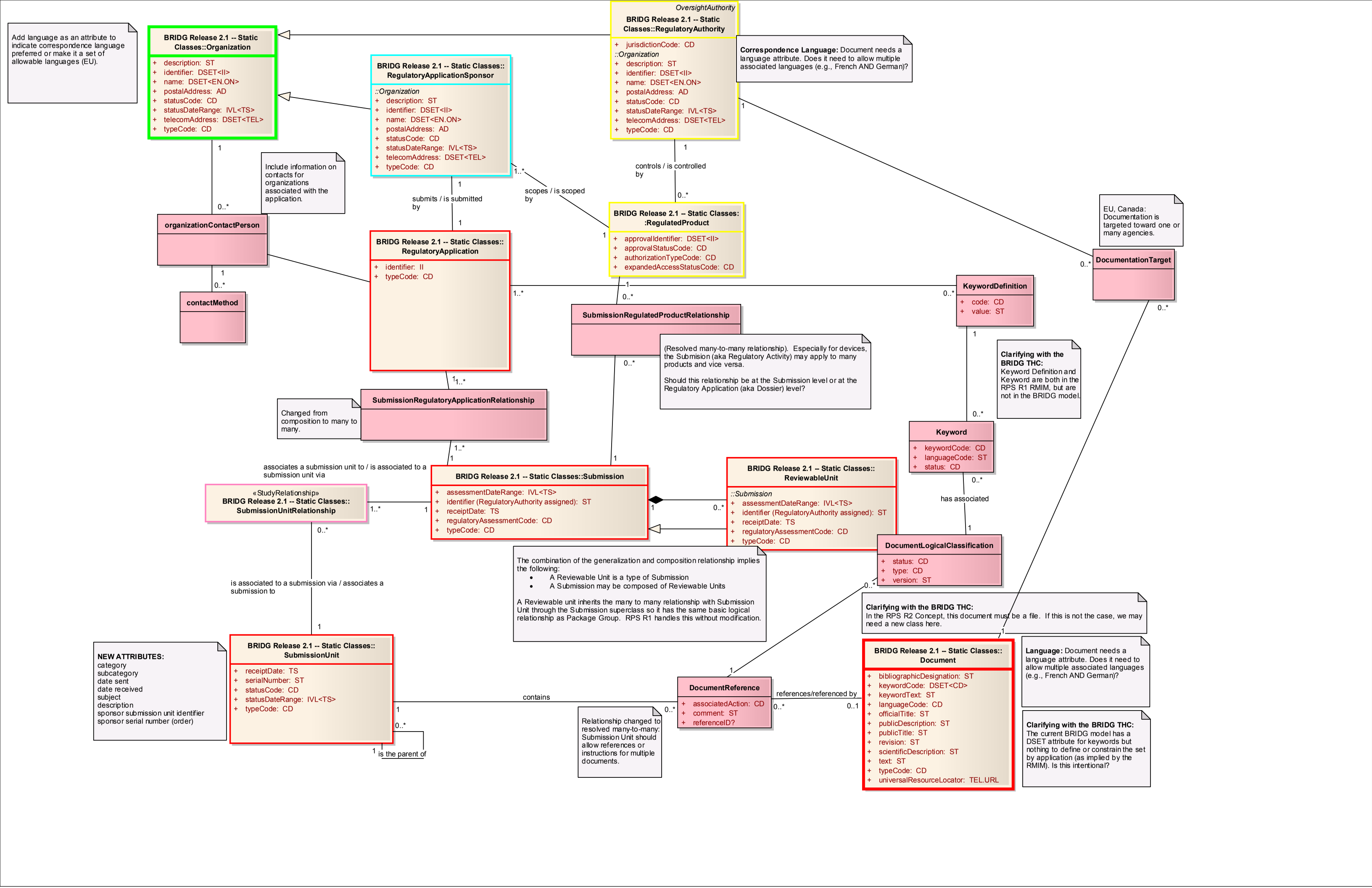

Add language as an attribute to indicate correspondence language preferred or make it a set of allowable languages (EU).
