORS) IS A WAY TO DEGRADE ENERGY AND IS NOT ACCEPTABLE → AT THE MOMENT STEAM CONSUMPTION OPTIMIZATION IS THE BEST OPTION

EXAMPLE: ELECTRIC STEAM GENERATOR CAPACITY UP TO 7,500 kg/h ~ 5 MW!!

Climate action - 11/12

NET ZERO CARBON & ISO 14644-16

- ISO 14644-16 SCOPE IS THE OPTIMIZATION OF ENERGY USAGE IN CLEANROOMS, PROVIDING GUIDANCE FOR THE DESIGN, CONSTRUCTION , COMMISSIONING AND OPERATION OF NEW AND EXISTING FACILITIES
- GUIDANCE IS BASED ON A METHOD (energy reduction evaluation and implementation process) AND ON THE SUGGESTION OF MANY ENERGY REDUCTION OPPORTUNITIES APPLICABLE TO ALL THE LIFE-CYCLE STAGES OF THE FACILITY
- SCIENCE IS PUT AT THE BASIS OF SUPPLY AIR FLOW RATE CALCULATION, THAT IS ONE OF THE MOST RELEVANT WAYS TO SAVE ENERGY IN A C.R., CONTRASTING THE «RULE OF THUMB» ASSUMPTIONS OF THE PAST
- OTHER QUOTED OPPORTUNITIES ARE: AVOIDING OVERDESIGN AND OVERSPECIFICATION, ADOPTION OF BARRIER TECHNOLOGY CONCEPT TO REDUCE THE DIMENSIONS OF CONTROLLED AREAS, V.A.V. INTRODUCTION, SET-BACK CAPABILITY FOR AIRFLOW RATE AND T/RH, ADAPTIVE CONTROL, ADOPTION OF HIGH-EFFICIENCY FANS AND MOTORS, ETC.

Climate action - 12/12

NET ZERO CARBON & ISO 14644-16

- MOREOVER, ISO 14644-16 DEFINES A SET OF BENCHMARKING INDEXES, VERY USEFUL TOOLS FOR CHALLENGING PROJECTS DURING ENERGY AUDIT SESSIONS

ALL THE PREVIOUS ENERGY-SAVING MEASURES PROMOTE THE REDUCTION OF SCOPE 1&2 GHG EMISSIONS AND CONTRIBUTE NOTICEABLY TO CLIMATE ACTION AND NET ZERO CARBON PROGRAMS

- ON THE OTHER HAND:
  - ISO 14644-16 SCOPE SPECIFICALLY EXCLUDE PROCESS SYSTEMS
  - DE-FACTO UTILITIES GENERATION SYSTEMS AND BUILDING ENVELOPE PERFORMANCE CRITERIA ARE OUT OF SCOPE TOO; DECARBONIZATION ACTIONS FOR THESE LAST TOPICS ARE GENERALLY SUPPORTED TO NATIONAL/INTERNATIONAL STANDARDS AND CORPORATE GUIDELINESFANS AND MOTORS, ETC.

Nature and resources preservation - 1/3

«NET NATURE POSITIVE» CONCEPT

- NATURE AND RESOURCES PRESERVATION ARE THE OTHER DRIVERS OF SUSTAINABILITY PRIORITIES
- CONSCIOUS AND AFFORDABLE USE OF NATURAL RESOURCES, FIGHT AGAINST POLLUTION, RESPONSIBLE WASTE MANAGEMENT ARE THE ACTIONS TO BE UNDERTAKEN IN SHORT TIME
- THE CONCEPT OF «NET NATURE POSITIVE» HAS BEEN INTRODUCED (OVERALL POSITIVE BALANCE BETWEEN WHAT IS TAKEN FROM NATURE AND WHAT IS GIVEN TO NATURE) IN ORDER TO ADDRESS AND EVALUATE NATURE PROTECTION, PRESERVATION AND RESTORATION ACTIONS
- IN THE FRAME OF SUSTAINABILITY MOST OF THE INDUSTRIAL COMPANIES HAS ESTABLISHED “NET NATURE POSITIVE” INITIATIVES IN PARALLEL WITH THE CORRESPONDING “NET ZERO CARBON” ONES; AMBITIOUS GOALS AND MILESTONES HAVE BEEN SET ALSO IN THIS CASE, REGARDING MANAGEMENT OF WATER, WASTE, SUSTAINABLE SOURCING OF MATERIALS, BIODIVERSITY, ETC.
- AN EXAMPLE OF NET NATURE INITIATIVES SET BY A BIG PHARMACEUTICAL COMPANY IS DISPLAYED IN THE NEXT SLIDE (information taken from their corporate 2021 ESG Performance Report)
- POSSIBLE ACTIONS ON WATER MANAGEMENT WILL BE EXAMINED WITH MORE DETAIL SUBSEQUENTLY