BRIDG Release 2.1 -- Static Classes::Organization
+ description: ST
+ identifier: DSET<II>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
BRIDG Release 2.1 -- Static Classes:: RegulatoryApplicationSponsor
::Organization
+ description: ST
+ identifier: DSET<II>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
OversightAuthority
BRIDG Release 2.1 -- Static Classes::RegulatoryAuthority
+ jurisdictionCode: CD
::Organization
+ description: ST
+ identifier: DSET<II>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
Correspondence Language: Document needs a language attribute. Does it need to allow multiple associated languages (e.g., French AND German)?
Include information on contacts for organizations associated with the application.
organizationContactPerson
contactMethod
submits / is submitted by
scopes / is scoped by
controls / is controlled by
BRIDG Release 2.1 -- Static Classes: :RegulatedProduct
+ approvalIdentifier: DSET<II>
+ approvalStatusCode: CD
+ authorizationTypeCode: CD
+ expandedAccessStatusCode: CD
BRIDG Release 2.1 -- Static Classes:: RegulatoryApplication
+ identifier: II
+ typeCode: CD
EU, Canada: Documentation is targeted toward one or many agencies.
DocumentationTarget
KeywordDefinition
+ code: CD
+ value: ST
SubmissionRegulatedProductRelationship
(Resolved many-to-many relationship). Especially for devices, the Submision (aka Regulatory Activity) may apply to many products and vice versa.
Should this relationship be at the Submission level or at the Regulatory Application (aka Dossier) level?
Clarifying with the BRIDG THC: Keyword Definition and Keyword are both in the RPS R1 RMIM, but are not in the BRIDG model.
SubmissionRegulatoryApplicationRelationship
Changed from composition to many to many.
Keyword
+ keywordCode: CD
+ languageCode: ST
+ status: CD
associates a submission unit to / is associated to a submission unit via
«StudyRelationship»
BRIDG Release 2.1 -- Static Classes:: SubmissionUnitRelationship
BRIDG Release 2.1 -- Static Classes::Submission
+ assessmentDateRange: IVL<TS>
+ identifier (RegulatoryAuthority assigned): ST
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
BRIDG Release 2.1 -- Static Classes:: ReviewableUnit
::Submission
+ assessmentDateRange: IVL<TS>
+ identifier (RegulatoryAuthority assigned): ST
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
has associated
DocumentLogicalClassification
+ status: CD
+ type: CD
+ version: ST
The combination of the generalization and composition relationship implies the following:
• A Reviewable Unit is a type of Submission
• A Submission may be composed of Reviewable Units
A Reviewable unit inherits the many to many relationship with Submission Unit through the Submission superclass so it has the same basic logical relationship as Package Group. RPS R1 handles this without modification.
is associated to a submission via / associates a submission to
Clarifying with the BRIDG THC: In the RPS R2 Concept, this document must be a file. If this is not the case, we may need a new class here.
NEW ATTRIBUTES:
category
subcategory
date sent
date received
subject
description
sponsor submission unit identifier
sponsor serial number (order)
BRIDG Release 2.1 -- Static Classes:: SubmissionUnit
+ receiptDate: TS
+ serialNumber: ST
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ typeCode: CD
contains
is the parent of
DocumentReference
+ associatedAction: CD
+ comment: ST
+ referenceID?
references/referenced by
Relationship changed to resolved many-to-many: Submission Unit should allow references or instructions for multiple documents.
BRIDG Release 2.1 -- Static Classes:: Document
+ bibliographicDesignation: ST
+ keywordCode: DSET<CD>
+ keywordText: ST
+ languageCode: CD
+ officialTitle: ST
+ publicDescription: ST
+ publicTitle: ST
+ revision: ST
+ scientificDescription: ST
+ text: ST
+ typeCode: CD
+ universalResourceLocator: TEL.URL
Language: Document needs a language attribute. Does it need to allow multiple associated languages (e.g., French AND German)?
Clarifying with the BRIDG THC: The current BRIDG model has a DSET attribute for keywords but nothing to define or constrain the set by application (as implied by the RMIM). Is this intentional?