Nature and resources preservation - 2/3

«NET POSITIVE NATURE» INITIATIVES: EXAMPLE FROM SUSTAINABILITY REPORT OF A LIFE-SCIENCES COMPANY

Nature

GSK

Our target is to be net positive on nature by 2030, by reducing our environmental impacts across water, materials and biodiversity and investing in protecting and restoring nature.[1]

Water

Our water targets are to:

– Achieve good water stewardship at 100% of our sites by 2025[1]
– Reduce overall water use in our operations by 20% by 2030
– Be water neutral in our own operations and at key suppliers in water stressed regions by 2030[1]
– Zero impact active pharmaceutical ingredient levels for all sites and key suppliers by 2030

Biodiversity

Our targets are:

– Positive impact on biodiversity at all sites by 2030
– 100% materials sustainably sourced and deforestation free by 2030

Materials and the circular economy

In 2020, we changed the scope of our waste targets to support the transition to a circular economy that keeps materials and resources in use[2].

Our targets are:

– Zero operational waste[1], including eliminating single-use plastics, by 2030
– 25% environmental impact reduction for our products and packaging by 2030
– 10% waste reduction from supply chain by 2030

Sustainable sourcing

Our target is:

– 100% of agricultural, forestry and marine derived materials sustainably sourced and deforestation free by 2030

Nature and resources preservation - 3/3

«NET POSITIVE NATURE» INITIATIVES - WATER

- WATER MANAGEMENT AND WATER POLLUTION PREVENTION ARE INITIATIVES THAT INVOLVE BOTH THE PROCESS AND THE UTILITIES AND IMPACT ON ENGINEERING AND OPERATIONS AS WELL
- THE FIRST MEASURES FOR WATER SAVING ARE USE REDUCTION AND FIXING POSSIBLE SPILLAGES
- IN LIFE-SCIENCES FIELD PROCESSES AND/OR REGULATIONS PUT CONSTRAINTS TO WATER CONSUMPTION REDUCTION MEASURES, EVEN THOUGH TECHNICAL PROGRESS AND GOOD ENGINEERING CAN HELP SOLVING THOSE LIMITATIONS (I.e.:clean utilities utilized for cleaning and sterilizing applications)
- FURTHER OPPORTUNITIES FOR WATER CONSUMPTION OPTIMIZATION ARE THE REUSE AND RECYCLE OF WATER COMING FROM A PREVIOUS USAGE AND THE REPLACEMENT WITH WATER COMING FROM OTHER SOURCES:
    - REUSE: USE AGAIN WITHOUT NEED OF RELEVANT TREATMENTS (i.e.: i.e.: CIP final rinse, RO reject water), LESS EXPENSIVE
    - RECYCLE: USE AGAIN FOR OTHER PROCESSES AFTER SPECIFIC TREATMENTS (i.e.: treated effluents waste water) , MORE EXPENSIVE
    - REPLACEMENT: REPLACE WITH DIFFERENT WATER SOURCE (i.e.: condensate from AHUs drains)
- REUSED AND REPLACED WATER TIPICALLY CAN BE USED FOR COOLING TOWER MAKE-UP AND OTHER SECONDARY PURPOSES

Final considerations

- HYSTORICALLY, ISO 14644-16 HAS BEEN DEVELOPED IN THE SAME PERIOD IN WHICH GLOBAL SUSTAINABILITY ACTIONS, ONU's SDGs AND PARIS AGREEMENT TOOK SHAPE
- PART-16 SCOPE DOESN'T INCLUDE SUSTAINABILITY TOPICS OTHER THAN THOSE DEALING WITH ENERGY EFFICIENCY OF CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS (GMP CLASSIFIED AREAS, SEPARATIVE DEVICES, ETC.)
- PART-16 SCOPE DOESN'T INCLUDE ENERGY OPTIMIZATION OF PROCESSES
- HOWEVER, PART-16 CAN GIVE A STRONG CONTRIBUTE FOR ENERGY OPTIMIZATION OF CLEAN-ROOMS AND OTHER FACILITIES, THUS SUPPORTING (DIRECTLY OR INDIRECTLY) DECARBONIZATION STRATEGIES IN SCOPE 1 AND 2
- RUSSIAN WAR TO UKRAINE HAS SUDDENLY AND STRONGLY INFLUENCED AVAILABILITY OF AN IMPORTANT RESOURCE (METHANE), DRAMATICALLY CHANGING ENERGY PRODUCTION STRATEGIES. **DECARBONIZATION ACTION MIGHT BE SEEN NOW AS A SECONDARY PRIORITY** RESPECT TO ENERGY PRODUCTION NEED; AN EXAMPLE: PREVIOUSLY TURNED-OFF COAL-FIRED POWER PLANTS ARE NOW OPERATIONAL AGAIN
- IN THIS SCENARIO **PART-16 ROLE COULD BE EVEN MORE RELEVANT** HELPING REDUCING CO2 EMISSIONS AND ALSO CONSUMPTION OF FOSSIL FUELS (RESERVES ARE SHORTENING IN ITALY AND OTHER EUROPEAN COUNTRIES)

Thanks for your kind attention!

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